



**US Environmental Protection Agency
Office of Pesticide Programs**

**Fenhexamid Minor Use - Exclusive Use
Period Extension Request**

May 12, 2009



Conn & Smith Inc.

Professionals in Pesticide Regulatory Services

May 12, 2009
HAND DELIVERED

Document Processing Desk
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Waller:

Re: Fenhexamid (a.k.a. TM-402 and KBR 2738)
ATTENTION: Minor Use - Exclusive Use Period Extension Request

This letter is submitted on behalf of the TM-402 (KBR 2738) Fungicide Task Force (Consortium No. 69436) which is comprised of Arysta LifeScience North America, LLC (formerly Tomen Agro, Inc.) and Bayer CropScience (formerly Bayer Corporation).

Fenhexamid was registered on May 21, 1999. Therefore, the standard exclusive use period expires on May 20, 2009. The TM-402 (KBR 2738) Fungicide Task Force requests a 2-year extension of the exclusive use period for fenhexamid through May 20, 2011 based upon a total of eight minor uses that were registered within the first seven years of registration of fenhexamid and for which the associated residue data were developed by the TM-402 (KBR 2738) Fungicide Task Force:

- | | |
|-----------------|--------------|
| 1. Strawberries | 5. Plums |
| 2. Almonds | 6. Cucumbers |
| 3. Peaches | 7. Lettuce |
| 4. Cherries | 8. Peppers |

The supporting documentation is attached.

Sincerely,

Cynthia Ann Smith
Vice President
Consultant Representative for Fenhexamid

Attachments

cc: B. Rhodes, Arysta LifeScience, LLC
B. Opitz, Bayer CropScience

Robert Perlis
EPA - Office of General Counsel
1200 Pennsylvania Avenue, N.W.
2333A
Washington, DC 20460

Pat Cimino - Specialty Crop Advisor
EPA - Office of Pesticide Programs
1200 Pennsylvania Avenue, N.W.
7503P
Washington, DC 20460

ATTACHMENT 1: STRAWBERRIES

The use of fenhexamid on strawberries was registered within the first seven years the first registration of fenhexamid.

- Date of first registration of fenhexamid: 1999/05/21
 - Date of first registration for use on strawberries: 1999/05/21*
- * Page 1 of the label is attached below.

Criterion satisfied to qualify for the exclusive use extension:

- The alternatives to the minor use pesticide pose a greater risk to the environment or human health.

Support that the above criterion has been satisfied:

- September 10, 1997 reduced risk determination for fenhexamid/strawberries. The January 9, 1998 letter that references the Agency's acceptance of fenhexamid for use on strawberries (grapes and ornamentals) as a reduced risk use is attached below.

Supporting residue chemistry data developed by the TM-402 (KBR 2738) Fungicide Task Force:

- MRID 44346765
Determination of Storage Stability of KBR 2738 Residues in Fortified Analytical Samples of Grapes, Processed Commodities of Grapes, Peach, Tomato and Strawberry
Lab: Bayer AG
- MRID 44366509
Storage Stability of TM-402 in Strawberries and Grapes - Extended Interval
Lab: Analytical Development Corporation
- MRID 44514002
Method Validation and Storage Stability of TM-402 in Strawberries and Grapes
Lab: Analytical Development Corporation
- MRID 44366510
Magnitude of TM-402 Residues in Strawberries (Amended)
Lab: Analytical Development Corporation
- MRID 44514004
Elevate 50 WDG Fungicide: Magnitude of the Residue in Strawberries from the 1997 Field Trial Conducted in Nova Scotia, Canada
Lab: Analytical Development Corporation

ELEVATE™ 50 WDG Fungicide (Containing TM-402)

EPA File Symbol 66330-G1

May 20, 1999 draft label proposed for EPA "Accepted" stamp

Based upon the April 20, 1999 draft label, revised per:

1. 5/19/99 EPA comments, and
2. Changes requested by Tomen to remove redundancies and improve label flow.

Page 1 of 7

(Front Panel)

ELEVATE™ 50 WDG FUNGICIDE

50% Water Dispersible Granule for Use in Water as a Spray
for Control of *Botrytis* Diseases of Grapes, Strawberries and Ornamentals

FOR AGRICULTURAL AND HORTICULTURAL USE ONLY

Not for Residential Use

INGREDIENTS

ACTIVE INGREDIENT:

Fenhexamid* 50.0%

INERT INGREDIENTS: 50.0%

Total 100.0%

* N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexane carboxamide

KEEP OUT OF REACH OF CHILDREN
CAUTION

See back panel for additional precautionary statements.

Tomen Agro, Inc.
100 First Street, Suite 1700
San Francisco, CA 94105

EPA Registration No. 66330 - _____
EPA Establishment No. 44616-MO-01

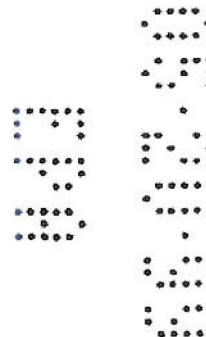
NET WEIGHT: _____ POUNDS (_____ KILOGRAMS)

ACCEPTED
with COMMENTS
In EPA Letter Dated:

5/21/99

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

66330-35





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

834.1 TOA
Sub. No. 97-1749

JAN 9 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Cynthia Ann Smith
C.A. Smith Consulting
6713 Catskill Road
Lorton, VA 22079-1113

Dear Ms. Smith:

Re: Fenhexamid Technical - Application for Registration and Shared PMRA/EPA/CDPR Review

The submission to register Fenhexamid, as a Technical Grade Active Ingredient (TGAI) for use in the manufacture of pesticides registered under:

- a) the Pest Control Products Act, was received November 14, 1997 in the Pest Management Regulatory Agency (PMRA).
- b) the Federal Insecticide, Fungicide and Rodenticide Act, was received July 11, 1997 in the US Environmental Protection Agency (EPA).

As per your request, it is being handled as a Joint Review (JR) with Canadian colleagues in line with the March 1996 Policy Letter issued by EPA and PMRA. EPA will be functioning as lead liaison Agency with CDPR regulatory colleagues.

Since US is functioning as lead country in the Joint Review (JR) of your product, EPA will be developing formal correspondence on behalf of both Agencies, i.e., US EPA and PMRA. Individual reviewers in both countries may also be in touch with you for clarification or discussion of technical issues that are amenable to speedy resolution between experts.

This submission was:

- i. assessed by EPA and accepted as a Reduced Risk (RR) candidate September 10, 1997; and
- ii. screened by the PMRA according to the requirements for Use Site Categories (USCs) 6 (Greenhouse Non-food), 14 (Terrestrial Food Crops) and 27 (Ornamentals Outdoors).

Unfortunately, the submission did not meet screening criteria. A complete list of deficiencies, organized by PMRA DACO Nos. is provided in Attachment 1.

By way of illustration, we are summarizing below, for your convenience, one of the key elements:

• **Toxicology** - Additional information and verification is required (see item 13, Attachment 1) Further screening comments are provided in Attachment 2. This information should be used in the preparation of future submissions.

The Agencies will retain your submission on file for 45 calendar days in order for all the deficiencies to be addressed. If your written response is inadequate or is not received by the PMRA within 45 days (of the date of this letter), the submissions will be returned to you at your expense. Please remember that the response to the list of deficiencies must be submitted in one consolidated package, organized by DACO.

Certain items in Attachment 1 (highlighted in grey text) relate to submission structure and formatting that is of particular interest to our Canadian colleagues and should be fully respected in your response letter and accompanying information. Other elements of a technical nature are of common interest to both countries.

Since PMRA will also be conducting the second round of screening on additional information and clarifications that you may submit, please direct your response and accompanying information to the PMRA c/o Rob Ward (Tel.: 613-736-3753), with a copy of the correspondence and at least all technical details (*ie.* those items not highlighted in grey in Attachment 1) to EPA c/o: Mary Waller, Acting Product Manager 21, Registration Division (7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

The adequacy of the data already submitted to the PMRA, or of the written justification for absence of data, have not been fully assessed at this time and will not be determined until further evaluation of the submission by the PMRA science divisions. As well, additional data gaps may be identified during the evaluation. Consequently, further information may be requested by the Agencies.

Additional administrative/financial aspects associated with Cost Recovery in Canada will be addressed in a separate letter which will be sent to you directly by our Canadian colleagues.

Sincerely,



Jim Jones, Director
Registration Division

encl.: Attachment 1 "Screening Deficiencies"
Attachment 2 "Screening Comments"

bcc. Kit Nelson, PMRA
Rob Ward, PMRA
Adrian Carter, PMRA
Wayne Ormrod, PMRA
Susan Lewis, US EPA
Luis Suguiyama, US EPA

ATTACHMENT 2: ALMONDS, PEACHES, CHERRIES, AND PLUMS

The use of fenhexamid on almonds, peaches, plums and cherries (stone fruit) was registered within the first seven years the first registration of fenhexamid.

- Date of first registration of fenhexamid: 1999/05/21
 - Date of first registration for use on almonds and stone fruit, excluding plums: 2000/03/31*
 - Date of tolerance for residues in/on plums: 2003/09/26**
 - Date of first stamped label that includes plums: 2003/10/24
- * Page 1 of the label is attached below.
** Page 1 of the final rule is attached below.

Criterion satisfied to qualify for the exclusive use extension:

- The alternatives to the minor use pesticide pose a greater risk to the environment or human health.

Support that the above criterion has been satisfied:

- March 18, 1999 reduced risk determination for fenhexamid use to control *Monilinia* spp. on almonds and stone fruit. The March 25, 1999 Agency letter is attached.

Supporting residue chemistry data developed by the TM-402 (KBR 2738) Fungicide Task Force:

Almonds

- MRID 44744406
Multiresidue Method Testing for TM-402 (KBR 2738) in Fatty Food According to Pam I, Appendix II, as Updated January 1994
Lab: ABC Laboratories
- MRID 44744407
Method Validation and Storage Stability for TM-402 in Almond Meat and Hulls
Lab: Analytical Development Corporation
- MRID 44744410
Magnitude of the Residue of TM-402 Fungicide (50 WDG) on Almonds (Including Amendment)
Lab: Analytical Development Corporation

Peaches, Cherries and Plums

- MRID 44346765
Determination of Storage Stability of KBR 2738 Residues in Fortified Analytical Samples of Grapes, Processed Commodities of Grapes, Peach, Tomato and Strawberry
Lab: Bayer AG
- MRID 44744408
Method Validation and Storage Stability for TM-402 in Peaches, Plums and Cherries
Lab: Analytical Development Corporation

- **MRID 44744409**
Storage Stability of TM-402 on Peaches, Plums, Cherries - Extended Interval
Lab: Analytical Development Corporation
- **MRID 44766604**
Elevate 50 WDG Fungicide: Magnitude of TM-402 Residues in Peaches, Plums and Sweet Cherries from the 1996 Crop Field Trials (Amended Report No. 2)
Lab: Analytical Development Corporation
- **MRID 44766605**
Magnitude of the Residues of TM-402 50 WDG on Tart Cherries, Peaches and Plums
Lab: Analytical Development Corporation
- **MRID 44766606**
Elevate 50 WDG Fungicide: Magnitude of TM402 Residues in Peaches from the 1997 Field Trial Conducted in Ontario, Canada
Lab: Analytical Development Corporation
- **MRID 45720101**
Magnitude of the Residue of Fenhexamid in Plum Raw Agricultural Commodities
Lab: Analytical Development Corporation
- **MRID 45720102**
Determination of Residues of KBR 2738 50 WG on Plum Following Spray Application in Italy
Lab: Bayer AG
- **MRID 45720103**
Supplement 001 of the Method 00362 for the Determination of Residues of KBR 2738 in/on Strawberry, Raspberry, Black Currant, Cherry, Kiwi, Nectarine, Plum and Tomato
Lab: Bayer AG

ELEVATE™ 50 WDG Fungicide (containing fenhexamid)
EPA Registration No. 66330-35
March 21, 2000 draft label based upon the May 21, 1999 stamped "Accepted" label.
Revised to add directions for use on almonds and stone fruit and clarify/amend directions for grapes, strawberries & ornamentals
Copy for EPA stamp - all changes have been implemented
Page 1 of 8

(Front Panel)

ELEVATE® 50 WDG FUNGICIDE

**50% Water Dispersible Granule for Use in Water as a Spray
for Control of *Botrytis cinerea* Diseases of Grapes, Strawberries and Ornamentals
and Control of *Monilinia* Diseases of Almonds and Stone Fruit**

FOR AGRICULTURAL AND ORNAMENTAL HORTICULTURAL USE ONLY

Not for Residential Use

INGREDIENTS

ACTIVE INGREDIENT:

Fenhexamid* 50.0%

INERT INGREDIENTS: 50.0%

Total 100.0%

* N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexane carboxamide

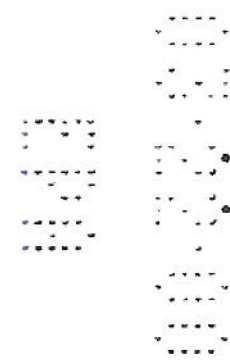
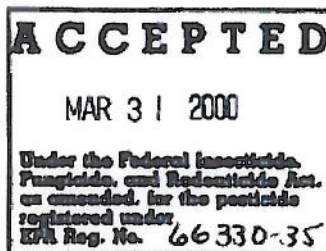
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back panel for additional precautionary statements.

Tomen Agro, Inc.
100 First Street, Suite 1700
San Francisco, CA 94105

EPA Registration No. 66330-35
EPA Establishment No. 44616-MO-01

NET WEIGHT: ____ POUNDS (____ KILOGRAMS)



((3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene) cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat by-products	0.050
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat by-products	0.050
Milk	0.030
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat by-products	0.050

(b) Section 18 emergency exemptions. [Reserved]
 (c) Tolerances with regional registrations. [Reserved]
 (d) Indirect or inadvertent residues. [Reserved]
 [FR Doc. 03-24371 Filed 9-25-03; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0301; FRL-7326-7]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenhexamid in or on cucumber; fruit, stone, group 12, except plum, prune, fresh, postharvest; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; plum, prune, dried; plum, prune, fresh; vegetable, fruiting, group 8, except

nonbell pepper. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain fenhexamid tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0301, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703) 308-9368; e-mail address: jamerson.hoyt@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 111), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., Pesticide manufacturing.

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-2003-0301. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. **Electronic access.** You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/, a beta site currently under development.

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.

II. Background and Statutory Findings

In the **Federal Register** of May 21, 2003 (68 FR 27799) (FRL-7308-4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6463, 2E6496, 3E6532, and 3E6541) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 25 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Desmond Byrne
Tomen Agro, Inc
100 First Street, Suite 1710
San Francisco, CA 94105


OPTIONAL FORM NO (7-89)

FAX TRANSMITTAL # of pages = 1

To <u>Cindy Smith</u>	From <u>Alan Dixon</u>
Dept./Agency	Phone #
Fax #	Fax # <u>703 339-1118</u>

NSN 7540-01-317-7200 5010-101 GENERAL SERVICES ADMINISTRATION

Dear Dr. Byrne:


Thank you for your submission on behalf of Tomen Agro, Inc and Bayer Corp. for the new fenhexamid uses to control *Monilinia* spp. on almonds and stone fruit. On March 18, 1999 the Reduced Risk Committee completed its review of your reduced risk rationale and granted reduced risk status to fenhexamid for the above uses. 

Please note that the reduced risk status of any chemical is an initial assessment. Should information warrant, the Agency may re-evaluate and possibly revoke your submission's reduced risk status. Also, should the Agency determine at any time that the data base for the chemical is unacceptable or incomplete, the Agency may stop the expedited process for the chemical until adequate data are submitted.

As a result of the decision to designate these uses as reduced risk, the Agency will begin working with its science divisions to schedule the data reviews and risk assessments needed for evaluating this chemical. The Agency has a goal of completing these evaluations in an expeditious manner. Mary Waller, the EPA product manager your product, will now handle all regulatory issues associated with this application. Mary can be reached at (703) 308-9354.

Thank you for your interest in reduced risk pesticides. If you have any questions regarding the reduced risk pesticide program please feel free to contact Alan Dixon at (703) 305-7237.

Sincerely yours,


Rick Keigwin, Chief
Registration Support Branch
Registration Division (7505C)

ATTACHMENT 3: CUCUMBER AND LETTUCE

The use of fenhexamid on cucumber and lettuce (leafy greens, subgroup 4A) was registered within the first seven years the first registration of fenhexamid.

- Date of first registration of fenhexamid: 1999/05/21
- Date of tolerance for residues in/on cucumbers and lettuce: 2003/09/26*
- Date of first stamped label that includes cucumbers and lettuce: 2003/10/24

* Page 1 of the final rule is attached below.

Criterion satisfied to qualify for the exclusive use extension:

- The minor use pesticide plays or will play a significant part in an integrated pest management program.

Support that the above criterion has been satisfied:

- The University of Connecticut has recommended fenhexamid for use in pest management with reference to the control of Botrytis and suppression of powder mildew on cucumber and leafy greens.

<http://www.hort.uconn.edu/ipm/greenhs/htms/ipmbtable1.html>

Supporting residue chemistry data developed by the TM-402 (KBR 2738) Fungicide Task Force:

Cucumber

- MRID 45736603
Fenhexamid: Magnitude of the Residue on Cucumber (Greenhouse) in Belgium, Italy, Spain and Germany
Lab: Bayer AG.
- MRID 45736604
Thompson, D. (1998) Fenhexamid: Magnitude of the Residue on Cucumber (Greenhouse) in Benelux, Italy, Greece and Spain
Lab: Bayer AG

Lettuce

- MRID 45795601
Determination of Residues of Teldor (50WG) in/on Lettuce Following Spray Application in the Greenhouse in Germany and Italy
Lab: Bayer AG
- MRID 45817101
Determination of Residues of KBR 2738 after Spray Application of Teldor 50 WG on Lettuce in the Greenhouse in Germany and Italy
Lab: Bayer AG

([1-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat by-products	0.050
Cotton, gm byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat by-products	0.050
Milk	0.030
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat by-products	0.050

(b) Section 18 emergency exemptions. [Reserved]
 (c) Tolerances with regional registrations. [Reserved]
 (d) Indirect or inadvertent residues. [Reserved]
 [FR Doc. 03-24371 Filed 9-25-03; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0301; FRL-7326-7]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenhexamid in or on cucumber; fruit, stone, group 12, except plum, prune, fresh, postharvest; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; plum, prune, dried; plum, prune, fresh; vegetable, fruiting, group 8, except

nonbell pepper. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain fenhexamid tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0301, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703) 308-9368; e-mail address: jamerson.hoyt@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 11), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., Pesticide manufacturing.

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-2003-0301. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

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.

II. Background and Statutory Findings

In the Federal Register of May 21, 2003 (68 FR 27799) (FRL-7308-4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6463, 2E6496, 3E6532, and 3E6541) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide

ATTACHMENT 4: PEPPERS

The use of fenhexamid on peppers was registered within the first seven years the first registration of fenhexamid.

- Date of first registration of fenhexamid: 1999/05/21
- Date of tolerance for residues in/on peppers: 2003/09/26*
- Date of first stamped label that includes peppers: 2003/10/24

* Page 1 of the final rule is attached below.

Criterion satisfied to qualify for the exclusive use extension:

- The minor use pesticide plays or will play a significant part in an integrated pest management program.

Support that the above criterion has been satisfied:

- Fenhexamid is included in, "A Pest Management Strategic Plan for Pepper Production in California" which was jointly prepared by the California Pepper Commission and The California Minor Crops Council. Please see page 13 of the publication.
<http://www.ipmcenters.org/pmsp/pdf/CAPepper.pdf>

Supporting residue chemistry data developed by the TM-402 (KBR 2738) Fungicide Task Force:

- MRID 45736605
Fenhexamid: Magnitude of the Residue on Pepper (Greenhouse) in Netherlands, France, Italy and Spain
Lab: Bayer AG
- MRID 45736606
Fenhexamid: Magnitude of the Residue on Pepper (Greenhouse) in Italy, Portugal and France
Lab: Bayer AG

((1-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene) cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat by-products	0.050
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat by-products	0.050
Milk	0.030
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat by-products	0.050

(b) Section 18 emergency exemptions. [Reserved]
 (c) Tolerances with regional registrations. [Reserved]
 (d) Indirect or inadvertent residues. [Reserved]
 [FR Doc. 03-24371 Filed 9-25-03; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0301; FRL-7326-7]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenhexamid in or on cucumber, fruit, stone, group 12, except plum, prune, fresh, postharvest; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; plum, prune, dried; plum, prune, fresh; vegetable, fruiting, group 8, except

nonbell pepper. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain fenhexamid tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0301, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001, telephone number: (703) 308-9368; e-mail address: jamerson.hoyt@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 111), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., Pesticide manufacturing.

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-2003-0301. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/, a beta site currently under development.

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.

II. Background and Statutory Findings

In the Federal Register of May 21, 2003 (68 FR 27799) (FRL-7308-4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6463, 2E6496, 3E6532, and 3E6541) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide