## ENVIRONMENTAL PROTECTION AGENCY

**[ER–FRL–6616–5]**

### Environmental Impact Statements; Notice of Availability

**Responsible Agency**

Office of Federal Activities, General Information (202) 564–7167 or *www.epa.gov/oeca/ofa* Weekly receipt of Environmental Impact Statements Filed March 12, 2001 Through March 16, 2001 Pursuant to 40 CFR 1506.9.

*EIS No. 010082,* Final EIS, NPS, AZ, Chiricahua National Monument, General Management Plan, To Protect Certain National Formations, Known as ''The Pinnacles,'' AZ , Wait Period Ends: April 23, 2001, Contact: Chris Marvel (303) 969–2840.

*EIS No. 010083,* Final EIS, NPS, AZ, Fort Bowie National Historic Site General Management Plan, Implementation, Cochise County, AZ, Wait Period Ends: April 23, 2001, Contact: Christine Maylath (303) 969–2851.

*EIS No. 010084,* Draft Supplement, FAA, MA, Logan Airside Improvements Planning Project (EOEA #10458), Construction and Operation of a new Unidirectional Runway 14/32, Centerfield Taxiway and Add'l Taxiway Improvements, New Information, Providing Clarification of the Delay Problems, Boston Logan Int'l Airport, Federal Funding, Airport Layout Plan and NPDES Permit, Boston, MA, Comment Period Ends: May 07, 2001, Contact: John Silva (781) 238–7602.

*EIS No. 010085,* Final EIS, AFS, MT, Clearwater Ecosystem Management and Timber Sale Project, Timber Harvesting, Burning, Weed Spraying and Road Management, Lola National Forest, Seeley Lake Ranger District, Missoula County, MT, Wait Period Ends: April 23, 2001, Contact: Sharon Klinkhammer (406) 677–3925.

*EIS No. 010086,* Final EIS, FHW, NC, US 17 New Bern Bypass Construction, Jones-Craven County Line to NC–1438 near Vanceboro, Funding, Section 404 and U.S. Coast Guard Bridge Permit, Craven County, NC, Wait Period Ends: April 23, 2001, Contact: Nicholas Graf (919) 856–4346.

*EIS No. 010087,* Final EIS, NPS, UT, Zion National Park, General Management Plan, Implementation, Washington, Iron and Kane Counties, UT, Wait Period Ends: April 23, 2001, Contact: Darla Sidles (435) 772–0211.

*EIS No. 010088,* Draft EIS, FHW, NB, Lincoln South and East Beltways Project, To Complete a Circumferential Transportation System linking I–80 on the north and U.S. 77 on the west, Funding, COE 404 Permit, Lancaster County, NB, Comment Period Ends: May 07, 2001, Contact: Edward Kosola (402) 437–5973.

*EIS No. 010089,* Draft Supplement, FAA, IN, Indianapolis International Airport Master Plan Development, Updated Information to Construct a Midfield Terminal, Midfield Interchange, and Associated Developments, Airport Layout Plan Approval, Funding and Section 404 Permit, Marion County, IN, Comment Period Ends: May 07, 2001, Contact: Prescott C. Snyder (847) 294–7538.

*EIS No. 010090,* Draft EIS, DOE, AZ, Sundance Energy Project, Interconnecting a 600-megawatt Natural Gas-Fired, Simple Cycle Peaking Power Plant with Western's Electric Transmission System, Construction and Operation on Private Lands, Pinal County, AZ, Comment Period Ends: May 07, 2001, Contact: John Holt (602) 352–2592.

*EIS No. 010091,* Draft EIS, FTA, CT, New Britain-Hartford Busway Project, Proposal to Build an Exclusive Bus Rapid Transit (BRT) Facility, Located in the Towns/Cities of New Britain, Newington, West Hartford and Hartford CT, Comment Period Ends: May 18, 2001, Contact: Richard H. Doyle (617) 494–2055.

*EIS No. 010092,* Draft EIS, AFS, ID, Clean Slate Ecosystem Management Project, Aquatic and Terrestrial Restoration, Nez Perce National Forest, Salmon River Ranger District, Idaho County ID, Comment Period Ends: May 07, 2001, Contact: Bill Shields (208) 839–2211.

*EIS No. 010093,* Final EIS, UAF, TX, Brooks City Base Project, To Improve Mission Effectiveness and Reduce Cost of Quality Installation Support, Implementation, Brooks Air Force Base, Bexar County, TX, Wait Period Ends: April 23, 2001, Contact: Roberta Preston (703) 695–4512.

**Amended Notices**

*EIS No. 010023,* Draft Supplement, NOA, AK, Groundfish Fishery Management Plan, Implementation, Bering Sea and Aleutian Islands, AK, Comment Period Ends: June 26, 2001, Contact: James W. Balsiger (907) 586–7221. Revision of FR notice published on 02/02/2001: CEQ Comment Date has been extended from 04/26/2001 to 06/25/2001.

*EIS No. 000463,* Draft Supplement, FHW, IL, FAP Route 340 (I–355 South Extension), Interstate Route 55 to Interstate Route 80, Additional Information for the Tollroad/Freeway Alternative, Funding, US Coast Guard Permit and COE Section 404 Permit, Cook, DuPage and Will Counties, IL, Comment Period Ends: April 30, 2001, Contact: Jon-Paul Kohler (217) 492–4988.

Published FR—12–29–00—Review Period Reestablished.

Dated: March 20, 2001.

**Joseph C. Montgomery,**

*Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 01–7321 Filed 3–22–01; 8:45 am]

**BILLING CODE 6560–50–U**

## ENVIRONMENTAL PROTECTION AGENCY

**[PF–1000; FRL–6767–3]**

### Notice of Filing Pesticide Petitions to Establish Tolerances 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 control number PF–1000, must be received on or before April 23, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1000 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS codes | Examples of potentially affected entities |
|---|---|---|
| Industry | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1000. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1000 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1000. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

### List of Subjects

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

Dated: March 12, 2001.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

### Summaries of Petitions

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

were prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petitioner's summaries 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.

**Rohm and Haas Company**

*PP 1F3989, 1F3995, and 2F4154*

EPA has received amended pesticide petitions (PP 1F3989, 1F3995, and 2F4154) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106–2399, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by making permanent the time-limited tolerances for the combined residues of fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile) and its metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone in or on the raw agricultural commodities (RACs) stone fruits (except plums and prunes) at 2.0 parts per million (ppm), pecans at 0.1 ppm, and bananas at (0.3 ppm). EPA has determined that the request contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petition.

*Background*

The tolerances that are the subject of this notice will, under current regulations, expire on December 31, 2001. The notices of filing concerning receipt of PP 3989 (fenbuconazole (only) tolerances in or on stone fruits and dried prunes at 2.0 ppm) and PP 3995 (fenbuconazole (only) tolerances in or on pecans at 0.1 ppm) were published in the **Federal Register**, at 56 FR 65080 and 65081 (December 13, 1991) (FRL–4004–1). In the **Federal Register**, at 59 FR 9985 (March 2, 1994) (FRL–4760–1), the Agency announced that Rohm and Haas had amended PP 3989 and PP 3995 by proposing to amend 40 CFR part 180 by establishing tolerances for fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile) and its metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone in or on stone fruits at 2.0 ppm and pecans at 0.1 ppm. Rohm and Haas subsequently amended PP 3989 to limit the crop group to stone fruits (except plums and prunes). There were no comments received on any of these notices. The final rule that established the tolerances for stone fruits (except plums and prunes) was published in the **Federal Register**, at 60 FR 11029 (March 1, 1995) (FRL–4938–3). The tolerances were established as time-limited tolerances because of the existence of a data gap for storage stability of fenbuconazole residues in other RACs. The notice of filing concerning receipt of PP 2F4154 (tolerances of fenbuconazole and its metabolite 5-(4-chlorophenyl)-dihydro-3-phenyl-3-(methyl-1H-1,2,4-triazole-1-yl)-2-3H-furanone in or on banana (pulp) at 0.05 ppm and banana (peel) at 0.3 ppm) was published in the **Federal Register**, at 57 FR 62334 (December 30, 1992) (FRL–4177–7). In the **Federal Register**, at 59 FR 33503 (June 29, 1994) (FRL–4866–3) the Agency announced that Rohm and Haas had amended PP 4154 by proposing to amend 40 CFR part 180 by establishing tolerances for fenbuconazole (alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile) and its metabolites cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone in or on banana (whole fruit) at 0.3 ppm, of which no more than 0.05 ppm can be contained in the banana pulp. No comments were received concerning these notices. The final rule that established the banana tolerances was published in the **Federal Register**, at 60 FR 27419 (May 24, 1995) (FRL–4955–3). These tolerances were also time-limited, based on a data gap for residues of fenbuconazole in or on unbagged bananas in field trials. The expiration date of each of the above tolerances was December 31, 1998. In the **Federal Register**, at 63 FR 67476 (December 7, 1998) (FRL–5791–5), the Agency published a notice of filing concerning the receipt of amended PP 1989, PP 3995, and PP 4154 that proposed to amend 40 CFR part 180 by extending the expiration date of the tolerances for fenbuconazole and its metabolites (as appropriate to each commodity) in or on stone fruits (except plums and prunes) at 2.0 ppm, pecans at 0.1 ppm, and banana (whole fruit) at 0.3 ppm (of which the pulp can contain no more than 0.05 ppm) until December 31, 2001. Data to fill the data gaps that had caused the tolerances to be established as time-limited tolerances had since been received from the company. No comments concerning this notice of filing were received. In the **Federal Register**, at 64 FR 7794 (February 17, 1999) (FRL–6059–7), the final rule that extended the subject tolerances until December 31, 2001, was published. The reason for extension of the time-limits on these tolerances (instead of making the tolerances permanent at that time) was that there was felt to still be a data gap for storage stability of fenbuconazole residues in other RACs.

*A. Residue Chemistry*

1. *Plant metabolism.* The metabolism of fenbuconazole in plants (peanuts, wheat, peaches, and sugar beets) is adequately understood for the purpose of these tolerances. It was qualitatively similar in all crops investigated. Metabolism of the test compound proceeded via three pathways. Oxidation at the benzylic carbon (pathway 1) led to the ketone and the lactone as metabolites. Oxidation or nucleophilic substitution on the carbon next to the triazole ring (pathway 2) led to triazole alanine (TA) and triazole acetic acid (TAA) presumably through free triazole. Metabolic pathway 3 presumably produced the phenolic metabolite RH–4911, and led to the glucose conjugates found in all crops.

2. *Analytical method.* An adequate enforcement method is available for the established and proposed tolerances. Quantitation of fenbuconazole residues (and lactones RH–9129 and RH–9130) at an analytical sensitivity of 0.01 milligrams/kilogram (mg/kg) is accomplished by soxhlet extraction of samples in methanol, partitioning into methylene chloride, redissolving in toluene, cleanup on silica gel, and gas liquid chromatography using nitrogen specific thermionic detection.

3. *Magnitude of residues.* i. *Stone fruit—peaches.* Ten field trials were conducted on peaches. Seven to 10 applications were made at the maximum use rate of 0.1 pounds of active ingredient per acre (lb ai/acre), and fruit was harvested on the last day of application. The highest field residue value was 0.51 ppm, and the average field residue value was 0.36 ppm.

ii. *Stone fruit—cherries.* Eleven field trials were conducted on cherries. Five to 6 applications were made at the maximum use rate of 0.1 lb ai/acre, and fruit was harvested on the last day of application. The highest field residue value was 0.64 ppm, and the average field residue value was 0.44 ppm.

iii. *Stone fruit—apricots.* Two field trials were conducted on apricots. Six applications were made at the maximum use rate of 0.125 lb ai/acre, and fruit was harvested on the last day

of application. The field residue values in four samples measured were 0.17, 0.23, 0.27, and 0.28 ppm.

iv. *Pecans*. Four field trials were conducted in pecans. Eight to 10 applications were made at the maximum use rate of 0.125 lb ai/acre, and nuts were harvested 28 days after the last application. Field residue values in nutmeat for the four trials were 0.004, 0.004, <0.01, and <0.01 ppm.

v. *Bananas*. Eighteen field trials were conducted on bagged bananas, which are typically used in commerce. Eight applications (five and seven applications in two trials) were made at the maximum use rate of 0.09 lb ai/acre and bananas were harvested on the last day of application. The highest field residue value in whole fruit or in pulp and peel combined was 0.062 ppm. The average field residue value in whole fruit or in pulp and peel combined was 0.03 ppm.

The results of these studies support the proposed permanent tolerances for fenbuconazole on stone fruit, pecans, and bananas.

*B. Toxicological Profile*

1. *Acute toxicity*. Fenbuconazole is practically non-toxic after administration by the oral and dermal routes, and was not significantly toxic to rats after a 4 hour inhalation exposure. Fenbuconazole is classified as not irritating to skin and inconsequentially irritating to the eyes. It is not a skin sensitizer.

2. *Genotoxicity*. Fenbuconazole was negative (non-mutagenic) in an Ames assay with and without hepatic enzyme activation. Fenbuconazole was negative in a hypoxanthine guanine phosphoribosyl transferase (HGPRT) gene mutation assay using chinese hamster ovary (CHO) cells in culture when tested with and without hepatic enzyme activation. In isolated rat hepatocytes, fenbuconazole did not induce unscheduled DNA synthesis (UDS) or repair. Fenbuconazole did not produce chromosome effects in rats *in vivo*. On the basis of the results from this battery of tests, it is concluded that fenbuconazole is not mutagenic or genotoxic.

3. *Reproductive and developmental toxicity*— i. *Developmental toxicity in the rat*. In the developmental study in rats, the maternal (systemic) no observed adverse effect level (NOAEL) was 30 (mg/kg/day) based on decreases in body weight and body weight gain at the lowest observed adverse effect level (LOAEL) of 75 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on an increase in post implantation loss and a significant decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day.

ii. *Developmental toxicity in the rabbit*. In the developmental study in rabbits, the maternal (systemic) NOAEL was 10 mg/kg/day based on decreased body weight gain at the LOAEL of 30 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on increased resorptions at the LOAEL of 60 mg/kg/day.

iii. *Reproductive toxicity*. In the 2–generation reproduction toxicity study in rats, the maternal (systemic) NOAEL was 4 mg/kg/day based on decreased body weight and food consumption, increased number of dams delivering nonviable offspring, and increases in adrenal and thyroid weights at the LOAEL of 40 mg/kg/day. The reproductive (pup) NOAEL was 40 mg/kg/day, the highest dose tested.

4. *Subchronic toxicity*—i. *Rat 90–day oral study*. A subchronic feeding study in rats conducted for 13 weeks resulted in a NOAEL of 20 ppm (1.3 and 1.5 mg/kg/day in males and females, respectively). Minimal liver hypertrophy was observed in males at the LOAEL of 80 ppm. Increased liver weight, hepatic hypertrophy, thyroid hypertrophy, and decreased body weight were observed at the higher doses of 400 and 1,600 ppm.

ii. *Mouse 90–day oral study*. A subchronic feeding study in mice conducted for 13 weeks resulted in a NOAEL of 60 ppm (11.1 and 17.6 mg/kg/day in males and females, respectively). Increased liver weight, hypertrophy in the liver (males), and increases in clinical chemistry parameters (males) were observed at the LOAEL of 180 ppm. These effects were all observed in females at 540 ppm, in addition to males.

iii. *Dog 90–day oral study*. A subchronic feeding study in dogs conducted for 13 weeks resulted in a NOAEL of 100 ppm (3.3 and 3.5 mg/kg/day in males and females, respectively). At the LOAEL of 400 ppm, increased liver weight, clinical chemistry parameters, and liver hypertrophy (males) were observed.

iv. *Rat 4–week dermal study*. In a 21–day dermal toxicity in the rat study, the NOAEL was greater than 1,000 mg/kg/day, with no effects seen at this limit dose.

5. *Chronic toxicity*—i. *Dog*. A one–year feeding study in dogs resulted in a NOAEL of 15 ppm (0.62 mg/kg/day) for females and 150 ppm (5.2 mg/kg/day) for males. Decreased body weight, increased liver weight, liver hypertrophy, and pigment in the liver were observed at the LOAEL of 150 and 1,200 ppm in females and males, respectively.

ii. *Mouse*. A 78–week chronic/oncogenicity study was conducted in male and female mice at 0, 10, 200 (males only), 650, and 1,300 ppm (females only). The NOAEL was 10 ppm (1.4 mg/kg/day), and the LOAEL was 200 ppm (26.3 mg/kg/day) for males and 650 ppm (104.6 mg/kg/day) for females based on increased liver weight and histopathological effects on the liver, which were consistent with chronic enzyme induction. There was no statistically significant increase of any tumor type in males. However, there was a statistically significant increase in combined liver adenomas and carcinomas in females at the high dose only (1,300 ppm; 208.8 mg/kg/day). There were no liver tumors in the control females, and liver tumor incidences in the high-dose females just exceeded the historical control range. In ancillary mode-of-action studies in female mice, the increased tumor incidence was associated with changes in several parameters in mouse liver following high doses of fenbuconazole, including an increase in P450 enzymes (predominately of the CYP 2B type), an increase in cell proliferation, an increase in hepatocyte hypertrophy, and an increase in liver weight. Changes in these liver parameters, as well as the occurrence of the low incidence of liver tumors, were non-linear with respect to dose (i.e., effects were observed only at high dietary doses of fenbuconazole). Similar findings have been shown with several pharmaceuticals, including phenobarbital, which is not carcinogenic in humans. The non-linear dose response relationship observed with respect to liver changes (including the low incidence of tumors) in the mouse indicates that these findings should be carefully considered in deciding the relevance of high-dose animal tumors to human dietary exposure.

iii. *Rat*. A 24–month chronic/oncogenicity study in male and female rats was conducted at 0, 8, 80, and 800 ppm fenbuconazole, and a second 24–month chronic/oncogenicity study was conducted in male rats at 0, 800, and 1,600 ppm. The NOAEL was 80 ppm (3 and 4 mg/kg/day in males and females, respectively), and the LOAEL was 800 ppm (31 and 43 mg/kg/day in males and females, respectively) based on decreased body weight, increased liver and thyroid weights, and liver and thyroid hypertrophy. Fenbuconazole produced a minimal but statistically significant increase in the incidence of combined thyroid follicular cell benign and malignant tumors. These findings

occurred only in male rats following life-time ingestion of very high levels (800 and 1,600 ppm in the diet) of fenbuconazole.

6. *Animal metabolism*. The absorption, distribution, excretion, and metabolism of fenbuconazole in rats, goats, and hens were investigated. Following oral administration, fenbuconazole was completely and rapidly absorbed, extensively metabolized by oxidation/hydroxylation and conjugation, and rapidly and essentially completely excreted, predominately in the feces. Fenbuconazole did not accumulate in tissues.

7. *Metabolite toxicology*. Common metabolic pathways for fenbuconazole have been identified in both plants (wheat, peaches, and sugar beets) and animals (rat, goat, and hen). The metabolic pathway common to both plants and animals involves oxidation of the benzylic position alpha to the chlorophenyl ring. The metabolites which result from this path are the benzylic alcohols and their conjugates, including sulfates and glucuronides, the iminolactones, the lactones, and the ketoacid, all resulting from intramolecular cyclization. A second pathway is oxidation of the unchlorinated ring to produce the 3– and 4–phenols and their conjugates. Combinations of the above two pathways produce phenol-lactones and their conjugates. A third pathway is cleavage of the triazole moiety, which produces free triazole and its conjugates. Extensive degradation and elimination of polar metabolites occurs in animals such that residues are unlikely to accumulate in humans or animals exposed to these residues through the diet.

8. *Endocrine disruption*. The mammalian endocrine system includes estrogen and androgens as well as other hormonal systems. Fenbuconazole is not known to interfere with reproductive hormones; thus, fenbuconazole should not be considered to be estrogenic or androgenic. There are no known instances of proven or alleged adverse reproductive or developmental effects to people, domestic animals, or wildlife as a result of exposure to fenbuconazole or its residues.

*C. Aggregate Exposure*

1. *Dietary exposure*. Time-limited tolerances have been established (40 CFR part 180) for the residues of fenbuconazole in the RACs stone fruits (except plum and prune) at 2.0 ppm, pecan at 0.1 ppm, and banana (whole fruit) at 0.3 ppm. Risk assessments were conducted by Rohm and Haas to assess dietary exposures and risks from fenbuconazole as follows.

i. *Food—Acute exposure and risk*. No acute endpoint was identified for fenbuconazole, and no acute risk assessment is required.

ii. *Chronic exposure and risk*. Risk associated with chronic dietary exposure from fenbuconazole was assessed on four levels. In the first assessment, tolerance level residues and 100% crop treated were assumed. In the second assessment, tolerance level residues and Rohm and Haas Company's conservative estimates of the highest achievable percent crop treated refinements were assumed. Rohm and Haas Company's percent of crop treated estimates used in the assessments are stone fruit = 30%, bananas = 20%, and pecans = 11%. In the third assessment, average field trial (anticipated) residues and 100% crop treated were assumed. In the fourth assessment, average field trial residues and Rohm and Haas Company's conservative percent of crop treated estimates indicated above were assumed. The anticipated residue contribution (ARC) from stone fruit (except plums and prunes), pecans, and bananas was assessed.

The reference dose (RfD) used for the chronic dietary analysis is 0.03 mg/kg/day. Potential chronic exposures were estimated using NOVIGEN'S dietary exposure evaluation model (DEEM~ version 7.075), which uses United States Department of Agriculture (USDA) food consumption data from the 1994–1996 survey. The existing and proposed fenbuconazole tolerances, and average fenbuconazole residues, result in ARCs that are equivalent to the following percentages of the RfD.

| Population Subgroup | DEEM[1] %RfD | DEEM[2] %RfD | DEEM[3] %RfD | DEEM[4] %RfD |
|---|---|---|---|---|
| U.S. population (48 states) | 1.5 | 0.4 | 0.2 | 0.1 |
| Nursing infants (<1–year old) | 5.1 | 1.4 | 0.8 | 0.2 |
| Non-nursing infants (<1–year old) | 10.8 | 3.1 | 1.7 | 0.5 |
| Children (1 to 6 years old) | 4.3 | 1.2 | 0.7 | 0.2 |
| Children (7 to 12 years old) | 2.0 | 0.6 | 0.3 | 0.1 |
| Females (13+ and nursing) | 1.9 | 0.5 | 0.3 | 0.1 |

[1]Assumes residues are present at tolerance levels and 100% crop treated.
[2]Assumes residues are present at tolerance levels and includes percent crop treated refinements.
[3]Assumes residues are present at their average field trial residue levels and 100% crop treated.
[4]Assumes residues are present at their average field trial residue levels and includes percent crop treated refinements.

iii. *Drinking water*. Fenbuconazole has minimal tendency to contaminate ground water or drinking water because of its adsorptive properties on soil, solubility in water, and degradation rate. USDA PRZM/GLEAMS computer modeling of laboratory and field dissipation data predict that fenbuconazole will not leach into ground water, even if heavy rainfall is simulated. The modeling predictions are consistent with the data from environmental studies in the laboratory and the results of actual field dissipation studies. There is no established maximum concentration level (MCL) for residues of fenbuconazole in drinking water. No drinking water health advisory levels have been established for fenbuconazole. There is no entry for fenbuconazole in the ''Pesticides in Ground Water Data Base'' (EPA 734–12–92–001; September 1992).

2. *Non-dietary exposure*. Fenbuconazole is not currently registered for any indoor or outdoor residential uses; therefore, no non-dietary residential exposure is anticipated.

3.*Aggregate cancer risk for U.S. population*. Fenbuconazole has been classified as a group C carcinogen with a $Q_1^*$ value of 0.00359 mg/kg/day$^{-1}$. Cancer risk assessments for fenbuconazole use on stone fruit (except plums/prunes), pecans, and bananas for the U.S. population are as follow.

| Assumptions/ Refinements | Stone fruits (except plums and prunes), pecans, and bananas |
|---|---|
| Tolerance residue levels and 100% crop treated assumed | $1.67 \times 10^{-6}$ |
| Tolerance residue levels and percent crop treated refinements assumed | $4.62 \times 10^{-7}$ |
| Anticipated residue levels and 100% crop treated assumed | $2.68 \times 10^{-7}$ |
| Anticipated residue levels and percent treated refinements assumed | $7.64 \times 10^{-8}$ |

*D. Cumulative Effects*

The potential for cumulative effects of fenbuconazole with other substances that have a common mechanism of toxicity was considered. Fenbuconazole belongs to the class of fungicide chemicals known as triazoles having demethylase inhibition capability. The toxicological effects of fenbuconazole are related to its effects on rodent thyroid and liver. Extensive data that are available on the biochemical mode of action by which fenbuconazole produces animal tumors in rats and mice indicate that the initiating events do not occur below a given dose, and that the processes are reversible. There are no data which suggest that the mode of action by which fenbuconazole produces these animal tumors or any other toxicological effect is common to all fungicides of this class. In fact, the closest structural analog to fenbuconazole among registered fungicides of this class is not tumorigenic in animals, even at maximally tolerated doses, and has a different spectrum of toxicological effects.

*E. Safety Determination*

1. *U.S. population*—i. *Acute exposure and risk*. Since no acute endpoint was identified for fenbuconazole, no acute risk assessment is required.

ii. *Chronic exposure and risk*. Using the conservative exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of fenbuconazole from the proposed permanent tolerances is 1.5% for the U.S. population, assuming residues are present at their tolerance levels and 100% crop treated. The percentage of the RfD that will be utilized by dietary (food only) exposure to residues of fenbuconazole from the proposed permanent tolerances is 0.1% for the U.S. population, assuming residues are present at their average field trial residue levels, and conservative percent crop treated refinements. Aggregate exposure is not expected to exceed 100%. EPA generally has no concern for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Rohm and Haas concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to fenbuconazole residues.

2. *Infants and children*—i. *General*. In assessing the potential for additional sensitivity of infants and children to residues of fenbuconazole, data from developmental toxicity studies in the rat and rabbit, and 2–generation reproduction studies in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

ii. *Developmental toxicity studies*—a. *Rat*. In the developmental study in rats, the maternal (systemic) NOAEL was 30 mg/kg/day based on decreases in body weight and body weight gain at the LOAEL of 75 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on an increase in post implantation loss and a significant decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day.

b. *Rabbit*. In the developmental study in rabbits, the maternal (systemic) NOAEL was 10 mg/kg/day based on decreased body weight gain at the LOAEL of 30 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on increased resorptions at the LOAEL of 60 mg/kg/day.

c. *Reproductive toxicity study*. In the 2–generation reproduction toxicity study in rats, the maternal (systemic) NOAEL was 4 mg/kg/day based on decreased body weight and food consumption, increased number of dams delivering nonviable offspring, and increases in adrenal and thyroid weights at the LOAEL of 40 mg/kg/day. The reproductive (pup) NOAEL was 40 mg/kg/day, the highest dose tested.

d. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology data base for fenbuconazole is complete with respect to current toxicological data requirements. There is a 10–fold difference between the developmental NOAEL of 30 mg/kg/day from the rat and rabbit developmental toxicity studies and the NOAEL of 3 mg/kg/day from the chronic rat feeding study which is the basis of the RfD. It is further noted that in the rabbit and rat developmental toxicity studies, the developmental NOAELs are similar to or greater than the respective maternal NOAELs. In the rat reproduction study, the maternal NOAEL (4 mg/kg/day) was 10 times lower than the developmental (pup) and reproductive NOAEL (40 mg/kg/day, the highest dose tested). These studies indicate that there is no additional sensitivity for infants and children in the absence of maternal toxicity for fenbuconazole.

e. *Acute risk*. No acute dietary risk has been identified for fenbuconazole.

f. *Chronic risk*. Using the exposure assumptions described above, exposure to fenbuconazole from food will utilize 10.8% of the RfD for non-nursing infants <1 year old and 5.1% for nursing infants <1 year old assuming residues are present at tolerance levels and 100% crop treated. Exposure to fenbuconazole will utilize only 0.5% of the RfD for non-nursing infants <1 year old and 0.2% for nursing infants <1 year old assuming residues are present at their average field trial residue levels and conservative percent crop treated refinements. The exposure to fenbuconazole from food will utilize 4.3% of the RfD for children 1 to 6 years old and 2.0% for children 7 to 12 years old assuming residues are present at tolerance levels and 100% crop treated, and will utilize only 0.2% of the RfD for children 1 to 6 years old and 0.1% for children 7 to 12 years old assuming residues are present at their average field trial residue levels and conservative percent crop treated refinements. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

g. *Conclusion*. It is concluded that reliable and complete data support the use of the 100–fold uncertainty factor (UF), and that an additional 10–fold factor is not needed to ensure the safety of infants and children from dietary exposure. Rohm and Haas concludes that there is a reasonable certainty that no harm will result from aggregate exposure of infants and children to fenbuconazole residues.

*F. International Tolerances*

There are currently no Codex maximum residue limits (MRLs) for fenbuconazole, but the fenbuconazole data base was evaluated by the world health organization (WHO) and the food and agriculture organization (FAO) expert panels at the joint meeting on pesticide residues (JMPR) in September 1997. An allowable daily intake (ADI; also called RfD) of 0.03 mg/kg/day and a total of 32 Codex MRLs were proposed in the JMPR report.

[FR Doc. 01–7287 Filed 3–22–01; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–6957–4]**

## Notice of Proposed Administrative Order on Consent Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as Amended, 42 U.S.C. 9622, Lehigh Portland Cement Company Superfund Site, Mason City, Iowa, Docket No. CERCLA–07–2001–0006

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed administrative order on consent, Lehigh Portland Cement Company superfund site, Mason City, Iowa.

**SUMMARY:** Notice is hereby given that a proposed administrative order on consent regarding Lehigh Portland Cement Company was signed by the United States Environmental Protection Agency (EPA) on February 6, 2001, and approved by the United States Department of Justice (DOJ) on February 19, 2001.

**DATES:** EPA will receive, for a period until on or before April 23, 2001, written comments relating to the proposed administrative order on consent.

**ADDRESSES:** Comments should be addressed to Barbara L. Peterson, Senior Assistant Regional Counsel, United States Environmental Protection Agency, Region VII, 901 N. 5th Street, Kansas City, Kansas 66101 and should refer to *the Lehigh Portland Cement Company Superfund Site Administrative Order on Consent.*

The proposed consent order may be examined or obtained in person or by mail at the office of the United States Environmental Protection Agency, Region VII, 901 N. 5th Street, Kansas City, KS 66101, (913) 551–7277.

**SUPPLEMENTARY INFORMATION:** The proposed consent order concerns the Lehigh Portland Cement Company Superfund Site located in Mason City, Cerro Gordo County, Iowa. The consent order resolves the liability of Lehigh under Section 107(a) of CERCLA, 42 U.S.C. 9607(a), for both EPA response costs and natural resource damages relating to the site. Under the Administrative Order, Lehigh will pay the United States $640,000 in settlement of EPA's past response costs and $35,000 in settlement of natural resource damages claims.

Dated: March 7, 2001.

**William W. Rice,**

*Acting Regional Administrator, United States Environmental Protection Agency, Region VII.*

[FR Doc. 01–7284 Filed 3–22–01; 8:45 am]

**BILLING CODE 6560–50–M**

## ENVIRONMENTAL PROTECTION AGENCY

**[PB–402404A–IN; FRL–6767–7]**

## Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; Approval of State of Indiana Lead Activities Program

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

**ACTION:** Notice.

**SUMMARY:** On April 12, 2000, the State of Indiana submitted an application for EPA approval to administer and enforce training and certification requirements, training program accreditation requirements, and work practice standards for lead-based paint activities in target housing and child-occupied facilities under section 402 of the Toxic Substances Control Act (TSCA). Indiana provided a self-certification letter stating that its program is at least as protective of human health and the environment as the Federal program and it has the legal authority and ability to implement the appropriate elements necessary to receive EPA approval. In the **Federal Register** of August 8, 2000 (65 FR 68498) (FRL–6593–2), EPA published a notice announcing receipt of the State's application. EPA did not receive any comments regarding any aspect of the Indiana program and/or application. This notice announces the approval of the Indiana application, and the authorization of the Indiana Department of Environmental Management's Lead-Based Paint Activities Program to apply in the State of Indiana, effective April 12, 2000, in leu of the corresponding Federal program under section 402 of TSCA.

**DATES:** Based upon the State's self-certification, Lead-Based Paint Activities Program authorization was granted to the State of Indiana effective on April 12, 2000.

**FOR FURTHER INFORMATION CONTACT:** Ludmilla Koralewska, Project Officer, Environmental Protection Agency, Region V, 77 West Jackson Blvd. (DT-8J), Chicago, IL 60604; telephone: (312) 886–3577; e-mail address: koralewska.ludmilla@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to firms and individuals engaged in lead-based paint activities in Indiana. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 Additional Information, Including Copies of this Document or Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PB–402404A–IN. The official record consists of the documents specifically referenced in this action, this notice, the State of Indiana's authorization application, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any