ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0297; FRL–7328–1]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of bifenazate and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on almond, hulls; nut, tree, group 14; okra; peppermint, tops; pistachio; spearmint, tops; vegetable, cucurbit, group 9; and, vegetable, fruiting, group 8; and increases the established tolerances for combined residues of bifenazate; diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in meat and meat byproducts of cattle, goat, hog, horse, and sheep and milk. EPA is also deleting the bifenazate time-limited tolerance for tomato, which is established in connection with a section 18 emergency exemption. Tomato is included in the tolerance established by this action for vegetable, fruiting group 8. The Interregional Research Project Number 4 (IR-4) requested these tolerances 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0297, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests– may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Industry (NAISC 111, 112, 311, 32532), e.g., Crop production, Animal production, Food manufacturing, and 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0297. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of January 15, 2003 (68 FR 2032) (FRL–7286–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petition (PP 2E6517) by IR–4, 681 US Highway 1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petition prepared by Crompton Manufacturing Company, Inc. (formerly Uniroyal Chemical Company), Middlebury, CT 06749, the registrant.

The petition requested that 40 CFR 180.572 be amended by establishing tolerances for combined residues of the miticide, bifenazate, (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on the following commodities: Nut, tree, group 14 at 0.20 ppm; okra at 2.0 ppm; peppermint, tops at 25 ppm; pistachio at 0.20 ppm; spearmint, tops at 25 ppm; vegetable, cucurbit, group 9 at 0.75 ppm; and vegetable, fruiting, group 8 at 2.0 ppm. The petition was subsequently amended by IR-4 to also propose tolerances for combined residues of bifenazate and diazinecarboxylic acid in or on almond hulls at 15 ppm; and to propose increases to the established bifenazate meat, meat byproducts and milk tolerances; and to change the tolerance expression for meat, meat byproducts and milk. IR-4 proposes tolerances for combined residues of bifenazate, (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate); diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in or on meat and meat byproducts of

cattle, goat, hog, horse, and sheep at 0.02 ppm and milk at 0.02 ppm. There were no comments received on these petitions.

EPA has received objections to tolerances it established for residues of bifenazate on a variety of food commodities in a final rule published in the **Federal Register** of February 1, 2002 (67 FR 4913) (FRL–6818–3). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7), which ended on October 16, 2002. Although that proceeding remains ongoing, prior to acting on this current tolerance action, EPA reviewed the bifenazate-specific objections raised by NRDC and has addressed them at relevant points throughout this preamble.

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) of the FFDCA 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) of the FFDCA 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 of the FFDCA 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) of the FFDCA, 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) of the FFDCA, for tolerances for combined residues of bifenazate and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) on almond, hulls at 15 ppm; nut, tree, group 14 at 0.20 ppm; okra at 2.0 ppm; peppermint, tops at 25 ppm; pistachio at 0.20 ppm; spearmint, tops at 25 ppm; vegetable, cucurbit, group 9 at 0.75 ppm; and vegetable, fruiting, group 8 at 2.0 ppm, and combined residues of bifenazate; diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in meat and meat byproducts of cattle, goat, hog, horse, and sheep at 0.02 ppm and milk at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 Table 1 of this unit 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

Guideline No.	Study	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

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

Guideline No.	Study	Results
870.3700	Prenatal developmental in nonrodents—rabbit	Maternal NOAEL = 200 mg/kg/day LOAEL = not established; the dosing in this study are considered adequate based on the results of a range finding study in which 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
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/Carcino-genicity 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.
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, demethylation, ring hydroxylation, and molecular scission with the loss of hydrazinecarboxylic acid portion with subsequent conjugation.

In its objection to a separate bifenazate tolerance action, NRDC, asserts that developmental toxicity is a data gap for bifenzate. NRDC appears to be referring to language in the Table 1, Unit III.A. of the **Federal Register** final rule of February 1, 2002, that states that a clear assessment of developmental toxicity was not possible in the range finding study used to choose the dose levels for the developmental toxicity study in rabbits. The Agency concludes there are acceptable developmental toxicity studies conducted with bifenazate in rats and in rabbits, and an acceptable 2-generation reproduction study in rats, which are described in Table 1. of this unit.

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 differences.

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 factors

(SF) 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 SF.

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 differences) 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 is shown in Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary; general population and females 13–50 years old	NA	NA	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributed to a single dose.
Chronic Dietary; all populations	NOAEL= 1.0 mg/kg/day UF = 100 cRfD = 0.01 mg/kg/day	Special FQPA SF = 1X cPAD = 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 for MOE ≤ 100 (residential)	Maternal LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period in the Rat Developmental Study
Incidental Oral, Intermediate Term (30 days-6 months)	oral NOAEL = 0.9 mg/kg/day	LOC for MOE ≤ 100 (residential)	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 six months to lifetime)	dermal NOAEL= 80 mg/kg/day	LOC for MOE ≤ 100 (residential)	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)	oral NOAEL= 10 mg/kg/day inhalation absorption rate = 100%	LOC for MOE ≤ 100 (residential)	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)	oral NOAEL= 0.9 mg/kg/day inhalation absorption rate = 100%	LOC for MOE ≤ 100 (residential)	LOAEL = 10.4/10.7 mg/kg/day based on changes in hematologic parameters in the 90-Day Dog Feeding Study
Long-Term Inhalation six months-lifetime)	Oral study NOAEL= 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (residential)	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)	NA	NA	Bifenazate is classified as not likely to be a human carcinogen

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 (diazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethylester), in or on a variety of food commodities.

Risk assessments were conducted by EPA to assess dietary exposures from bifenazate in food as follows:

i. *Acute exposure.* An acute dietary reference dose (RfD) for the females 13–50 years of age and the general population, including infants and children, was not selected because an acute oral endpoint attributed to a single-dose exposure could not be identified in any of the studies in the toxicology data base, including

developmental and maternal toxicity in the developmental toxicity studies.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions was made for the chronic exposure assessment: The chronic dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed crops excluding tomato where average field trial residues were used. DEEM (ver 7.73) default processing factors were assumed for all commodities excluding apple juice, grape juice, wine/sherry, tomato paste, and tomato puree. The processing factors for these commodities were reduced to 0.23, 0.17, 0.17, 5.0, and 5.0, respectively, based on data from processing studies.

In its objections to the earlier bifenazate tolerance action, NRDC claims that EPA relied upon unsupported and apparently arbitrary processing factors to reduce estimates of dietary exposure to bifenazate on apples and grapes. NRDC was incorrect to assert that the processing factors for apples and grapes were unsupported and arbitrary. The DEEM processing factors for apple juice and grape juice used for this action and the earlier bifenazate tolerance action are based on data from processing studies. In this action, the Agency used DEEM (ver 7.73) default processing factors when processing studies were not available. These default factors are worst case assumptions regarding pesticide partitioning into component commodity fractions. DEEM (ver 7.73) default processing factors assume that 100 percent of the pesticide that was originally present in the commodity is present in the processed fractions. This is a worst case theoretical concentration factor since it assumes that processing does not result in any reduction in pesticide content.

iii. *Cancer*. EPA has classified bifenazate as a not likely human carcinogen. Therefore, a quantitative cancer dietary exposure and risk assessment was not performed.

2. *Dietary exposure from drinking water*. 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 model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The 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. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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 risks in Unit III.E.

Parent bifenazate degrades rapidly in aerobic soil conditions with a half-life of approximately 30 minutes. The first degradate formed (D3598 (diazinecarboxylic acid, 2-(4-methoxy-1,1'- biphenyl-3-yl) (half-life of 7 hours)) was reported in a concentration of 95% of the applied radioactivity. D3598 degrades to D1989 (4-methylethylester) (reported at a maximum of 26% of the applied radioactivity), which is moderately persistent with an EPA-calculated half-life of approximately 96 days. Photodegradation and other routes of dissipation of parent bifenazate do not appear to be significant.

The Agency concluded that the residue of concern in drinking water is D1989. Parent and D3598 were not included as a residue of concern in drinking water due to the short half-lives of these compounds and the lack of an acute dietary endpoint (toxicity of D3598 is assumed to be equivalent to bifenazate). Since ground or surface water monitoring data to calculate a quantitative aggregate exposure are not available, EPA provided Tier I ground (SCI-GROW) and surface water (FIRST) EECs for D1989. Both models were conducted using the strawberry application scenario (one application at 0.75 lbs ai/acre; highest registered/proposed application rate). The resulting ground and surface water chronic EECs are < 0.001 ppb and 6.4 ppb, respectively.

In its objections to a separate bifenazate tolerance action, NRDC asserts that EPA failed to complete an assessment of drinking water exposure to bifenazate degradates. As stated in the **Federal Register** final rule of February 1, 2002, and restated in this document, EPA considered the environmental persistence of bifenazate and its two major metabolites D3598 and D1989. Aqueous photolysis and soil metabolism studies demonstrated that the parent bifenazate and the D3598 degradate quickly metabolize under aerobic soil conditions. Noting the lack of persistence of these two compounds and the absence of any acute dietary endpoint, EPA focused its drinking water exposure assessment for bifenazate on the degradate (D1989) that had a possibility of being present in drinking water. Accordingly, NRDC is incorrect to assert that potential exposure to bifenazate degredates in drinking water was not assessed by EPA.

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). In its objections to a separate bifenazate tolerance action, NRDC asserts that EPA failed to assess and incorporate residential uses as a source of aggregate exposure. In the current risk assessment, EPA calculated short-term residential risks to homeowner applicators.

However, the Agency concluded that no significant post-application exposure is aniticipated from landscape ornamentals; therefore, no residential post-application assessment was conducted.

Bifenazate is currently registered for use on the following residential non-dietary sites: Commercial application to ornamental plants (including bedding plants, flowering plants, foliage plants, bulb crops, perennials, trees and shrubs; not turf) and all fruit trees which will not bear fruit for a minimum of 12 months. The registrant has proposed an amendment to the Floramite (EPA Reg. No. 400–508) label to permit application to home ornamental plants and fruit trees that will not bear fruit within 12 months by residents/homeowners. The risk assessment was conducted using the following residential exposure assumptions: EPA anticipates only short-term dermal and short-term inhalation exposure for the residential handler (applicator). The proposed formulation is appropriate for application via pump up sprayers, garden hose-end sprayers or similar homeowner pesticide devices. A larger area per day may be treated with a hose-end sprayer than with a pump up compressed air sprayer, which in turn results in possibly greater contact with the active ingredient per day. Therefore, exposure from a hose-end sprayer is assessed rather than that of a compressed air sprayer. For the treatment of shrubs and ornamentals, EPA assume 100 gallons of finish spray are applied per day. The unit exposure value for a residential handler using open pour mixing/loading for a garden hose-end sprayer is 11 mg/lb handled (dermal) and 0.013 mg/lb handled (inhalation). Exposures were calculated using the Agency's draft Residential Standard Operating Procedures.

The highest label rate of application is 8 fl oz product/100 gal water.
2.0 lb ai/gal ÷ 128 fl oz/gal = 0.015625 lb ai/fl oz.
(8 fl oz/100 gal)(100 gal/day)(0.015625 lb ai/fl oz) = 0.125 lb ai/day

i. *Dermal Exposure Assessment and MOE.*
((11.0 mg ai/lb handled)(0.125 lb ai handled/day)) ÷ 70 kg bw = 0.019 mg/kg/day
MOE = NOAEL ÷ ADD = 80 mg/kg/day ÷ 0.019 mg/kg bw/day = 4,200

ii. *Inhalation Exposure Assessment and MOE.*
((0.013 mg ai/lb handled)(0.125 lb ai handled/day)) ÷ 70 kg bw = 0.0000232 mg/kg/day
MOE = NOAEL ÷ ADD = 10 mg/kg/day ÷ 0.0000232 mg/kg/day = 430,000

MOEs are combined for the dermal and inhalation routes of exposure since the short term toxicological effects are the same (reduced body weight gain and food consumption).

iii. *Combined MOE.*
combined MOE = $1 \div ((1 \div MOE_{dermal}) + (1 \div MOE_{inhalation}) = 4{,}200$

An MOE of 100 is adequate to protect a residential handler under the circumstances described. The estimated MOE is > 100 therefore this use is not of concern.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of the FFDCA 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. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to bifenazate and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov\pesticides\cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA 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 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 indication of qualitative or quantitative increased susceptibility of rats and rabbits during in utero exposure or post-natal exposure based on developmental toxicity and reproductive toxicity studies performed with bifenazate.

3. *Conclusion.* There is a complete toxicity data base for bifenazate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X for the following reasons:

Acceptable developmental toxicity studies in the rat and the rabbit are available, as is an acceptable 2-generation reproduction study in the rat and there is no indication of qualitative or quantitative increased susceptibility of rats and rabbits to *in utero* or postnatal exposure. A developmental neurotoxicity study is not required for bifenazate. The dietary (food and water) and non-dietary (residential) exposure assessments are not expected to underestimate the potential exposures for infants and children from the use of bifenazate.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking 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 residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be

taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute exposure.* Acute dietary 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 one day or single exposure. Bifenazate is not expected to pose an acute risk to humans.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifenazate from food will utilize 24% of the cPAD for the U.S. population, 59% of the cPAD for all infants < 1 year old, 85% of the cPAD for children 1–2 years old (the most highly exposed population subgroup), and 17% of the cPAD for females 13–49 years old. Based on the use pattern, chronic residential exposure to residues of bifenazate is not expected. In addition, there is potential for chronic dietary exposure to bifenazate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BIFENAZATE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.01	24	6.4	<0.001	260
All Infants (<1 year old)	0.01	59	6.4	<0.001	40
Children (1–2 years old)	0.01	85	6.4	<0.001	15
Females (13–49 years old)	0.01	17	6.4	<0.001	250

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). In its objections to a separate bifenazate tolerance action, NRDC claims that residential short- and intermediate-term risk assessments are data gaps for bifenazate. In the current risk assessment, EPA calculated short-term residential risks to homeowner applicators. However, the Agency concluded that no significant post-application exposure is aniticipated from landscape ornamentals; therefore, no residential post-application assessment was conducted. In addition, intermediate-term aggregate exposure (30 days to 6 months) is not expected since homeowner exposure is not expected to exceed 1 to 30 days.

Bifenazate is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for bifenazate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 2,069 for the U.S. population; 2,418 for youth 13–19 years old; 2,429 for adults 20–49 years old; 2,467 for females 13–49 years old; and 2,377 for adults 50+ years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of bifenazate in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BIFENAZATE

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	2,100	100	6.4	<0.001	3,300
Youth 13–19 years old	2,400	100	6.4	<0.001	2,900
Adults 20–49 years old	2,400	100	6.4	<0.001	3,400
Females 13–49 year old	2,500	100	6.4	<0.001	2,900
Adults 50+ years old	2,400	100	6.4	<0.001	3,400

4. *Aggregate cancer risk for U.S. population*. Bifenazate is classified as not likely to be a human carcinogen. The Agency concludes that bifenazate is not expected to pose a cancer risk to humans.

5. *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

1. *Plant*. The enforcement method for plant tolerances associated with these petitions is method UCC–D2341, which uses high pressure liquid chromatography with an oxidative coulometric electrochemical detector.

2. *Livestock*. The enforcement method for animal products utilizes high pressure liquid chomatography with oxidative coulometric electrochemical detection.

3. *Multiresidue method*. Multiresidue Enforcement Method Protocol C has been shown to be adequate for enforcing these tolerances.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of bifenazate in/on the proposed crops. Therefore, harmonization is not an issue.

V. Conclusion

Therefore, tolerances are established for combined residues of bifenazate, and diazinecarboxylic acid; 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on almond, hulls at 15 ppm; nut, tree, group 14 at 0.20 ppm; okra at 2.0 ppm; peppermint, tops at 25 ppm; pistachio at 0.20 ppm; spearmint, tops at 25 ppm; vegetable, cucurbit, group 9 at 0.75 ppm; and vegetable, fruiting, group 8 at 2.0 ppm, and combined residues of bifenazate; diazinecarboxylic acid, (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol)] in [meat and meat byproducts of cattle, goat, hog, horse, and sheep at 0.02 ppm and milk at 0.02 ppm.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2003–0297 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 November 25, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2003–0297, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statutory and Executive Order Reviews

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). 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 section 408(d) of the FFDCA, such as the tolerances 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

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 recordkeeping requirements.

Dated: September 15, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.572 is amended:

i. In paragraph (a)(1) by revising the introductory text and alphabetically adding commodities to the table;

ii. By revising paragraph (a)(2); and

iii. In paragraph (b), by revising the introductory text and removing the commodities ''Hop'' and ''Pear'' from the table.

The amendments read as follows:

§ 180.572 Bifenazate; tolerances for residues.

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

Commodity	Parts per million
Almond, hulls	15
* * * * *	
Nut, tree, group 14	0.20
Okra	2.0
* * * * *	
Peppermint, tops	25
Pistachio	0.20
* * * * *	
Spearmint, tops	25
* * * * *	
Vegetable, cucurbit, group 9.	0.75
Vegetable, fruiting, group 8.	2.0

(2) Tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate); diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in or on the following food commodities:

Commodity	Parts per million
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

* * * * *

[FR Doc. 03–24370 Filed 9–25–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0304]; FRL–7325–8]

Thiacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiacloprid ([3-[(6-chloro-3-pridinyl)methyl]-2-thiazolidinylidene]cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on apple, wet pomace; cotton, undelinted seed; cotton, gin by-products; fruit, pome group 11; fat, meat, liver, kidney and meat by-products of cattle, sheep, goat and horse; and milk. Bayer CropScience requested these tolerances 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0304], must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests– may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Marilyn Mautz, Registration Division, 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703 305–6785; e-mail address: *mautz.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)]

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0304. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_(_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket