and will terminate at 11:59 p.m. on June 15, 2002.

Dated: January 8, 2002.

J.A. Servidio,

Commander, U.S. Coast Guard, Captain of the Port.

[FR Doc. 02–2543 Filed 1–31–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301206; FRL–6818–3]

RIN 2070–AB78

Bifenazate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for (i) combined residues of bifenazate (hydrazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester) and D3598 (expressed as bifenazate; diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethylester) in or on raw agricultural commodities (apple, wet pomace; cotton, undelinted seed; cotton gin byproducts (gin trash); fruit, pome group; grape; grape, raisin; hop, dried cones; nectarine; peach; plum; strawberry and in fat of cattle, goat, hog, horse and sheep and (ii) combined residues of bifenazate, D3598 (expressed as bifenazate), A1530 (1,1'-biphenyl, 4-ol) and A1530-sulfate (expressed as A1530; 1,1'-biphenyl, 4-oxysulfonic acid) in meat and meat byproducts of cattle, goat, horse, hog and sheep and milk. Uniroyal Chemical Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective February 1, 2002. Objections and requests for hearings, identified by docket control number OPP–301206, must be received by EPA on or before April 2, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301206 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Suku Oonnithan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0368; and e-mail address: oonnithan.suku@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301206. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 18, 2001; (66 FR 19935) (FRL–6777–4), 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 FQPA of 1996 (Public Law 104–170) announcing the filing of a pesticide petition (PP 0F6108) for tolerance by Uniroyal Chemical Company, Benson Road, Middlebury, CT 06749. This notice included a summary of the petition prepared by Uniroyal Chemical Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the insecticide bifenazate in or on the raw agricultural commodities apple, wet pomace at 1.2 parts per million (ppm); cotton seed at 0.5 ppm; cotton, gin byproducts (gin trash) at 20 ppm; fruit, pome, group at 0.75 ppm; fruit, stone, group (except cherries) at 1.5 ppm; grape at 0.75 ppm; hop at 15 ppm and strawberry at 1.5 ppm. As cotton processed commodities fed to animals may be transferred to milk and edible tissue of ruminants, tolerances were also proposed for meat at 0.02 ppm and milk at 0.01 ppm.

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).

III. 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 tolerances for combined residues of bifenazate and D3598 (expressed as bifenazate) in or on apple, wet pomace at 1.2 ppm; cattle, fat at 0.1 ppm; cotton, gin byproducts at 35 ppm; cotton, undelinted seed at 0.75 ppm; fruit, pome, group at 0.75 ppm; goat, fat at 0.1 ppm; grape at 0.75 ppm; grape, raisin at 1.2 ppm; hog, fat at 0.1 ppm; hop, dried cones at 15 ppm; horse, fat at 0.1 ppm; nectarine at 1.7 ppm; peach at 1.7 ppm; plum at 0.3 ppm; sheep, fat at 0.1 ppm; strawberry at 1.5 ppm and combined residues of bifenazate and D3598 (expressed as bifenazate), A1530 and A1530-sulfate (expressed as A1530) in: cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm. EPA's assessment of 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 bifenazate are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

OPPTS Guideline No.	Study Type (All Studies Acceptable)	Results
870.3100	90–Day oral toxicity rodents-rat	NOAEL = 13.8 mg/kg/day in males, 3.2 mg/kg/day in females. LOAEL = 27.7 mg/kg/day in males, 16.3 mg/kg/day in females based on decreased body weight gain in both sexes, decreased liver weight in males, increased spleen weight in females, and histopathology in liver in both sexes, and histopathological changes in the spleen and adrenal cortex in males.
870.3150	90–Day oral toxicity nonrodents-dog	NOAEL = 0.9 mg/kg/day in males, 1.3 mg/kg/day in females. LOAEL = 10.4 mg/kg/day in males, 10.7 mg/kg/day in females based on changes in hematological parameters in both sexes, increased bilirubin in the urine in males, increased absolute and relative liver weight in females and liver histopathologic effects in both sexes.
870.3200	21–Day dermal toxicity-rat	NOAEL = 80 mg/kg/day in males and females LOAEL = 400 mg/kg/day in males and females based on decreased body weight in females, decreased food consumption in both sexes, increased urinary ketones, increased urinary protein, increased urinary specific gravity, and decreased urinary volume in both sexes, and increased incidence of extramedullary hematopoiesis in the spleen in both sexes.
870.3700	Prenatal developmental in rodents-rat	Maternal NOAEL = 10 mg/kg/day. LOAEL = 100 mg/kg/day based on increased clinical signs, and decreased body weight, body weight gain, and food consumption. Developmental NOAEL = 500 mg/kg/day LOAEL = not established
870.3700	Prenatal developmental in nonrodents-rabbit	Maternal NOAEL = 200 mg/kg/day LOAEL = not established; Doses for the main study were selected based on a range-finding study in which groups of 5 rabbits each received 0, 125, 250, 500, 750, or 1,000 mg/kg/day during gestation days 6–19 by gavage.

TABLE 1—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

OPPTS Guideline No.	Study Type (All Studies Acceptable)	Results
		Maternal toxicity was seen as increased deaths and decreased body weight at 750 mg/kg/day and above. A treatment-related increase in the number of does aborting was seen at 250 mg/kg/day and above. Developmental NOAEL = 200 mg/kg/day. LOAEL = not established; Due to only one or two litters available in each of the treated groups in the range finding study, a clear assessment of developmental toxicity was not possible. Based on these results, doses of 10, 50, and 200 mg/kg/day were selected for the main study.
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 1.6 mg/kg/day in males, 1.8 mg/kg/day in females. LOAEL = 6.5 mg/kg/day in males and 7.4 mg/kg/day in females based on decreased body weight, body weight gain, and food consumption in both sexes. Reproductive NOAEL = 16.4 mg/kg/day in males, 18.3 mg/kg/day in females. LOAEL = not established. Offspring NOAEL = 16.4 mg/kg/day in males, 18.3 mg/kg/day in females. LOAEL = not established.
870.4100	Chronic toxicity dogs	NOAEL = 1.01 mg/kg/day in males, 1.05 mg/kg/day in females LOAEL = 8.95 mg/kg/day in males, 10.42 mg/kg/day in females based on changes in hematological and clinical chemistry parameters in both sexes and histopathological effects in bone marrow, liver, and kidney in both sexes.
870.4300	Chronic/Carcinogenicity rats	NOAEL = 3.9 mg/kg/day in males, 4.8 mg/kg/day in females. LOAEL = 9.7 mg/kg/day in males and 9.7 mg/kg/day in females based on decreased body weight, body weight gain, and food consumption in both sexes. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 1.5 mg/kg/day in males, 19.7 mg/kg/day in females. LOAEL = 15.4 mg/kg/day in males, 35.7 mg/kg/day in females based on decreased body weight and body weight gain in females and hematological effects and decreased kidney weight in males. No evidence of carcinogenicity
870.5265	Gene Mutation	Non-mutagenic when tested up to 5000 ug/plate, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537 and *E. coli* strain WP2uvra.
870.5300	Gene Mutation	Non-mutagenic at the TK locus in L5178Y mouse lymphoma cells tested up to cytotoxic concentrations or limit of solubility, in presence and absence of S-9 activation.
870.5375	Chromosome aberration	Did not induce structural chromosome aberration in CHO-K1 cell cultures in the presence and absence of activation up to cytotoxic concentrations.
870.5385	Chromosomal aberration	Non-mutagenic in ICR mouse bone marrow micronucleus chromosomal aberrations assay up to cytotoxic concentrations.

TABLE 1—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

OPPTS Guideline No.	Study Type (All Studies Acceptable)	Results
870.7485	Metabolism and pharmacokinetics -rat	Total recovery of the administered dose was > 93% for all treatment groups. Fecal excretion was the major route of elimination (66–83% of the dose), with eight primary metabolites detected. These metabolites, as well as those identified in the urine and bile, were the result of metabolic reactions including hydrazine oxidation to the diazene (D3598), demethylation, ring hydroxylation, and molecular scission with the loss of hydrazinecarboxylic acid portion to methoxybiphenyl (D1989) with subsequent conjugation. The Metabolism Assessment Review Committee (MARC) determined that D1989 is not likely to be more toxic than the parent compound.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species variations.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies variations) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for bifenazate used for human risk assessment is shown in the following Table 2:

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BIFENAZATE FOR USE IN HUMAN RISK ASSESSMENT[1]

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary for general population and females 13–50 years old	None	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributed to a single dose	None
Chronic Dietary all populations	NOAEL= 1.0 mg/kg/day; UF = 100; Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1X; cPAD = cRfD/FQPA; SF = 0.01 mg/kg/day	LOAEL = 8.9/10.4 mg/kg/day [M/F] based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the One Year Dog Feeding Study
Incidental Oral, Short Term (1–30 days)	Oral NOAEL = 10 mg/kg/day	LOC = 100	LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period in the Rat Developmental Study

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BIFENAZATE FOR USE IN HUMAN RISK ASSESSMENT[1]—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral, Intermediate Term (30 days – 6 months)	Oral NOAEL = 0.9 mg/kg/day	LOC = 100	LOAEL = 10.4/10.7 mg/kg/day [M/F] based on changes in hematologic parameters in the 90–Day Subchronic Dog Study
Short-, Intermediate- and Long-Term Dermal (1–30 days, 30 days–6 months, and 6 months to lifetime) (Occupational/Residential)	Dermal NOAEL = 80 mg/kg/day	LOC for MOE = 100	LOAEL = 400 mg/kg/day based on decreased body weight and food consumption, hematologic effects, increased spleen weight and extramedullary hemapoiesis in the spleen in the 21–Day Dermal Toxicity Study in Rats
Short-Term Inhalation (1–30 days) (Occupational/Residential)	Oral NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	LOAEL = 100 mg/kg/day based on decreased body weight and food consumption in the Rat Developmental Study
Intermediate-Term Inhalation (30 days–6 months) (Occupational/Residential)	Oral study NOAEL= 0.9 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	LOAEL = 10.4/10.7 mg/kg/day based on changes in hematologic parameters in the 90–Day Dog Feeding Study
Long-Term Inhalation (6 months-lifetime) (Occupational/Residential)	Oral study NOAEL= 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	LOAEL = 8.9/10.4 mg/kg/day [M/F] based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the One Year Dog Feeding Study
Cancer (oral, dermal, inhalation)	Cancer classification not likely	Risk Assessment not conducted	No evidence of carcinogenicity

[1] FQPA SF = Food Quality Protection Act safety factor, LOAEL = lowest observed adverse effect level, LOC = level of concern, MOE = margin of exposure, NOAEL = no observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, UF = uncertainty factor.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established 40 CFR 180.572 for the combined residues of bifenazate and D3598 (expressed as bifenazate) in or on raw agricultural commodities and animal fat and combined residues of bifenazate, D3598 (expressed as bifenazate), A1530 and A1530-sulfate (expressed as A1530) in animal tissues (excluding fat) and milk. Risk assessments were conducted by EPA to assess dietary exposures from bifenazate in food as follows:

i. *Acute exposure.* The Agency did not identify an acute endpoint for the general population, infants, children, and females 13 to 50 years old. Therefore, an acute dietary exposure analysis is not necessary.

ii. *Chronic exposure.* A chronic dietary exposure analysis was conducted using the Dietary Exposure Evaluation Model (DEEM® ver 7.73) which incorporates consumption data from the USDA 1989–92 Continuing Surveys of Food Intake by Individuals (CSFII). The dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed crops. Processing factors for apple juice and grape juice were reduced to 0.23 and 0.17, respectively. The DEEM® default processing factor ratio between juice and concentrate was maintained and default processing factors were assumed for all other commodities.

There is a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) sec 18 registration for application of bifenazate to greenhouse grown tomatoes. The potential for fresh market tomatoes to enter the processed market channel from this use is minimal for the following reasons: (a) this sec 18 approval will treat only about 300 acres of greenhouse grown tomatoes in Colorado, Texas and Virginia, (b) the tomato variety grown is an indeterminant type unsuitable for processing due to less solids and higher water content, (c) fresh market tomatoes do not tolerate the bulk handling required for processing, (d) higher price for fresh tomatoes would dictate the growers not to divert greenhouse grown tomatoes to the processing market. Therefore, the dietary contribution of bifenazate residues from treated tomatoes was determined to be negligible and a zero residue in/on tomatoes was assumed for this action.

The chronic dietary food exposure estimates to bifenazate were less than The Agency 's level of concern (< 100% cPAD) for the general U.S. population and all population subgroups. The most highly exposed population was infants (< 1 year) at 52% of the cPAD.

iii. *Cancer.* The Agency classified bifenazate as ''not likely'' to be a human carcinogen according to EPA *Proposed Guidelines for Carcinogen Risk Assessment* (April 10, 1996). Therefore, a cancer dietary exposure analysis is not necessary.

2. *Dietary exposure from drinking water.* The available environmental fate data indicate that bifenazate may not persist in the environment nor have the ability to leach into ground water resources. Bifenazate dissipates quickly through metabolic processes under aerobic soil conditions (with a half-life of 30 minutes), by aqueous photolysis (half-life of 0.67 day), and by hydrolysis, especially in alkaline water (half-life of 0.08 day). In neutral and acidic water systems, bifenazate may persist for approximately one day or longer (half-lives of 0.8 day at pH 7, and 5.4 days in pH 5). Although photodegradation of bifenazate in soil may be possible, it could not be confirmed in the laboratory

due to rapid biodegradation of bifenazate under aerobic soil conditions. In the laboratory soil column studies, bifenazate showed low to no mobility in the soils tested.

Two major degradates of bifenazate were identified in the aqueous photolysis and aerobic soil metabolism studies D3598 (diazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethylester) and D1989 (4-methoxybiphenyl). Similar to parent bifenazate, D3598 seemed to metabolize quickly under aerobic soil conditions (half-life of 8.3 hours). D1989 on the other hand, is believed to be more persistent and have some potential to leach into the ground water resources. D1989 has an aerobic soil metabolism half-life of 60 days and was observed to have slight mobility in laboratory leaching studies. D1989 was the only degradate of bifenazate detected in terrestrial field dissipation studies, but only the 0 – 6 inches soil depth.

Since parent bifenazate and its degradate D3598 are not persistent in the environment and since there are no acute dietary endpoint data for these compounds, the Agency has decided not to consider bifenazate and D3598 as residues of concern in drinking water. Instead, D1989 was assumed to have the possible potential to contaminate the drinking water resources.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for bifenazate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of bifenazate.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to bifenazate they are further discussed in the aggregate risk sections below.

Based on the FIRST or PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of D1989 for acute exposures are estimated to be 18 parts per billion (ppb) for surface water and less than 1 part per trillion (ppt) for ground water. The EECs for chronic exposures are estimated to be 5 parts per billion (ppb) for surface water and <1 ppt for ground water. These concentrations were based on one application of bifenazate on hops at a maximum rate of 0.75 lb ai/acre/year, and on the assumption that bifenazate totally metabolizes and degrades to D1989.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The currently registered Floramite® (EPA Reg. No. 400–481) and the proposed new product for food uses (Acramite®; EPA File Symbol: 400 LNG) of bifenazate are not expected to result in residential exposures. The Floramite® label allows application of bifenazate to landscape ornamentals at residential/recreational sites by commercial applicators only. The Acramite® label specifies agricultural use only. Therefore, this action assumes that bifenazate products will not be used by homeowners, so no homeowner exposure assessment is included. With respect to post-application residential exposures, the Agency contends that no significant post-application exposure is anticipated from treated ornamentals, either by residents or professional applicators; therefore, no residential post-application assessment is warranted.

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 bifenazate 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, bifenazate 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 bifenazate 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. Safety Factor for Infants and Children

1. *In general*. 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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.

2. *Prenatal and postnatal sensitivity*. There is no qualitative or quantitative toxicity evidence of increased susceptibility of rats and rabbits during

in utero exposure or during post-natal exposure based on developmental toxicity and reproductive toxicity studies performed with bifenazate.

3. *Conclusion*. There is a complete toxicity database for bifenazate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the lack of increased susceptibility and the completeness of the toxicity and exposure databases, EPA has concluded that an additional 10X safety factor is not needed to protect infants and children.

E. Aggregate Risks and Determination of Safety

Because The Agency does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, DWLOCs were calculated. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. The Agency uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water. The Agency compares DWLOC values for each relevant population subgroup to the estimated concentration of bifenazate in surface water and ground water from the Agency' screening models. If the DWLOC values are greater than the estimated concentration of bifenazate in surface water and ground water, The Agency concludes with reasonable certainty that exposures to bifenazate in drinking water do not pose a significant human health risk.

To calculate the chronic DWLOCs, the food estimates (from DEEM®) were subtracted from the appropriate PAD value to obtain the maximum water exposure level. DWLOCs were then calculated using the standard body weights and drinking water consumption figures: 70kg/2L (adult male and U.S. population), 60 kg/2L (adult female), and 10kg/1L (infants and children). Because there is no residential exposure to bifenazate, only chronic aggregate exposures are necessary.

1. *Acute risk*. The Agency did not identify an acute endpoint for the general U.S. population, infants, children, and females 13–50 years old. Therefore, an acute risk is expected.

2. *Chronic risk*. The chronic dietary food exposure to bifenazate was estimated at 0.005242 mg/kg/day (52% of cPAD) for infants (< 1 year old) and 0.001557 mg/kg/day (16% of cPAD) for the general U.S. population. The calculated DWLOCs ranged between 48 to 320 ppb for all the population subgroups. The surface and ground water chronic EECs for the bifenazate metabolite D1989 were estimated to be 5 ppb and < 1 part per trillion (ppt), respectively. Since the chronic EECs are less than the Agency's DWLOCs for all population subgroups including infants, the chronic aggregate risk estimates are below the Agency's level of concern. Table 3 summarizes the chronic aggregate exposure to bifenazate.

TABLE 3—CHRONIC AGGREGATE EXPOSURES TO BIFENAZATE RESIDUES.

Scenario/Population Subgroup	cPAD, mg/kg/day	Chronic Food Exposure mg/kg/day	Maximum Chronic Water Exposure[1] mg/kg/day	Ground Water EEC[2], ppt	Surface Water EEC[2], ppb	Chronic DWLOC[3], ppb
U.S. Population	0.01	0.001557	0.008443	<1	5	300
All infants (< 1 year old)	0.01	0.005242	0.004758	<1	5	48
Children (1–6 years old)	0.01	0.003941	0.006059	<1	5	61
Children (7–12 years old)	0.01	0.002343	0.007657	<1	5	77
Females (13–50 years old)	0.01	0.001088	0.008912	<1	5	270
Males (13–19 years old)	0.01	0.000931	0.009069	<1	5	320
Males (20+ years old)	0.01	0.001050	0.00895	<1	5	310
Seniors (55+ years old)	0.01	0.001924	0.008076	<1	5	280

[1] Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM® (mg/kg/day); no residential exposure

[2] EECs resulting from one applications at 0.75 lbs ai/acre;

[3] The chronic DWLOCs were calculated as follows: DWLOC (µ/L) = maximum water exposure (mg/kg/day) x body weight (kg)/consumption (L/day) x 0.001 mg/µg

3. *Short-term risk*. A short term risk assessment was not performed because there are no significant exposures anticipated from registered residential non-food uses of bifenazate.

4. *Intermediate-term risk*. An intermediate term risk assessment was not performed because there are no significant post-application exposures anticipated from registered residential non-food uses of bifenazate.

5. *Aggregate cancer risk for U.S. population*. Bifenazate is not carcinogenic.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical methods used in the field trial, processing, and ruminant feeding have been adequately validated and are appropriate for data gathering purposes. The following paragraphs pertain to the proposed plant and livestock enforcement methods.

1. *Plant*. The method proposed for enforcement of the plant tolerances

associated with this petition has been adequately radiovalidated and validated by an independent laboratory. The Agency's Analytical Chemistry Laboratory (ACL) is currently doing a Petition Method Validation (PMV). After reviewing the independent validation, EPA believes that the PMV will at most show that relatively minor modifications or revisions may need to be made. The registrant will be required to make any modifications or revisions to the proposed enforcement method resulting from the PMV.

2. *Livestock.* The method proposed for enforcement of the animal product tolerances associated with this petition has been adequately validated by an independent laboratory. The independent laboratory validation study resulted in marginal recoveries for bifenazate (milk and kidney), D3598 (liver), and A1530-sulfate (kidney). A radiovalidation of the method was not undertaken by the registrant, as the total radioactive bifenazate and its metabolite residues were very low for analytical purposes. However, the analytical method used for quantifying residues in animal tissues were satisfactorily validated on freshly spiked matrices. The ACL is currently doing a PMV. After reviewing the independent validation, EPA believes that the PMV will at most show that relatively minor modifications or revisions may need to be made. The registrant will be required to make any modifications or revisions to the proposed enforcement method resulting from the PMV.

3. *Multiresidue method (MRM).* The registrant submitted data concerning the recovery of bifenazate and D3598 using FDA multiresidue method protocols A, C, D, E, and F (Pesticide Analytical Manual Vol. I). Acceptable results were only attained using Protocol C. These data were forwarded to FDA for inclusion in the Pesticide Analytical Manual I. The tolerance expression for livestock commodities includes A1530 and A1530-sulfate. The registrant should submit information concerning the behavior of these compounds through the FDA multiresidue protocols.

Adequate enforcement methodology (utilizing reversed phase high pressure liquid chromatography (HPLC) and oxidative coulometric electrochemical detection) is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov. In addition, Mulitresidue Enforcement Method, Protocol C, has been shown to be adequate for enforcing these tolerances.

B. International Residue Limits

There is neither a CODEX proposal, nor Canadian or Mexican limits for residues of bifenazate and D3598 in/on pome fruit, stone fruit, strawberry, hops, cotton, or grape or for resides of bifenazate, D3598, A1530 and A1530-sulfate in/on livestock commodities. Therefore, harmonization is not an issue for this pesticide tolerance.

C. Conditions

The submitted residue chemistry and toxicological studies are adequate for a conditional registration of bifenazate for food uses. There is high confidence in the hazard end points used for human health risk assessment. However, the following data are being required within 2 years time in order to confirm the results of the studies already reviewed by the Agency and/or to complete the database requirements prior to approval of an unconditional registration of bifenazate:

a. Confirmatory method and interference study for proposed plant and livestock enforcement.

b. Radio validation of proposed livestock enforcement method.

c. FDA multi residue methods testing of A1530 and A1530-sulfate.

d. Storage stability data for hops, strawberry, apple juice, and wet apple pomace.

e. Additional peach field trial data.

f. Additional plum field trial data.

g. Additional grape field trial data.

h. Additional cotton field trial data.

i. 28–day inhalation toxicity study. This study was requested by the Agency for further characterization of inhalation risk assessments. Due to the potential for inhalation exposure, there is concern for toxicity by the inhalation route. The 28–day inhalation toxicity study would give a dose and endpoint examined via the route of exposure of concern (i.e., route specific study) and thus would avoid using an oral study and route-to-route extrapolation. The protocol for the existing 90–day inhalation toxicity study (OPPTS 870.3465) should be followed with the exposure (treatment) ending after 28 days, instead of 90 days.

The rationale for not requiring these data before registration of food uses are provided below:

1. *Deficiencies a, b and c.* Adequate analytical methods are available for enforcement purposes. These methods were independently validated and a petition method validation is in progress at the Agency's Analytical Chemistry Laboratory. In addition, a Mulitresidue Enforcement Method, Protocol C, has been shown to be adequate for enforcing these tolerances.

2. *Deficiencies d through h.* The storage interval of almost all commodity samples collected from the field trial and processing have been validated. The storage interval for hops, strawberry, apple juice, and wet apple pomace were not validated as required and are necessary to confirm the submitted residue chemistry data. The Agency concluded that the interval from sampling until analysis was reasonable and will not invalidate the submitted data due to lack of stability of bifenazate residues of concern. For peach, plum, grape and cotton, the requirements are additional field trials to fulfil the geographical distribution and also to confirm the data already submitted and reviewed by the Agency. The crops and number of trials required are peach(2), plum(1), grape(1) and cotton(1).

3. *Deficiency i.* Bifenazate is not acutely toxic by oral, dermal or inhalation routes (Toxicity category IV). Because of low inhalation toxicity, the registrant did not do a subchronic inhalation toxicity and its absence, the Agency used for endpoint selection the oral NOAELs for short-, intermediate- and long-term inhalation exposure risk assessment for this action. To fully characterize the toxicity potential by inhalation route of exposure over long term use of bifenazate, a 28–day inhalation study is required.

V. Conclusion

Therefore, the tolerances are established for combined residues of bifenazate and D3598 (expressed as bifenazate) in or on apple, wet pomace at 1.2 ppm; cattle fat at 0.1 ppm; cotton, undelinted seed at 0.75 ppm; cotton, gin byproducts at 35 ppm; fruit, pome, group at 0.75 ppm; goat fat at 0.1 pm; grape 0.75 ppm; grape, raisin at 1.2 ppm; hog fat at 0.1 ppm; hop, dried cones at 15 ppm; horse fat at 0.1 ppm; nectarine at 1.7 ppm; peach at 1.7 ppm; plum at 0.30 ppm; sheep fat at 0.1 ppm strawberry at 1.5 ppm and combined residues of bifenazate, D3598 (expressed a bifenazate), A1530 and A1530-sulfate (expressed as A1530) in cattle meat at 0.01 ppm; cattle meat byproducts at 0.01 ppm; goat meat at 0.01 ppm; goat meat byproducts at 0.01 ppm; hog meat at 0.01 ppm; hog meat byproducts at 0.01 ppm; horse meat at 0.01 ppm; horse meat byproducts at 0.01 ppm; milk at 0.01 ppm; sheep meat at 0.01 ppm; and sheep meat byproducts at 0.01 ppm.

Some of the tolerance values requested by the registrant in their petition are different from that

determined by the Agency. The differences are due to the following reasons: The registrant requested a group tolerance for stone fruits. This is not appropriate at this time as no field trial data were submitted on cherry and apricot and/or the maximum peach (1.45 ppm) and plum (0.15 ppm) residue varied by a factor > 5x. In the case of undelinted cotton seeds and cotton gin byproducts, the Agency concluded that a higher tolerance of 0.75 ppm and 35 ppm are required as compared with 0.5 ppm and 20 ppm, respectively, for the combined residues of bifenazate and D3598 (expressed as bifenazate) due to the correction factors applied to the percent recoveries of residues for concern in the storage stability study. For meat of cattle, goat, hog, horse and sheep the registrant requested a 0.02 ppm tolerance; however, the Agency concluded that the bifenazate level used in the animal feeding study (maximum theoretical dietary burden) supports only 0.01 ppm for the combined residues of bifenazate, D3598 (expressed as bifenazate), A1530 and A1530-sulfate (expressed as A1530).

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301206 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 2, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

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 the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301206, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does 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 to 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 this final rule in the **Federal Register**. This final 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 record keeping requirements.

Dated: January 15, 2002.

James Jones,

Acting Director, 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), 346(a) and 371.

2. Section 180.572 is amended by adding text to paragraph (a) to read as follows:

§ 180.572 Bifenazate; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of bifenazate (hydrazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethyl ester) and D3598 expressed as bifenazate (diazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethylester) in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	1.2
Cattle, fat	0.1
Cotton, gin byproducts	35
Cotton, undelinted seed	0.75
Fruit, pome, group	0.75
Goat, fat	0.1
Grape	0.75
Grape, raisin	1.2
Hog, fat	0.1
Hop, dried cones	15
Horse, fat	0.1
Nectarine	1.7
Peach	1.7
Plum	0.3
Sheep, fat	0.1
Strawberry	1.5

(2) Tolerances are established for combined residues of bifenazate (hydrazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethyl ester) and D3598 expressed as bifenazate (diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethylester), A1530 (1,1'-biphenyl, 4-ol) and A1530-sulfate expressed as A1530 (1,1'-biphenyl, 4-oxysulfonic acid) in the following animal commodities:

Commodity	Parts per million
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01

* * * * *

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