TABLE 1 — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
45639–59	Turcam	Bendiocarb	Non Bearing Nut, Citrus and other Fruit Trees
45639–1	Ficam W	Bendiocarb	Use in Aircrafts, Mausoleums
45639–2	Bendiocarb WP	Bulk Pack	Use in Aircrafts, Mausoleums
45639–3	Ficam D	Bendiocarb	Use in Aircrafts, Mausoleums
45639–10	Homeowner Dust	Bendiocarb	Use in Aircrafts, Mausoleums
45639–66	Ficam PLUS	Bendiocarb, Pyrethrin Piperonyl Butoxide	Use in Aircrafts, Mausoleums

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2 — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Company No.	Company Name and Address
45639	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 90 days after the effective date of use deletions. This determination was based in part on the voluntary agreement of these registrants to cease selling product bearing previously approved labeling within that time period.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: February 10, 1999

Richard D. Schmitt,

Acting Director, Information Resources Services Division, Office of Pesticide Programs.

[FR Doc. 99–4438 Filed 2-23-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[PF–857; FRL–6058–9]

Notice of Filing of Pesticide Petitions

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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–857, must be received on or before March 26, 1999.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	e-mail Address
Bipin Gandhi	Rm. 707A, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy, Arlington, VA; 703–308–8380	Bipin.Gandhi@epamail.epa.gov.
Mary Waller	Rm. 249, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA; 703–308–9354	Waller.Mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 supports grantinig of the

petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–857 (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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (insert docket number) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: February 16, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. ICI Surfactants

PP 9E5063

EPA has received a pesticide petition (PP) from ICI Surfactants, 3411 Silverside Road, Wilmington, DE 19803-8340 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and (e) to establish an exemption from the requirement of a tolerance for polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,300 when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest or to animals. EPA has determined that the petition 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Magnitude of residues. ICI Americas is petitioning that polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000, be exempt from the requirement of a tolerance based upon the low risk polymer criteria per 40 CFR 723.250. Therefore, an analytical method to determine residues in raw agricultural commodities has not been proposed. No residue chemistry data or environmental fate data are presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for a low risk polymer inert ingredient.

B. Toxicological Profile (Low Risk Polymer Criteria)

1. *Acute toxicity*. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compounds compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting these criteria will present minimal or no risk. Polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000, conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the criteria used to identify low risk polymers under 40 CFR 723.250(e) and is not an excluded polymer per 40 CFR 723.250(d), i.e.:

i. The polymer is not a cationic polymer, nor is it capable of becoming a cationic polymer in the natural aquatic environment.

ii. It contain as an integral part of its composition only the atomic elements carbon, hydrogen, and oxygen.

iii. It does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(iii).

iv. It is not designed to, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize.

v. It is not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

vi. It is not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.

vii. Its minimum number-average molecular weight is greater than 1,000 and less than 10,000 daltons. It contains less than 10% oligomeric material below molecular weight 500 and less than 25% oligomeric material below 1,000 daltons molecular weight. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin, and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the GI tract are generally incapable of eliciting a toxic response.

viii. It does not contain any reactive functional groups.

ICI believes sufficient information was submitted in the petition to assess the hazards of polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester

having a minimum molecular weight of 1,300. No toxicology data were presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for a low risk polymer inert ingredient.

Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with toxicity.

2. *Endocrine disruption*. There is no evidence that polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000, is an endocrine disrupter. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

EPA is not requiring information on the endocrine effects of this substance at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*. Polyoxyethylated sorbitol fatty acid esters may come in contact with food when used as inert ingredients in pesticide formulations applied to growing crops only per 40 CFR 180.1001(d). Such use typically involves low application rates for the inert where potential residues of inert ingredients are indirectly controlled through tolerances established for the active ingredient. Polyoxyethylated sorbitol esters with a molecular weight greater than 1,000 daltons are not readily absorbed through the intact gastrointestinal tract and are considered incapable of eliciting a toxic response.

2. *Non-dietary exposure*. Typical uses of polyoxyethylated sorbitol fatty acid esters are in the synthetic fiber manufacturing industry as emulsifiers for oils used in lubricants at low end product use rates. In these uses the primary exposures is dermal, however, and polyoxyethylated sorbitol esters with a molecular weight significantly greater than 400 are not readily absorbed through the intact skin and are considered incapable of eliciting a toxic response.

D. Cumulative Effects

There is data to support a conclusion of negligible cumulative risk from polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,300. Polymers with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. Therefore, there is no reasonable expectation of increased risk due to cumulative exposure. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with cumulative effects.

E. Safety Determination

1. *U.S. population*. ICI believes sufficient information was submitted in the petition to assess the hazards of polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with any potential exposure to adults. There are no known additional pathways of exposure (non-occupational, drinking water, etc.) where there would be additional risk.

2. *Infants and children*. ICI believes sufficient information was submitted in the petition to assess the hazards of polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with any potential exposure to infants and children. There are no known additional pathways of exposure (non-occupational, drinking water, etc.) where infants and children would be at additional risk.

F. International Tolerances

We are not aware of any country requiring a tolerance for polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,000. Nor have there been any CODEX Maximum Residue Levels (MRL's) established for any food crops at this time. (Bipin Gandhi)

2. Zeneca Ag Products

PP 0E3853

EPA has received a pesticide petition (PP 0E3853) from Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE 19850-5458, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of hexaconazole in or on the imported raw agricultural commodity bananas at 0.7 parts per million (ppm). EPA has determined that the petition 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the residue in plants is adequately understood. Plant metabolism studies have been conducted in apples, grapes, and wheat. The predominant residues in each of these studies are hexaconazole and its diol metabolites. EPA has determined that only the parent, hexaconzole, should appear in the tolerance expression, but that the diol metabolites are to be included in the risk assessment.

2. *Analytical method*. Analytical method SOPRAM 108/3 was used to

determine residues (parent) of hexaconazole in or on bananas. This method is proposed as the regulatory enforcement method. The method uses gas liquid chromatography for identification and quantification of hexaconazole. Results are confirmed by mass spectroscopy. The method has been independently validated.

3. *Magnitude of residues*. Twenty-six separate residue trials on bananas have been conducted and submitted to the EPA. Six of these trials were conducted on unbagged bananas per EPAs request and the remaining 20 trials were conducted on bagged bananas. The trials on unbagged bananas were conducted in Mexico (3), Costa Rica (2), and Guatemala (1). The trials on bagged bananas were conducted in Mexico (4), Guatemala (4), Colombia (3), Equador (3), Costa Rica (1), Panama (2), and Honduras (3). The results of these trials show that residues of hexaconazole in the raw agricultural commodity bananas will not exceed the proposed tolerance of 0.7 ppm. There are no livestock feed stuffs derived from bananas and therefore no secondary residues are expected in animal products.

B. Toxicological Profile

1. *Acute toxicity*. Acute toxicity data are not required for an import tolerance; however hexaconazole has been shown to have low acute toxicity with an acute oral LD_{50} of 2,189 mg/kg in female rats and 6,071 mg/kg in male rats, a dermal LD_{50} of > 2,000 mg/kg in rats, and an inhalation LC_{50} of > 5.91 mg/L. Hexaconazole is a non-irritant to rabbit skin and mild eye irritant in the rabbit. It is a skin sensitizer in guinea pigs.

2. *Genotoxicty*. A battery of *in vitro* and *in vivo* mutagenicity studies (5) have been conducted on hexaconazole. These studies included an Ames assay, a mouse lymphoma assay, an *in vitro* cytogenetics assay in human lymphocytes, an assay for unscheduled DNA synthesis in rat hepatocytes, and a mouse micronucleus test. The results of these tests were all negative indicating that hexaconazole is not genotoxic.

3. *Reproductive and developmental toxicity*. Developmental toxicity studies have been conducted in rats and rabbits. Pregnant Wistar rats were treated from day 7–16 of gestation with 0, 2.5, 25, or 250 mg/kg hexaconazole. Administration of 250 mg/kg was associated with maternal toxicity which consisted of reduced body weight gain and food consumption. Also at this dosage level, increased post-implantation loss and reduced fetal weights were seen when compared to the control group. There was no evidence of a teratogenic effect. Developmental toxicity at 250 mg/kg consisted of an increased incidence of extra 14th ribs, unossified calcanea, and partially ossified 5th sternebrae, and mean manus and pes scores. The incidence of extra 14th ribs was statistically increased at 25 mg/kg on a fetal, but not litter, basis. At 25 mg/kg, the incidence of extra 14th ribs was increased compared to the control group, but not statistically by either fetal or litter incidence. The no observed adversed effect level (NOAEL) for maternal toxicity was 25 mg/kg and the NOAEL for developmental toxicity was 2.5 mg/kg.

The developmental toxicity of hexaconazole was determined in two New Zealand rabbit studies. In the first study, dose levels of 0, 2.5, 12.5, or 50 mg/kg were administered to pregnant rabbits on days 7–19 of gestation. The NOAEL for maternal and developmental toxicity in this study was 50 mg/kg (the highest dosage level tested). Therefore, a second study was conducted using dose levels of 0, 25, 50, and 100 mg//kg. In the repeat study, reduced maternal body weight gain was observed at 100 mg/kg and reduced fetal weights at 50 and 100 mg/kg. The NOAEL for maternal toxicity was 50 mg/kg and the NOAEL for fetotoxicity was 25 mg/kg.

In a 2–generation reproduction study, dose levels of 0, 20, 100, or 1,000 ppm (equivalent to 0, 1, 5, and 50 mg/kg/day) were administered in the diet to Wistar rats. Liver pathology was seen in both parental animals and in the pups at 100 and 1,000 ppm. Reduced pup weight was seen at 1,000 ppm in the F^1 generation from postnatal day 5 onwards. There was a slight effect on pup survival at 1,000 ppm in the F^2b generation. The systemic NOAEL was 20 ppm and the reproductive NOAEL was 100 ppm.

4. *Subchronic toxicity*. Subchronic toxicity studies have been conducted in rats and dogs. Male and female Wistar rats were fed diets containing 0, 50, 500, or 5,000 ppm hexaconzole for a period of 90 days. Findings included decreased body weight gain (500 and 5,000 ppm), fatty changes and liver hypertrophy (500 and 5,000 ppm), and adrenal cortical vacuolation (50, 500, and 5,000 ppm). A clear NOAEL was not determined in this study.

Beagle dogs were orally administered 0, 5, 25, or 125 mg/kg/day hexaconazole in gelatin capsules for 90 days. At 25 and 125 mg/kg/day, increased alkaline phosphatase activity, increased liver weight, and increased lipid accumulation in liver parenchymal cells were seen. The NOAEL was 5 mg/kg/day.

5. *Chronic toxicity*. Chronic toxicity studies have been conducted in rats, mice, and dogs. In a 2-year feeding study in Alpk:APfSD rats, hexaconazole was tested at dose levels of 0, 10, 100, and 1,000 ppm (equivalent to 0, 0.47, 4.7, and 47 mg/kg/day in males and 0, 0.61, 6.1, and 61 mg/kg/day in females). At 1,000 ppm and to a lesser extent at 100 ppm, increased hepatocyte hypertrophy and reduced body weight gain were observed. The NOAEL in this study was determined to be 10 ppm, equivalent to 0.47 mg/kg/day in males and 0.61 mg/kg/day in females. An increased incidence of Leydig cell tumors was seen in male rats at 1,000 ppm.

The oncogenic potential of hexaconazole was assessed in C57/BL/10JfCD-1/Alpk mice. Dosage levels were 0, 5, 40, and 200 ppm administered in the diet for a period of 2 years. At 200 ppm, decreased body weight gain (10%) in males was observed. Food utilization was decreased in male and female mice at this dosage level. Fatty changes were seen in the livers of treated mice at 200 ppm. Hexaconazole was not considered oncogenic to mice. The NOAEL was determined to be 40 ppm which is equivalent to 4.7 mg/kg/day in male mice and 5.9 mg/kg/day in female mice.

Beagle dogs were orally administered 0, 2, 10, or 50 mg/kg/day hexaconazole daily in capsules for 1 year. At 10 and 50 mg/kg/day, increased alkaline phosphatase activity, increased liver weight, and increased fatty changes in the liver were observed. The NOAEL was 2 mg/kg/day.

6. *Animal metabolism*. In the rat, ^{14}C-hexaconazole is readily absorbed, extensively metabolized, and readily excreted. The major route of metabolism involves oxidation of the *n*-butyl chain. In male rats the majority of the radioactivity is excreted in the feces and in female rats in the urine. The sex difference in the proportions of hexaconazole excreted in urine and feces is due to quantitative differences in biliary elimination of hexaconazole metabolites.

7. *Metabolite toxicology*. The EPA metabolism committee considered that only the parent hexaconazole should be included in the tolerance expression. The diol metabolites of hexaconazole, however, were to be considered in risk assessments. The Committee further considered that the diol metabolites were toxicologically similar to hexaconazole and therefore, testing of hexaconazole metabolites was not considered necessary.

8. *Endocrine disruption*. Results of developmental and reproductive studies on hexaconazole did not provide any

indication that hexaconazole disrupted endocrine function. In a 2-year rat chronic toxicity study, an increased incidence of benign Leydig cell tumors was seen at the highest dose level tested (1,000 ppm). Also in this study a slightly increased incidence of adrenal cortical vacuolation was seen in male rats; however, the toxicologic significance of this finding is not known because the spontaneous incidence in untreated male rats was very high. Zeneca has conducted studies to determine the mechanism of induction of the Leydig cell tumors in isolated rat and human Leydig cells.

Hexaconazole inhibits steroid production in both cell types through inhibition of C_{17-20} lyase, a cytochrome P450-dependent enzyme, leading to a decrease in testosterone production. Zeneca postulates that the decrease in testosterone production leads to a direct effect on the Leydig cell resulting in a compensatory hyperplasia and eventually to tumors.

C. Aggregate Exposure

1. *Dietary exposure.* — i. *Chronic.* For purposes of assessing the potential dietary exposure from bananas at the tolerance level, Zeneca has calculated the anticipated residue concentration (ARC) for the U.S. population and various subgroups, including infants and children. In performing this assessment, Zeneca used conservative assumptions, including assuming that 100% of bananas imported into the U.S. would be treated with hexaconazole. Actual residue data from the trials listed in section 1.3 above were used in the assessment. Residue levels, which included levels of hexaconazole plus its diol metabolites, from whole bananas were averaged. Most of the residue values obtained were below the level of quantification of the analytical method. In these cases 1/2 of the quantified level was used. Therefore, the safety determinations outlined in section E. below represent conservative estimates of potential exposure of the U.S. population and various subgroups to residues of hexaconazole on bananas.

ii. *Acute.* EPA does require acute dietary assessments for import tolerances and therefore, an acute dietary assessment was not conducted. However, results of residue trials indicate that levels of hexaconazole and its metabolites are not expected to reach the tolerance level.

2. *Food.* Aggregate exposure to residues of hexaconazole on food products is not expected. There are no registrations for food uses of hexaconazole within the U.S.; there is an import tolerance on bananas only. Therefore, the only food source of hexaconazole residues to the U.S. population is bananas.

3. *Drinking water.* No drinking water exposure is expected because there are no U.S. registrations for hexaconazole uses. The only existing U. S. tolerance is an import tolerance on bananas.

4. *Non-dietary exposure.* There are no registered uses of hexaconazole within the U.S. and therefore no non-dietary exposure to hexaconazole or its metabolites is expected.

D. Cumulative Effects

Although other triazole fungicides are registered for uses in the U.S., Zeneca has no information to indicate that the toxic effects of these fungicides (primarily liver toxicity) would be cumulative with those of hexaconazole in the U.S. population.

E. Safety Determination

1. *U.S. population.* —i. *Cancer.* EPA has classified hexaconazole as a Group C (Possible Human) carcinogen with a Q^{1*} of 0.023 $(mg/kg/day)^{-1}$. This classification was based on a statistically significant increase in benign Leydig cell tumors in male rats fed hexaconazole in the diet at a level of 1,000 ppm for 2 years. In addition, this tumor type is an uncommon tumor in the strain of rat used in this study and the tumors occurred at an accelerated rate. The classification was also supported by a marginal increase in mouse liver tumors and the structural similarity of hexaconazole to other triazole fungicides that are mouse liver carcinogens.

Using the conservative assumptions outlined in section C.1, an assessment of the potential cancer risk, based on a Q^{1*} of 0.023 $(mg/kg/day)^{-1}$, from dietary consumption of hexaconazole (bananas) resulted in an exposure of 0.00025 mg/kg/day and a lifetime risk to the U.S. population of 5.7×10^{-7}. EPA considers a lifetime cancer risk of one in a million to be acceptable.

ii. *Threshold effects.* Prior to the enactment of FQPA, EPA calculated a reference dose (RfD) for hexaconazole of 0.02 mg/kg/day based on the NOAEL from a 1-year dog study of 2 mg/kg/day and an uncertainty factor of 100. In calculating the dietary risk of hexaconazole to the U.S. population, Zeneca added an additional uncertainty factor of 3 (to be protective of infants and children; see section E.2 below) which gives a RfD of 0.007 mg/kg/day. Zeneca considered adding an additional uncertainty factor of 10; however, it did not believe that the effects seen at non-maternally toxic doses in the rat and rabbit developmental toxicity studies were of a serious enough concern to warrant an additional factor of 10.

Using the conservative assumptions outline in section C.1 and a RfD of 0.007 mg/kgday, an assessment of the dietary risk to the U.S. population resulted in an ARC of 0.00011 mg/kg/day or 0.4% of the RfD.

2. *Infants and children.* When assessing the potential for extra sensitivity of infants and children to hexaconazole, Zeneca considered the results of developmental (rat and rabbit) and reproductive (rat) toxicity studies. The developmental toxicity NOAELs in the rat and rabbit teratology studies were lower than the NOAELs for maternal toxicity. The NOAEL (2.5 mg/kg/day) for developmental toxicity in rat study was based on an increased incidence of extra 14^{th} ribs at doses of 25 mg/kg/day and higher. The NOAEL in the rabbit developmental toxicity study was 25 mg/kg/day based on decreased fetal body weight at doses of 50 mg/kg/day and higher. The results of a rat 2-generation reproduction study did not provide any evidence of an increased sensitivity of the offspring to hexaconazole-induced toxicity, including to the liver. As noted in section E.1.b above, when calculating the RfD Zeneca added an additional safety factor of 3 to account for the slightly increased sensitivity of the developing fetus to the effects of hexaconazole. The NOAEL (2.0 mg/kg/day) for effects (liver toxicity) attributed to hexaconazole in the dog is close to the NOAEL for effects of hexaconazole on rat fetuses and lower than the NOAEL for rabbit fetuses. Therefore the dietary risk assessment for infants and children was performed using a RfD of 0.007 mg/kg/day.

Using the conservative assumptions outline in section C.1 and a RfD of 0.007 mg/kg/day, an assessment of the dietary risk to non-nursing infants (the most sensitive population subgroup) resulted in ARC of 0.00011 mg/kg/day or 1.6% of the RfD.

F. International Tolerances.

Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for hexaconazole have been established on apples (0.1 ppm), bananas (0.1 ppm), coffee beans (0.05 ppm), grapes (0.1 ppm), wheat (0.1 ppm), and wheat straw and dry fodder (0.5 ppm). (Mary Waller)

[FR Doc. 99–4321 Filed 2–23–99; 8:45 am]

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