| Commodity | Parts per million | Expiration/revocation date |
|---|---|---|
| * * * * * | | |
| Caneberries | 5.0 | 12/31/00 |
| * * * * * | | |

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[FR Doc. 99–16544 Filed 6–29–99; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–300871; FRL–6084–4]**

**RIN 2070–AB78**

### Hexaconazole; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of the fungicide hexaconazole, [alpha-butyl-alpha-(2,4-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol] in or on the imported raw agricultural commodity bananas at 0.7 parts per million (ppm). Zeneca Ag Products requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective June 30, 1999. Objections and requests for hearings must be received by EPA on or before August 30, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300871], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300871], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300871]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, waller.mary@epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 24, 1999 (64 FR 9147) (FRL–6058–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 0E3853) for tolerance by Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.488 be amended by establishing a tolerance for residues of the fungicide hexaconazole, [alpha-butyl-alpha-(2,4-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol], in or on the imported raw agricultural commodity bananas at 0.7 ppm.

## I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of hexaconazole, [alpha-butyl-alpha-(2,4-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol] on the imported raw agricultural commodity bananas at 0.7 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as

the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by hexaconazole are discussed in this unit.

1. *Acute toxicity*. Hexaconazole possesses a low order acute toxicity by the oral, dermal and inhalation routes of exposure [categories 3/4]. It is slightly to moderately irritating to the eye and non-irritating to the skin. Hexaconazole tested positive in animal studies for skin sensitization.

2. *Subchronic toxicity and chronic toxicity*. Subchronic and chronic dietary feeding studies in mice, rats and dogs indicate that the liver is the primary target organ as generally seen by increased enzyme levels, liver cell hypertrophy, and fatty infiltration of the liver across species. Decreased body weight gain was also seen across species.

Groups of male and female mice fed dietary doses ranging from 3.75 milligrams (mg)/kilograms (kg)/day to 225 mg/kg/day for 29 days manifested group mean body weight decreases of 17% in males and 14% in females at the lowest observed adverse effect level (LOAEL) of 15 mg/kg/day concurrent with hepatotoxicity. The no observed adverse effect level (NOAEL) was 3.75 mg/kg/day.

Male and female rats were given dietary levels of compound in feed for a period of either 90 days or 2 years at doses ranging from 2.5 to 250 mg/kg/day for 90 days or 2 years at doses ranging from 0.47 mg/kg/day to 61 mg/kg/day. Body weight gains in the 90–day study were statistically significantly decreased at 250 mg/kg/day in both sexes at this high dose. The LOAEL of 25 mg/kg/day for both sexes was based on slight fatty changes in the liver of males and cortical parenchymal vacuolation for the adrenal gland in both sexes. The NOAEL was 2.5 mg/kg/day.

Dogs in a 90–day study given hexaconazole by capsule at doses of 0, 5, 25 or 125 mg/kg/day reduced to 50 mg/kg/day with the addition of a new group and the termination of the original group at 125 mg/kg/day as a result of extreme toxicity manifested increases in alkaline phosphatase and serum glutamic pyruvic transaminase (SGPT) and decreases in cholesterol and triglycerides as well as fatty infiltration of the liver at the LOAEL of 25 mg/kg/day. The NOAEL was 5 mg/kg/day. Liver organ weight increases on a relative and absolute basis were increased at the highest dose tested (HDT) accompanied by pallor and enlargement of the liver and an accumulation of lipid.

Male and female dogs in a 12–month oral gavage study given either 0, 2, 10 or 50 mg/kg/day of hexaconazole showed fatty infiltration of the liver in males and an increase in the liver weights of females at the LOAEL of 10 mg/kg/day. The NOAEL was 2 mg/kg/day. Albumin, total protein, calcium, cholesterol, and triglyceride were decreased at 50 mg/kg/day at all time periods. Females showed an increase in SGPT and a decrease in plasma urea at the HDT. Alkaline phosphatase was also increased in both sexes at the HDT. Liver and kidney weight were increased at the high dose. Fatty infiltration of the liver was seen at the high dose in all dogs.

3. *Carcinogenicity*. In a 3 dose chronic dietary/carcinogenicity rat feeding study, males and females received either 0, 10, 100 or 1,000 ppm of compound in the diet. The NOAEL was 4.7 and 6.1 mg/kg/day for males and females respectively. The LOAEL was 47 for males and 61 mg/kg/day females based on decreased body weight gains in females of 7% and fatty changes in the centrilobular region of the liver of males as well as increased incidence of cortical vacuolation of the adrenal gland and tubular atrophy of the testes in males which was considered to be an acceleration of natural occurring lesions. Effects at the HDT LOAEL were essentially an extension of the effects at the lower doses. There was a dose responsive positive trend in the number of benign Leydig cell tumors in the testes and a significant pair wise comparison between the HDT and the controls. These tumors were considered uncommon in the test strain and occurred at an accelerated rate.

Male and female mice fed hexaconazole for a period of 2 years at doses ranging from 0.57 to 29.6 mg/kg/day showed body weight gain decreases and decreased food efficiency at the LOAEL of 23.5 mg/kg/day for males and 29.6 mg/kg/day for females. Increased liver weight and an increase in hepatocellular hypertrophy as well as an increase in centrilobular fatty infiltration of the liver in both sexes was also reported at the high dose. However, the HDT was not considered to be the maximum tolerated dose for the purpose of carcinogenicity testing. Therefore the negative finding for carcinogenicity in the mouse should be viewed with caution.

4. *Developmental toxicity*. In a rat developmental study, pregnant females were gavaged with either 0, 2.5, 25, or 250 mg/kg/day of hexaconazole. The parental NOAEL was 25 mg/kg/day and the LOAEL was 250 mg/kg/day based on decreased body weight gain and decreased food consumption. The developmental NOAEL was 2.5 mg/kg/day and the developmental LOAEL was 25 mg/kg/day based on delayed ossification of the 7th cervical transverse process and the presence of the extra 14th rib. At 250 mg/kg/day there was a statistically significant increase in late uterine deaths.

In a rabbit developmental study, animals tested at doses of 0, 25, 50, and 100 mg/kg/day also showed increased susceptibility to the effects of compound. The maternal NOAEL was 50 mg/kg/day and the LOAEL for maternal effects was 100 mg/kg/day based on a decreased body weight gain. The developmental NOAEL was 25 mg/kg/day and the developmental LOAEL was 50 mg/kg/day based on a decrease in mean fetal body weight.

5. *Two-generation reproduction study in rats*. Animals were fed either 0, 1, 5, or 50 mg/kg/day of test compound. There were no treatment related effects on reproductive performance of either sex for the $F_0$ or the $F_1$ generations. The parental NOAEL was 1 mg/kg/day. The parental systemic LOAEL was determined to be 5 mg/kg/day based on liver pathology (fatty infiltration) which was considered to be minimal. At 50 mg/kg/day, liver weight was increased accompanied with fatty changes in the liver. There was also an increased incidence of cytoplasmic vacuolation of the adrenal cortex in both sexes. The NOAEL for offspring was 5 mg/kg/day. The LOAEL for offspring was 50 mg/kg/day based on decreased body weight gain in pups, decreased litter size and decreased pup survival. Liver weights were increased and fatty infiltration was also observed.

6. *Mutagenicity*. Hexaconazole is not considered to be a mutagen with the currently available data from the Gene Mutation *Salmonella* Ames Assay, Micro-nucleus Assay in Mice, *In Vitro* Cytogenetics Human Lyphocytes Cells, and the Unscheduled DNA Synthesis in Primary Rat Hepatocytes studies.

7. *Dermal penetration*. Hexaconazole administered dermally to rats over a period of 21 days for 6 hours a day at dose levels of 0, 100, 300, and 1,000 mg/kg/day induced no systemic toxicity and was not irritating to the skin. The LOAEL was concluded to be greater than 1,000 mg/kg/day the HDT.

8. EPA determined that a developmental neurotoxicity study in rats is not required for hexaconazole because:

i. Hexaconazole is not structurally related to a neurotoxic agent.

ii. There is no evidence in the acute, subchronic, or chronic studies that indicate that hexaconazole induces neurotoxic effects.

iii. The developmental and reproductive studies do not indicate that the chemical is neurotoxic. Developmental effects occurred at dose levels that were below maternally toxic levels for both rat and rabbit but were not associated with neurotoxicity.

9. *General metabolism*. Hexaconazole is readily absorbed and excreted in both urine and feces in both males and females. Metabolites underwent extensive glucuronidation, biliary excretion, and enterohepatic recirculating. Radio labeled hexaconazole concentrated in liver, kidney, and adrenal at 24 hours. About 94–98% of the radio labeled material was excreted in 7 days by both sexes with males excreting 77% in 3 days and females excreting 88–95% in 3 days. Males excreted 41% in urine and 52% in feces compared to females 64% and 29% in urine and feces, respectively. The majority of the metabolites were oxidation products of the *n*-butyl chain (hexaconazole acid, 5-hydroxy-hexaconazole, 5-keto hexaconazole and an unspecified hydroxy-keto-hexaconazole). Preferential elimination of hexaconazole was seen in the urine of females as 5-hydroxy-hexaconazole.

*B. Toxicological Endpoints*

1. *Acute toxicity*. An acute reference dose (RfD) of 0.025 mg/kg/day was established for the subpopulation group, females 13+ only, based on a NOAEL of 2.5 mg/kg/day from a developmental study in the rat. Effects at the next higher dose level of 25 mg/kg/day were an increase in the delayed ossification of the 7th cervical transverse process and the presence of the extra 14th rib. Effects were dose responsive and statistically significant. These effects are presumed to occur after a single exposure *in utero* and therefore are considered to be appropriate for this risk assessment. The acute population adjusted dose (aPAD) is 0.0025 mg/kg/day and includes the additional 10x FQPA safety factor. The FQPA Safety Factor will be applied for acute food risk assessment for females 13+ only because the effects occur only during *in utero* exposure and are not postnatal effects. Thus, it is not appropriate to apply this safety factor to the acute food risk assessment of the general population including infants and children. An acute dose and endpoint were not selected for the general population group (including infants and children) because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure dose.

2. *Short- and intermediate-term toxicity*. Risk assessments for short- and intermediate-term toxicity are used for addressing residential or other similar non-dietary, non-occupational exposures. No short-, intermediate-, or long-term dermal or aggregate exposure risk assessments were performed for hexaconazole because hexaconazole has no registered residential uses.

3. *Chronic toxicity*. EPA has established the RfD for hexaconazole at 0.02 mg/kg/day. This RfD is based on a 1–year oral gavage study in dogs. The NOAEL in this study was 2 mg/kg/day. Fatty infiltration of the liver and an increase in liver weights occurred at the LOAEL of 10 mg/kg/day. An FQPA safety factor was not applied for chronic dietary risk assessment because:

i. The NOAEL used in deriving the RfD was based on liver effects in the chronic dog study.

ii. The developmental effects on which the FQPA factor is based were seen in pregnant animals of a different species (rats, and rabbits).

iii. The developmental effects are considered to be ''acute'' effects. Therefore, the chronic population adusted dose (PAD) and the RfD are the same.

4. *Carcinogenicity*. The EPA Cancer Peer Review Committee (CPRC) classified hexaconazole as a Group C (likely) carcinogen based on benign Leydig cell tumors in the male rats. A revised $Q_1$* was calculated using the body weight 3/4 interspecies scaling factor. This resulted in a revised potency factor of $1.6 \times 10^{-2}$ $(mg/kg/day)^{-1}$.

*C. Exposures and Risks*

1. *From food and feed uses*. Time-limited tolerances were established (40 CFR 180.488) for the residues of hexaconazole, [alpha-butyl-alpha-(2,4-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol], in or on the imported agricultural commodity bananas at 0.1 ppm; however, this tolerance expired on March 26, 1999. Risk assessments were conducted by EPA to assess food exposures from hexaconazole as follows:

There are no proposed or existing residential uses for hexaconazole. The proposed use is limited to import bananas only. The aggregate exposure risk is limited to dietary exposure only. If new uses are added in the future, the Agency will reassess the impact of these uses, which may result in the necessity of residential and water exposure assessments.

For all food analyses, the anticipated residue levels based on the field trials on banana pulp were used. The use of banana pulp residue levels provides a more realistic food exposure as individuals do not usually eat the banana peel. The residue levels of the diol metabolites were also included in the food exposure analysis. The diol metabolites are expected to be of comparable toxicity to the parent compound. EPA will require residue data on these metabolites for bananas, as well as future food uses.

The food exposure analyses for hexaconazole is a conservative but more realistic estimate of food exposure with the use of the pulp residue values and 100% of the commodities assumed to be treated. The residue level value of 0.56 ppm, which was the highest residue level for pulp (hexaconazole-0.17 ppm + diol metabolites-0.39 ppm), was used in the acute dietary analysis. The residue level value of 0.11 ppm, which was the average from the field trials for pulp (hexaconazole-0.03 ppm + diol metabolites-0.08 ppm), was used in the chronic dietary analysis.

i. *Acute exposure and risk*. Acute food risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The acute food exposure analysis for the population subgroup females 13+ was performed using the highest pulp residue level (parent + diol metabolites) and 100% crop treated. The FQPA Safety Factor of 10x was retained for the acute food analysis only for the population subgroup females 13+. The acute population adjusted dose (aPAD) used in the acute food analysis was 0.0025 mg/kg/day.

ii. *Chronic exposure and risk*. The FQPA Safety Factor was removed (i.e., reduced to 1x) for chronic food exposure. Therefore, the chronic PAD (cPAD) and the chronic RfD are the same. For chronic food risk, EPA's level of concern is greater than 100% chronic PAD. All chronic (non-cancer) percent cPADs for all subgroups were ≤1%. The results of the chronic food exposure analysis indicate that the chronic food risk associated with the proposed use of hexaconazole is below the Agency's level of concern.

2. *From drinking water*. Hexaconazole is not registered for use in the United States (U.S.). Therefore, no water or occupational exposure assessment was performed.

3. *From non-dietary exposure*. The use of bananas is for import use only.

There are currently no proposed or registered domestic or residential uses for this product. Therefore, no occupation exposure assessment is required. If domestic uses are added in the future, an occupational exposure assessment will have to be completed.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether hexaconazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hexaconazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that hexaconazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

*D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk*. The acute food exposure analysis for hexaconazole is a conservative but more realistic estimate of dietary exposure with the use of the pulp residue values. The acute food exposure analysis for the population subgroup females 13+ was performed using the highest pulp residue (parent + diol metabolite) levels and 100% crop treated (CT). The FQPA Safety Factor of 10x was retained for the acute dietary analysis only. The aPAD used in the acute dietary analysis was 0.0025 mg/kg/day. The percent aPADs were below EPA's level of concern at the 95th percentile of exposure for the females 13+ subgroup. The highest percent aPAD at the 95th percentile of exposure was 47% for the subgroup, females 13+ (pregnant, not nursing). Therefore, the acute dietary risk associated with the proposed use of hexaconazole on bananas is below the Agency's level of concern. The table below summarizes the acute food exposure.

Summary of Acute Food Exposure and Risk for Hexaconazole at 95th Percentile of Exposure

| Population Subgroup | Exposure (mg/kg/day) | Population Adjusted Dose (PAD) |
|---|---|---|
| Females (13+, pregnant, not nursing). | 0.001181 | 47.2 |
| Females (13+, nursing). | 0.001136 | 45.4 |
| Females (13–19 yrs., not pregnant, not nursing). | 0.000892 | 35.7 |
| Females (10+ years, not pregnant, not nursing). | 0.001030 | 41.2 |
| Females (13–50 years). | 0.000954 | 38.1 |

2. *Chronic risk*. The chronic (non-cancer) and cancer Dietary Exposure Evaluation Model (DEEM) analyses used mean consumption (3–day average). Average pulp residues from field trials and 100% CT information were used. The FQPA Safety Factor was removed (equivalent to a factor of 1x) for chronic exposures. Therefore, the chronic PAD and the chronic RfD are identical. For chronic dietary risk, EPA's level of concern is greater than 100% cPAD. All chronic (non-cancer) percent PADs for all subgroups were ≤1%. The results of the chronic dietary analysis indicate that the chronic dietary risk associated with the existing and proposed uses of hexaconazole is below the Agency's level of concern (<100% PAD). The table below summarizes the chronic dietary exposure and includes the U.S. general population and other subgroups. The other subgroups included are all infant and children subgroups and the highest dietary exposures for the respective adult population subgroups (i.e., females and the other general population subgroup higher than U.S. population).

Summary of Chronic (non-cancer) Dietary Exposure and Risk for Hexaconazole

| Population Subgroup | Exposure (mg/kg/day) | %RfD |
|---|---|---|
| U.S. Population (the contiguous 48 states). | 0.000033 | <1 |
| Non-Hispanic other than black or white. | 0.000050 | <1 |
| All infants (< 1 year). | 0.000167 | <1 |
| Nursing infants (< 1 year). | 0.000077 | <1 |
| Non-nursing infants (< 1 year). | 0.000205 | 1.0 |
| Children (1–6 years old). | 0.000091 | <1 |
| Children (7–12 years old). | 0.000037 | <1 |
| Females (13+/nursing). | 0.000035 | <1 |

3. *Aggregate cancer risk for U.S. population*. The Agency generally considers 1 x $10^{-6}$ as negligible risk (i.e, less than 1 in 1 million) for cancer. The results of this analysis indicate that the cancer dietary risk of 5.3 x $10^{-7}$ associated with the proposed use of hexaconazole is below the Agency's level of concern.

| Subgroup | Exposure (mg/kg/day) | Lifetime Risk |
|---|---|---|
| U.S. Population (the contiguous 48 states). | 0.000033 | 5.3 x $10^{-7}$ |

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to hexaconazole residues.

*E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children* — i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of hexaconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure 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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the database unless

EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. The available data indicated evidence of increased susceptibility of rat and rabbit fetuses to the *in utero* exposure of hexaconazole in developmental studies. In both the rat and rabbit developmental toxicity studies, developmental effects occurred at dose levels lower than those causing maternal toxicity; in rats developmental toxicity was manifested as delayed ossification and an extra 14th rib; and in rabbits, decreased fetal weights occurred at doses below maternally toxic levels.

iii. *Reproductive toxicity study*. In the 2-generation reproduction study, no increased susceptibility was observed. Effects in the offspring occurred only at or above treatment levels which resulted in evidence of parental toxicity.

iv. *Conclusion*. There is a complete toxicity database for hexaconazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The 10x FQPA safety factor will be applied only to subpopulation group females 13+ for the determination of acute dietary risk because the effects occur only during utero exposure and are not post natal effects. The FQPA safety factor will not be applied for chronic dietary risk assessment because: (a) the NOAEL used in deriving the RfD is based on liver effects from the chronic dog study; (b) the developmental effects on which the FQPA factor is based were seen in pregnant animals of a different species (rats and rabbits); and (c) the developmental effects are considered to be ''acute'' effects, and not a result of chronic exposure.

2. *Acute risk*. A dose and endpoint were not selected for the general population including infants and children subpopulation group because their were no effects observed in the oral toxicity studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure dose.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to hexaconazole from food will utilize 1% of the RfD for infants and children. 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.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to hexaconazole residues.

## III. Other Considerations

### *A. Metabolism In Plants and Animals*

The nature of the residue in plants is understood. Plant metabolism studies were conducted on grapes, apples, and wheat and found acceptable. As the nature of the residue is understood in these crops, no additional metabolism studies for bananas were required. The data indicate that the major terminal residues in plants will be parent hexaconazole, its diol metabolites [(±)-5-(2,4-dichlorophenyl)-6-(1*H*-1,2,4-triazol-1-yl)hexan-2,6-diol, (±)-5-(2,4-dichlorophenyl)-5-hydroxy-6-(1*H*-1,2,4-triazol-1-yl)hexanoic acid, (±)-2-(2,4-dichlorophenyl)-1-(1*H*-1,2,4-triazol-1-yl)hexan-2,5-diol, and (±)-2-(2,4-dichlorophenyl)-1-(1*H*-1,2,4-triazol-1-yl)hexan-2,4-diol, free and conjugated] resulting from oxidation of the alkyl side chain of hexaconazole, and its triazole metabolites [1*H*-1,2,4-triazole, (*RS*)-3-(1*H*-1,2,4-triazol-1-yl) alanine (also known as triazole alanine), (1*H*-1,2,4-triazole-1-yl) acetic acid (also known as triazole acetic acid)], resulting from the cleavage of the triazolyl moiety of the parent compound. The predominant residues in apples and grapes are hexaconazole and its diol metabolites. The metabolism in wheat apparently differs in that while hexaconazole and its diol metabolites were the major terminal residues in straw and chaff, the major terminal residues in grain were the triazole degradation products. Any residues in banana flesh will result from extensive translocation through leaves, stalk, and skin.

EPA determined that parent hexaconazole is the only terminal residue that should be included in the tolerance expression for bananas, which is the only food use pending at this time. The diol metabolites are not being included in the tolerance expression or in the risk assessments since they are of low toxicity and are not likely to be present at detectable levels in bananas.

### *B. Analytical Enforcement Methodology*.

The petitioner has proposed ''Agrochemical Residue Analytical Method 108/1 for Residues of Hexaconazole in Crops'' as the analytical enforcement method. Samples of homogenized whole bananas are weighed into a round bottom flask (fortification occurs at this step). The sample is extracted by refluxing with methanolic sodium hydroxide for 1–hour. Aqueous sodium chloride is then added, and the hexaconazole is partitioned from the methanol/aqueous solution into dichloromethane. The extracts in dichloromethane are cleaned up using silica adsorption micro-columns. Parent hexaconazole is then determined using capillary column gas liquid chromatography (GLC)/nitrogen phosphorous (NP) or GLC/electron capture (EC). EPA concluded that Method 108/1 is adequate for enforcement purposes. An independent laboratory validation (ILV) of the method has been submitted and a satisfactory petition method validation (PMV) by EPA was completed.

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

### *C. Magnitude of Residues*.

A total of 18 field trials were submitted and reviewed by the Agency. The residue levels of hexaconazole (parent only) in whole unbagged bananas from all trials ranged from < 0.01 limit of quantitation (LOQ) to 0.64 ppm. The residue levels of hexaconazole in unbagged banana pulp from all field trials ranged from < 0.01 ppm (LOQ) to 0.17 ppm. The residue levels of the diol metabolites in whole unbagged bananas from all trials ranged from < 0.03 (LOQ) to 1.6 ppm. The residue levels of the diol metabolites in unbagged banana pulp from all field trials ranged from < 0.03 ppm (LOQ) to 0.39 ppm. The submitted data indicate that residues of hexaconazole in whole bananas will exceed the existing time-limited tolerance level of 0.1 ppm for bananas. The appropriate tolerance level is 0.7 ppm for bananas. A revised

section F was submitted amending the tolerance to 0.7 ppm for bananas.

There are no processed commodities associated with bananas; therefore, no tolerances for processed commodities are required.

There are no animal feed items associated with bananas; therefore, no tolerances for meat, milk, poultry, and eggs are required. For any future petition in which there is a potential for transfer of residues to animals (meat, milk, poultry, eggs, etc.), animal metabolism studies will be required.

Anticipated residues were calculated from field trial data. The residue levels from banana pulp for parent and diol metabolites were used. The residue level value of 0.56 ppm, which was the highest residue level for pulp (hexaconazole-0.17 ppm + diol metabolites-0.39 ppm), was used in the acute dietary analysis. The residue level value of 0.11 ppm, which was the average from the field trials for pulp (hexaconazole-0.03 ppm + diol metabolites-0.08 ppm), was used in the chronic dietary analysis.

To provide for the re-evaluation of the anticipated residues, the Agency will require under section 408(b)(2)(E) that additional data be submitted within 5 years. EPA will require additional residue data on the diol metabolites for future food uses. If monitoring data for the parent need to be used in the future for dietary risk assessments, then diol residues may be estimated based on their ratio to parent hexaconazole.

*D. International Residue Limits.*

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of hexaconazole in bananas. Therefore, a compatibility issue is not relevant to the proposed tolerance.

## IV. Conclusion

Therefore, the tolerance is established for residues of hexaconazole, [alpha-butyl-alpha-(2,4-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol] in the imported raw agricultural commodity bananas at 0.7 ppm.

## V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 30, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information 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.

## VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300871] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

## VII. Regulatory Assessment Requirements

*A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

*B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

*C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

## VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

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

Dated: June 10, 1999.

**James Jones,**

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

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

**Authority**: 21 U.S.C. 321(q), (346a) and 371.

2. § 180.488 is revised 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-dichlorophenyl)-1*H*-1,2,4-triazole-1-ethanol], in or on the imported raw agricultural commodity bananas at 0.7 parts per million (ppm). There are no U.S. registrations as of June 30, 1999.

[FR Doc. 99–16545 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300860A; FRL–6087–3]**

## Aspergillus flavus AF36; Exemption from Temporary Tolerance, Technical Amendment

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

**ACTION:** Final rule; Technical amendment.

**SUMMARY:** EPA is issuing a technical amendment to the expiration date for an exemption from temporary tolerance regulation for *Aspergillus flavus* AF36 that published in the **Federal Register** on May 26, 1999 (64 FR 28371) (FRL–6081–2). This amendment corrects the expiration date for the exemption from temporary tolerance for residues of the atoxigenic *Aspergillus flavus* AF36 on cotton grown in certain Counties in Arizona to December 30, 2001, in order to allow clearance of the treated food/feed commodities through the channels of trade.

**DATES:** This regulation is effective June 30, 1999. You may submit an objection