

Regulation Development Section, Regulation Development Branch (AR-18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the State submittal and USEPA's analysis of it are available for inspection at: Regulation Development Section, Regulation Development Branch (AR-18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

**FOR FURTHER INFORMATION CONTACT:** William Jones, Environmental Engineer, Regulation Development Section, Regulation Development Branch (AR-18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6058.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule published in the final rules section of this Federal Register.

Dated: December 15, 1995.

Valdas V. Adamkus,

*Regional Administrator.*

[FR Doc. 96-1849 Filed 1-30-96; 8:45 am]

**BILLING CODE 6560-50-P**

#### 40 CFR Part 152

[OPP-250110; FRL-4984-9]

RIN 2070-AC18

#### Notification to the Secretary of Agriculture

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

**ACTION:** Notification to the Secretary of Agriculture.

**SUMMARY:** Notice is given that the Administrator of EPA has forwarded to the Secretary of Agriculture a final regulation under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The rule (OPP-300350A) exempts certain substances from regulation under FIFRA. This action is required by FIFRA section 25(a)(2).

**FOR FURTHER INFORMATION CONTACT:** By mail: Robert S. Brennis, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington DC 20460. Office location and telephone number: Rm. 713, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703-305-7501), e-mail Brennis.robert@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Section 25(a)(2) of FIFRA provides that the

Administrator shall provide the Secretary of Agriculture with a copy of any final regulation at least 30 days before signing it for publication in the Federal Register. If the Secretary comments in writing regarding the final regulation within 15 days after receiving it, the Administrator shall issue for publication in the Federal Register, with the final regulation, the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing within 15 days after receiving the final regulation, the Administrator may sign the regulation for publication in the Federal Register anytime thereafter.

Authority: 7 U.S.C. 136 et seq.

Dated: January 22, 1996.

Daniel M. Barolo,

*Director, Office of Pesticide Programs.*

[FR Doc. 96-1718 Filed 1-30-96; 8:45 am]

**BILLING CODE 6560-50-F**

#### 40 CFR Part 180

[PP 0E3853/P640; FRL-4993-6]

RIN 2070-AC18

#### Pesticide Tolerance for Hexaconazole

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish a time-limited tolerance, to expire on (3) years after the signature date of the final rule), for residues of the fungicide hexaconazole, [(alpha-butyl-alpha-(2,4-dichloro-phenyl)-1H-1,2,4-triazole-1-ethanol)], in or on the imported raw agricultural commodity bananas at 0.1 part per million (ppm). Zeneca Agrochemicals Products (Zeneca) petitioned for this regulation to establish a maximum permissible level for residues of the fungicide.

**DATES:** Comments, identified by the document control number [PP 0E3853/P488], must be received on or before March 1, 1996.

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all

of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number, "[PP 0E3853/P640]." No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below.

**FOR FURTHER INFORMATION CONTACT:** By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway., Arlington, VA 22202, (703) 305-6900, e-mail: welch.connie@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA is proposing to establish a time-limited tolerance for residues of the fungicide hexaconazole, [(alpha-butyl-alpha-(2,4-dichlorophenyl)-1H-1,2,4-triazole-1-ethanol)], in or on the raw agricultural commodity bananas at 0.1 part per million (ppm). The proposed regulation to establish a maximum permissible level of the fungicide pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, by amending 40 CFR part 180 to include this commodity was requested in a petition (0E3853) submitted by Zeneca, New Murphy Road, Concord Pike, Wilmington, DE 19897. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data

considered in support of the proposed tolerance include the following:

1. In a 2-year feeding study in rats, hexaconazole was tested at 10, 100 and 1,000 ppm (equivalent to 0.47, 4.7 and 47 mg/kg/day in females and 0.61, 6.1 and 61 mg/kg/day in males). The no-observed-effect level (NOEL) was established at 100 ppm (equivalent to 0.61 and 0.47 mg/kg/day in males and females, respectively) for body weight gain reduction and liver pathology (centrilobular fatty changes and hypertrophy).

2. A 1-year dog feeding study using doses of 2, 10 and 50 mg/kg/day, tested hexaconazole in male and female Beagle dogs. The chemical was administered in gelatin capsules. The NOEL was established at 2 mg/kg/day based upon fatty infiltration of the liver and increased liver weight.

3. In a developmental toxicity study, hexaconazole was tested at 2.5, 25 and 250 mg/kg/day in Wistar rats. The NOEL/LOEL for maternal toxicity were considered to be 25 and 250 mg/kg/day based upon reduced body weight gain. The LOEL for developmental toxicity was established at 25 mg/kg/day based upon delayed skeletal ossification and increased incidence of the 14th rib (bilateral). The NOEL for developmental toxicity was found to be 2.5 mg/kg/day.

In two developmental toxicity studies involving New Zealand White rabbits, hexaconazole was tested at 25, 50 and 100 mg/kg/day. The NOEL/LOEL for maternal toxicity were established at 50 and 100 mg/kg/day based upon reduced maternal body weight gain. The NOEL/LOEL for developmental toxicity were considered to be 25 and 50 mg/kg/day based upon decreased mean fetal body weight.

The Agency is requiring an occupational exposure risk assessment based on the NOEL of 2.5 mg/kg/day demonstrated in the developmental toxicity study in rats, as well as, an acute dietary exposure study in rats.

4. In a 2-generation reproduction study in Wistar rats, the chemical was tested at 20, 100 and 1,000 ppm (equivalent to 1, 5 and 50 mg/kg/day). On the basis of abnormal liver pathology, a systemic NOEL was set at 20 ppm. The NOEL/LOEL for reproductive toxicity were established at 100 and 1,000 ppm based upon decreased weight gain and survival in pups. Reproductive toxicity of hexaconazole was considered minimal.

5. From a 2-year carcinogenicity study in Wistar rats, hexaconazole was classified as a Group C (possible Human) carcinogen with a  $Q_1^*$  of 0.023 mg/kg/day based on testicular Leydig cell tumors. This classification was

recommended based upon a statistically significant increase in benign Leydig cell tumors, with a positive dose-related trend in rats. Moreover, the Leydig cell tumor is an uncommon tumor in this strain of rats, and occurred at an accelerated rate and at a dose level below what would be considered an adequate level to determine the carcinogenic potential of hexaconazole. There was also some indication of marginal increases in liver cell tumors in mice. The classification was further supported by structural similarity of hexaconazole to other triazole pesticides known for their potential as liver carcinogens in mice.

6. The Reference Dose (RfD) value for use in dietary exposure analysis was 0.02 mg/kg body weight(bwt)/day, basis of a NOEL of 2 mg/kg bwt/day and an uncertainty factor of 100. This NOEL was derived from a 1-year feeding study in dogs that showed increased liver weight accompanied by fatty infiltration of the liver observed at 10 mg/kg/day.

7. A chronic dietary exposure analysis for use of hexaconazole in/on imported bananas was performed to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 population subgroups. Results show the TMRC and %RfD for the U.S. population is 0.023  $\mu$ g/kg/day and 0.11% for the RfD, respectively. The highest exposed subgroup is non-nursing infants (<1 year old) for which TMRC and %RfD are 0.108  $\mu$ g/kg/day and 0.45%, respectively.

The Agency concluded from this analysis that chronic dietary risk is not a concern.

8. From cancer risk assessment, the upper-bound carcinogenic risk from food uses of hexaconazole for the general U.S. population as calculated using the following equation:

$$\text{Upper Bound Cancer Risk} = \text{Dietary Exposure (TMRC)} \times Q_1^*$$

Based on a  $Q_1^*$  of 0.023 (mg/kg/day)<sup>-1</sup> the upper bound cancer risk was calculated to be  $5.3 \times 10^{-7}$ , contributed by the upper bound excess lifetime carcinogenic risk appears to be below the range that the Agency generally considers to be negligible.

9. Mutagenicity assays including an Ames test, an invitro cytogenetics assay in human lymphocytes, an assay for unscheduled DNA synthesis in rat hepatocytes, and a micronucleus assay in mice were conducted on this chemical. The results of these tests produced no evidence of mutagenicity due to hexaconazole.

Acute toxicity testing is not required for import tolerances and those data are not presented here.

The nature of the residue in bananas is adequately understood. The residue to be regulated is parent hexaconazole. Based on the residue data submitted which reflected application to bagged bananas (the typical agricultural practice in the countries of origin), residue levels in bananas treated with hexaconazole are not likely to exceed the requested 0.1 ppm tolerance. However, the Agency's current practice is to review data on unbagged bananas as well as bagged bananas to insure that a worst case scenario is examined. Therefore, the petitioner is required to conduct at least four residue trials on unbagged bananas. Ample time is provided for completion of these trials over the duration of this proposed time-limited tolerance.

Adequate analytical methodology is available for enforcement. Prior to their publication in the Pesticide Analytical Manual, Vol. II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 1128C, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5232.

The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below. By way of public reminder, this notice also reiterates the registrant's responsibility under section 6(a)(2) of FIFRA, to submit additional factual information regarding adverse effects on the environment and to human health by these pesticides.

#### Public Docket

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDC.

Interested persons are invited to submit written comments on the proposed regulation. A record has been established for this rulemaking under docket number [PP 0E3853/P640] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

#### Administrative Assessment Requirements

##### A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3)

materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

##### B. Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

##### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 17, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

#### **PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding new § 180.488, to read as follows:

##### **§ 180.488 Hexaconazole; tolerance for residues.**

A tolerance is established for residues of the fungicide hexaconazole, [alpha-butyl-alpha-(2,4-dichloro-phenyl)-1H-1,2,4-triazole-1-ethanol], in or on the imported raw agricultural commodity bananas at 0.1 part per million. This tolerance will expire on [ 3 years after the signature date of the final rule]. There are no U.S. registrations as of January 31, 1996 for use on bananas. [FR Doc. 96-1917 Filed 1-30-96; 8:45 am]

BILLING CODE 6560-50-F

#### **40 CFR Part 300**

[FRL-5403-3]

#### **National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List for Uncontrolled Hazardous Waste Sites; Notice of Intent to Delete 29th and Mead Ground Water Contamination Site from the National Priorities List (NPL): Request for Comment**

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

**ACTION:** Notice of intent to delete and request for comment.

**SUMMARY:** The Environmental Protection Agency (EPA) announces its intent to delete the 29th and Mead Ground Water Contamination Site in Wichita, Sedgwick County, Kansas, from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended.

Because of the unique circumstances surrounding the 29th and Mead Ground Water Contamination Site, the Agency has determined that no further federal steps under CERCLA are appropriate. The Site will instead, in a pilot project, be deferred to the State of Kansas and addressed by the Kansas Department of Health and Environment (KDHE). EPA will consider the effectiveness and efficiency of the Site cleanup as well as the likelihood that a similarly favorable outcome could be reproduced elsewhere before determining whether such a policy will be considered for other sites. The rationale supporting this action is explained in the Basis for Intended Site Deletion section.

**DATES:** Comments concerning the proposed deletion of the 29th and Mead Ground Water Contamination Site should be submitted on or before March 1, 1996.

**ADDRESSES:** Mail original and three copies of comments (no facsimiles or tapes) to Docket Coordinator, Headquarters; U.S. Environmental Protection Agency; CERCLA Docket Office; (Mail Code 5201G); 401 M Street, SW; Washington, D.C. 20460; (703) 603-8917.

Comprehensive information on the 29th and Mead Ground Water Contamination Site is maintained in the public docket, which is available for public review at the information