1999 final rule, which established the exemption from temporary tolerance for residues of the atoxigenic *Aspergillus flavus* AF36 on cotton grown in certain Counties in Arizona, is discussed in the preamble for the final rule (64 FR 28371, at 28373).

VI. Will EPA Submit this Final Rule to Congress and the Comptroller General?

Yes. 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 the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental Protection, Administrative Practice and Procedure, Agricultural Commodities, Pesticides and Pests, Reporting and Recordkeeping Requirements.

Dated: June 10, 1999.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention 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.

§ 180.1206 [Amended]

2. Section 180.1206 is amended by revising the date in the last sentence therein to read ''December 30, 2001''.

[FR Doc. 99–16546 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300888; FRL–6089–9]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide bifenthrin, (2-methyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, in or on the food commodities: cabbage at 4.0 part per million (ppm); the cucurbit vegetable crop group (Crop Group 9) at 0.4 ppm; edible- podded legume vegetable subgroup (Crop Subgroup 6A) at 0.6 ppm; eggplant at 0.05 ppm; globe artichoke at 1.0 ppm; head and stem Brassica subgroup (Crop Subgroup 5A), except cabbage, at 0.6 ppm; rapeseed at 0.05 ppm, succulent shelled pea and bean subgroup (Crop Subgroup 6B) at 0.05 ppm; sweet corn kernel plus cob with husk removed at 0.05 ppm; and corn forage at 3.0 ppm. The Interregional Research Project (IR-4) and FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

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

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300888], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300888], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300888]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9368, e-mail: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 7, 1998 (63 FR 53902) (FRL–6026–3), and May 19, 1999 (64 FR 27262) (FRL–6079–8), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions for tolerances by the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experimental Station, P.O. Box 231, Rutgers University, New Brunswick, NJ, and FMC Corporation, 1753 Market Street, Philadelphia, PA 19103. These notices included summaries of the petitions prepared by FMC Corporation, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.442 be amended by establishing tolerances for residues of the insecticide bifenthrin, in or on various food commodities, as follows:

1. IR-4 petition 6E4629 proposes the establishment of a tolerance for globe artichoke at 1.0 ppm. IR-4 first proposed the tolerance for the commodity ''artichokes,'' but the petition was amended to specify the food commodity as ''globe artichoke.''

2. IR-4 petition 6E4760 proposes the establishment of a tolerance for the cucurbit vegetable crop group at 0.4 ppm.

3. IR-4 petition 8E4993 proposes the establishment of a tolerance for the edible-podded legume vegetable subgroup at 0.6 ppm. The initial proposal was for a tolerance for the edible- podded legume vegetable group at 0.2 ppm. Based on EPA's review of the field residue data submitted by IR-4, the petition was revised by the petitioner to propose the tolerance at 0.6 ppm.

4. IR-4 petition 8E5009 proposes the establishment of a tolerance for eggplant at 0.05 ppm.

5. IR-4 petition 9E5084 proposes the establishment of a tolerance for rapeseed (including canola and crambe seed) at 0.05 ppm.

6. IR-4 petition 9E5064 proposes the establishment of a tolerance for succulent shelled pea and bean subgroup at 0.05 ppm.

7. IR-4 petition 9E5069 proposes the establishment of a tolerance for the head and stem Brassica subgroup, except cabbage, at 0.6 ppm; and cabbage at 4.0 ppm.

8. FMC Corporation petition 8F5014 proposes the establishment of a tolerance for sweet corn grain at 0.05 ppm and corn forage at 3.0 ppm. The petition was amended by changing the commodity term ''sweet corn grain'' to read ''sweet corn kernel plus cob with husk removed.''

I. Background and Statutory Findings

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

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of bifenthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of bifenthrin on cabbage at 4.0 ppm; the cucurbit vegetable crop group at 0.4 ppm; edible-podded legume vegetable subgroup at 0.6 ppm; eggplant at 0.05 ppm; globe artichoke at 1.0 ppm; head and stem Brassica subgroup, except cabbage, at 0.6 ppm; rapeseed at 0.05 ppm; succulent shelled pea and bean subgroup at 0.05 ppm; sweet corn kernel plus cob with husk removed at 0.05 ppm; and corn forage at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 bifenthrin are discussed in this unit.

1. *Genotoxicity*. The following genotoxicity tests conducted with bifenthrin all yielded negative results including: gene mutation in Salmonella (Ames); chromosomal aberrations in Chinese hamster ovary and rat bone marrow cells; HGPRT locus mutation in mouse lymphoma cells; and unscheduled DNA synthesis in rat hepatocytes. Bifenthrin tested positive in a mouse lymphoma forward mutation assay, with and without metabolic activation.

2. *Developmental toxicity*. In the rabbit developmental toxicity study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal no observed adverse effect level (NOAEL) was 2.67 milligrams (mg)/kilogram (kg)/day based on head and forelimb twitching at the lowest observed adverse effect level (LOAEL) of 4 mg/kg/day. In the rat developmental study, the maternal NOAEL was 1 mg/kg/day, based on tremors at the LOAEL of 2 mg/kg/day. The developmental (pup) NOAEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOAEL of 2 mg/kg/day. There were 5 of 23 (22 percent) litters affected with each litter having only one affected pup in the 2 mg/kg/day group, compared with zero in the control, 1 and 0.5 mg/kg/day groups. According to recent historical data (1992-1994) for this strain of rat, incidence of distended ureter averaged 11 percent with a maximum incidence of 90 percent.

3. *Reproductive toxicity*. In the rat reproduction study, parental toxicity occurred as decreased body weight at 5.0 mg/kg/day with a NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested)(HDT).

4. *Chronic toxicity/carcinogenicity*. In a 1-year chronic/carcinogenicity study dogs were fed diets containing 0, 0.75, 1.5, 3, or 5 mg/kg/day. No mortality occurred during the study and there were no treatment-related effects on body weight, food consumption, organ weights, and gross or microscopic pathology. In addition, there were no treatment-related ophthalmological changes. Tremors were noted in all males and females at 5 mg/kg/day during weeks 15-29 and in 1 of 4 males and 2 of 4 females at 3 mg/kg/day during weeks 16-23. A significant increase in platelets was noted at 52 weeks in males fed 5 mg/kg/day . Serum sodium levels were significantly increased in males at 3 and 5 mg/kg/day and serum chloride was increased in males fed 5 mg/kg/day. The LOAEL for this study is 3 mg/kg/day based on the increased incidence of tremors in both sexes. The NOAEL is 1.5 mg/kg/day.

5. *Chronic/carcinogenicity study*. In this study mice were fed doses of 0, 50, 200, 500, or 600 ppm (0, 2.5, 10, 25, or 30 mg/kg/day) in the diet for 87 weeks (males) or 92 weeks (females). The chronic LOAEL was established at 10 mg/kg/day based on the incidence of tremors in both sexes. The chronic NOAEL is established at 2.5 mg/kg/day. Carcinogenic potential was evidenced by a statistically significant increased trend for hemangiopericytomas in the urinary bladders of males, a significant dose-related trend for combined hepatocellular adenomas and carcinomas in males, and a significantly higher incidence of combined lung adenomas and carcinomas in females.

6. *Chronic/carcinogenicity study*. In this study rats were fed diets containing 0, 12, 50, 100, or 200 ppm (0, 0.6, 2.5,

5, or 10 mg/kg/day). The chronic LOAEL is 5 mg/kg/day based on the increased incidence of tremors in both sexes and possible increases in organ-to-body weight ratios in males, and the chronic NOAEL is established at 2.5 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

7. *Animal metabolism*. Metabolism studies in rats demonstrated that distribution patterns and excretion rates in multiple oral dose studies are similar to single-dose studies. There was an accumulation of unchanged compound in fat upon chronic administration with slow elimination. Otherwise, bifenthrin was rapidly metabolized and excreted. Unchanged bifenthrin is the major residue component of toxicological concern in meat and milk.

B. Toxicological Endpoints

1. *Acute dietary toxicity*. The acute reference doses (RfD) for dietary exposure is established at 0.01 mg/kg/day. The acute RfD is based on a developmental toxicity study in the rat with a maternal NOAEL of 1.0 mg/kg of body weight/day and an uncertainty factor (UF) of 100. The FQPA Safety Factor for the protection of infants and children was reduced to 1x. (See Unit II.E.iv. in the preamble of this document for discussion of pre- and post-natal sensitivity to bifenthrin.) The acute population adjusted dose (acute PAD) is determined by dividing the acute RFD by the FQPA factor: acute PAD = 0.01 / 1 = 0.01 mg/kg /day. Since the FQPA Safety Factor is 1X, the acute RfD is identical to the acute PAD. This acute PAD applies to all population subgroups.

2. *Short- and intermediate-term residential dermal toxicity.* For short- and intermediate- term dermal endpoints, EPA selected the maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats (same study as for acute dietary exposure). The dermal absorption rate is 25% and a MOE of 100 was selected, which includes FQPA considerations.

3. *Chronic residential dermal exposure*. For the chronic dermal endpoint, EPA selected the NOAEL of 1.5 mg/kg/day from the 1-year oral study in dogs (same study as for chronic dietary exposure). The dermal absorption rate is 25% and a MOE of 100 was selected, which includes FQPA considerations.

4. *Chronic dietary toxicity*. EPA has established the chronic RfD for bifenthrin at 0.015 mg/kg/day. This RfD is based on a 1-year oral feeding study in dogs with a NOAEL of 1.5 mg/kg/day and an uncertainty factor (UF) of 100. The FQPA Safety Factor for the protection of infants and children was reduced to 1x. The chronic population adjusted dose (chronic PAD) is determined by dividing the chronic RfD by the FQPA factor. Since the FQPA safety factor is 1X, the chronic RfD is identical to the chronic PAD. This chronic PAD applies to all population subgroups.

5. *Carcinogenicity*. Bifenthrin has been classified as a Group C Carcinogen (a possible human carcinogen). A cancer risk assessment using the RfD approach is required.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin, in or on a variety of food commodities. Tolerances are established on plant commodities ranging from 0.05 ppm on field corn grain to 10 ppm on dried hops. Tolerances are also established on animal commodities including meat, meat byproducts and fat of cattle, goats, hogs, horses, poultry, sheep, and milk and eggs. Risk assessments were conducted by EPA to assess dietary exposures from bifenthrin as follows:

The acute dietary (food only) risk assessment was conducted by Novigen Science, Inc. In this acute analysis, Monte Carlo analysis (Tier 3) was used. For those foods identified by EPA as single-serving commodities, Monte Carlo simulation is based on iterative sampling from individual residue values from field trial data reflecting maximum application rates and minimum preharvest intervals. For those considered to be blended or processed, mean field trial residues were calculated, substituting those samples for which residues were reported at or below the limit of detection (LOD) with one-half of the LOD. It was assumed that 100% crop treated for all pending registrations: citrus, snap beans, peas, lima beans, canola, sweet corn, cucurbits, eggplant, and Brassica vegetable. Secondary residues for meat and milk were derived from the total dietary burden and tissue- to- feed ratio, using the highest ratio for meat, and the average ratio for milk.

This analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of exposure to residues in food. This is a highly refined assessment since percent of crop treated was used for registered crops and anticipated residues for all crops.

In conducting this DEEM analysis for chronic food risk assessment, Novigen used anticipated residue values which were determined from field trial data conducted at maximum label conditions of maximum application rates and minimum preharvest intervals. Mean anticipated residue values were calculated, substituting one-half of the LOD for those samples for which residues were reported below the LOD. It was assumed that 100% crop treated for all crops except hops at 43%, cottonseed-oil and cottonseed-meal at 4%. Secondary residues for meat and milk were derived from the total dietary burden and tissue- to- feed ratio, using the average ratio for meat and milk. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent of crop treated as required by the section 408(b)(2)(F), EPA may

require registrants to submit data on PCT.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. A range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which bifenthrin may be applied in a particular area.

i. *Acute exposure and risk (food).* 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 1-day or single exposure. The percentages of the acute PAD utilized at the 99.9th percentile of exposure are 53% for the U.S. population, 63% for infants (<1 year), 58% for non-nursing infants (< 1 year) and 96% for children (1-6 years old), the most highly exposed population subgroup. An acute dietary exposure (food plus water) of 100% or less of the acute PAD is needed to protect the safety of all population subgroups.

ii. *Chronic exposure and risk (food).* The most highly exposed population subgroup (children 1-6 years) will utilize 6.7% of the chronic PAD. The exposure for the U.S. population is 2.4% of the chronic PAD. A chronic dietary exposure (food plus water) of 100% or less of the chronic PAD is needed to protect the safety of all population subgroups.

2. *From drinking water.* A Drinking Water Level of Comparison (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, and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments. The estimated acute and chronic drinking water concentrations were generated with the PRZMI/EXAMS model using the highest application rate of 0.5 pounds/acre, which is registered for use on cotton.

i. *Acute exposure and risk (water).* For purposes of this acute risk assessment, the estimated acute maximum concentration for bifenthrin in surface and ground waters is 0.10 µg (micrograms)/L (liter), which was used for comparison to the back- calculated DWLOCs for the acute endpoint. The DWLOCs for various population categories are 165 µg/L for the U.S. population, 200 µg/L for females 13 years and older, and 4 µg/L for children 1 to 6 years. Acute exposure to bifenthrin in drinking water is below the calculated drinking water levels of concern.

ii. *Chronic exposure and risk (water).* For purposes of chronic risk assessment, the estimated chronic maximum concentration for bifenthrin in surface and ground waters is 0.032 µg/L, which was used for comparison to the back-calculated human health DWLOCs from the chronic (non-cancer) endpoint. These DWLOCs for various population categories are 530 µg/L for the U.S. population, 450 µg/L for females 13 years and older, and 140 µg/L for children 1 to 6 years. Chronic exposure to bifenthrin in drinking water is below the calculated drinking water levels of concern. iii. Short- and intermediate-term exposure and risk (water). For purposes of short- and intermediate-term risk assessment, the estimated chronic maximum concentration for bifenthrin in surface and ground waters is 0.032 µg/L, which was used for comparison to the back-calculated human health DWLOCs from the short- and intermediate-term endpoints. The DWLOCs for various population categories are 290 µg/L for the U.S. population, 250 µg/L for females 13 years and older, and 77 µg/L for children 1 to 6 years. Short- and intermediate-term exposure to bifenthrin in drinking water is below the calculated drinking water levels of concern.

3. *From non-dietary exposure.* Bifenthrin is currently registered for use on the residential non-food sites outdoor lawn and garden, inside households and termiticide use. These registered uses constitute short- and/or intermediate-term, and chronic exposure.

i. *Chronic exposure and risk (residential).* Although the registered termiticide use of bifenthrin constitutes a chronic exposure scenario, the exposure from this termiticide use is negligible considering the application technique of the termiticide use (buried underground) and the fact that vapor pressure of bifenthrin is extremely low (1.8×10^{-7} torr). .

ii. *Short- and intermediate-term exposure and risk (residential).* This risk assessment is based on post-application to treated lawns (turf use), a worst case scenario estimate of residential exposure. An assessment of applicator exposure was not included since the registered products are primarily limited to commercial use and, therefore, applied by professional lawn care operators. Inhalation, dermal and oral non-dietary routes of exposure were evaluated by this short- and intermediate-term risk assessment. For adults, the routes of exposure from these registered residential uses include dermal and inhalation, and for infants and children, the routes of exposure include dermal, inhalation, and oral (nondietary). The MOEs for residential exposures are 1600 for adults, 610 for children (1 to 6 years), and 600 for infants (<1 year). These MOE's are well above the acceptable short-term aggregate MOE of 100.

4. *Cumulative exposure to substances with 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.''

Bifenthrin is a member of a class of chemicals commonly referred to as ''Synthetic Pyrethroids.'' Other members of this class include cyfluthrin, cypermethrin, lambda-cyhalothrin, zeta-cypermethrin, deltamethrin, esfenvalerate,

fenpropathrin, tefluthrin and tralomethrin.

EPA does not have, at this time, available data to determine whether bifenthrin 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, bifenthrin 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 bifenthrin 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).

5. *Endocrine disrupter effects*. EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

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

1. *Acute risk (food + water).* Using the Monte Carlo analysis, it is estimated that the acute exposure to bifenthrin from food for the U.S. population subgroup will utilize 53% of the acute PAD. Children 1 to 6 years are the most highly exposed population subgroup. (See discussion in Unit II.E.) An acute dietary exposure (food plus water) of 100% or less of the acute PAD is needed to protect the safety of all population subgroups. Despite the potential for exposure to bifenthrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the acute PAD for adults, infants and children. The estimated maximum concentration of bifenthrin in surface and ground water for acute exposure is below the DWLOC.

2. *Chronic risk (food + water + residential).* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 2.4% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years. [See discussion in Unit II.E. in the preamble of this document] EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to bifenthrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the chronic PAD, the estimated maximum concentration of bifenthrin in surface and ground water for chronic exposure is very small compared to the DWLOC. Although the registered termiticide use of bifenthrin constitutes a chronic exposure scenario, the exposure from this termiticide use is negligible considering the application technique of the termiticide use (buried underground) and the fact that vapor pressure of bifenthrin is extremely low (1.8×10^{-7} torr).

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. In the case of bifenthrin, the registered residential use sites include outdoor lawn/gardens, inside households and termiticide. These uses constitute a short- and intermediate-term exposure scenario. The short- and intermediate-term aggregate risk assessment for bifenthrin includes inhalation, dermal, oral non-dietary, chronic food, and water exposure routes. The acceptable MOEs for short- and intermediate-term exposures are all at 100. For adults, the routes of exposure from these registered, residential uses include dermal and inhalation, and for infants and children, the routes of exposure include dermal, inhalation, and oral (nondietary). The MOEs for food (excluding water) and residential exposures is 1200 for adults, 430 for children 1 to 6 years, and 500 for infants less than 1 year. These MOEs are well above the acceptable short-term aggregate MOE of 100.

Since residue values in drinking water are not available, the DWLOCs have to be back- calculated. The short- and intermediate-term DWLOCs are 290 µg/L for adult males, 250 µg/L for adult females, 77 µg/L for children 1 to 6 years, and 77 µg/L for infants (less than 1 year old). The estimated maximum concentration of bifenthrin in surface and ground water for chronic exposure 0.032 µg/L is very small compared to the DWLOCs.

4. *Aggregate cancer risk for U.S. population*. Bifenthrin has been classified as a group C carcinogen, using the RfD approach. Based on the recommendation that the RfD approach be used, a quantitative (q*) dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of bifenthrin are adequately addressed by the DEEM chronic exposure analysis using the chronic PAD (RfD). For the U.S. population, only 2.4% of the chronic PAD (RfD) is occupied by chronic food exposure. As stated previously, based on a comparison of the calculated DWLOCs and the estimated exposure to bifenthrin in drinking water (0.032 g/L), EPA does not expect the aggregate exposure to exceed 100% of the chronic PAD (RfD) for adults.

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

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually

100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOAEL of 4 mg/kg/day. In the rat developmental study, the maternal NOEL was 1 mg/kg/day, based on tremors at the LOAEL of 2 mg/kg/day. The developmental (pup) NOEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOAEL 2 mg/kg/day. There were 5 of 23 (22%) litters affected with each litter having only one affected pup in the in the 2 mg/kg/day group, compared with zero in the control, 1 and 0.5 mg/kg/day groups. According to recent historical data (1992-1994) for this strain of rat, incidence of distended ureter averaged 11% with a maximum incidence of 90%.

iii. *Reproductive toxicity study*. In the rat reproduction study, parental toxicity occurred as decreased bwt at 5.0 mg/kg/day with a NOEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (HDT).

iv. *Pre- and post-natal sensitivity* — a. *Pre-natal*. Since there was not a dose-related finding of hydroureter in the rat developmental study and in the presence of similar incidences in the recent historical control data, the marginal finding of hydroureter in rat fetuses at 2 mg/kg/day (in the presence of maternal toxicity) is not considered a significant developmental finding. Nor does it provide sufficient evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

b. *Post-natal*. Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

v. *Conclusion*. There is a complete toxicity database for bifenthrin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the toxicity data and pre- and post-natal toxicity of bifenthrin, no additional safety factor is needed to protect infants and children.

2. *Acute risk. (Food + Water.)* The percentages of the acute PAD utilized at the 99.9th percentile of exposure are 63% for infants (less than 1 year) and 96% for children (1 to 6 years), the most highly exposed population subgroup. An acute dietary exposure (food plus water) of 100% or less of the acute PAD is needed to protect the safety of all population subgroups. Despite the potential for exposure to bifenthrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the acute PAD for infants and children. The estimated maximum concentration of bifenthrin in surface and ground water for acute exposure is below the DWLOC.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 6.7% of the chronic PAD (RfD) for children (1 to 6 years). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to bifenthrin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. The MOEs for food (excluding water) and residential exposures is 430 for children (1 to 6 years), and 500 for infants (less than 1 year). These MOEs are well above the acceptable short-term aggregate MOE of 100. The short- and intermediate-term DWLOCs are 77 µg/L for children (1 to 6 years), and 77 µg/L for infants (less than 1 year). The estimated maximum concentration of bifenthrin in surface and ground water for chronic exposure (µg/L) is very small compared to the DWLOCs.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of bifenthrin in plants and animals is adequately understood. Studies conducted to delineate the metabolism of radio-labeled bifenthrin in various crops and animals show similar results. The residue of concern is the parent compound only.

B. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of the regulated bifenthrin residue in plants and animals. Residues of bifenthrin are recoverable under Protocols D and E of the FDA Multiresidue Methods.

C. Magnitude of Residues

An adequate number of residue field trials reflecting the proposed use rates were submitted to EPA to demonstrate that tolerances for cabbage at 4.0 ppm; the cucurbit vegetable crop group at 0.4 ppm; edible-podded legume vegetable subgroup at 0.6 ppm; eggplant at 0.05 ppm; globe artichoke at 1.0 ppm; head and stem Brassica subgroup, except cabbage, at 0.6 ppm; rapeseed at 0.05 ppm, succulent shelled pea and bean subgroup at 0.05 ppm; sweet corn at 0.05 ppm; and corn forage at 0.6 ppm will not be exceeded when bifenthrin products labeled for these uses are used as directed.

D. International Residue Limits

There are no Codex Maximum Residue Levels (MRL's) for these commodities.

E. Rotational Crop Restrictions

Crops with established U.S. tolerances may be rotated at any time. Leafy vegetable and root crops may be rotated 30 days following the final application. All other crops may be rotated seven months following the final application.

IV. Conclusion

Therefore, the tolerance is established for residues of bifenthrin in cabbage at 4.0 part per million (ppm); the cucurbit vegetable crop group (Crop Group 9) at 0.4 ppm; edible- podded legume vegetable subgroup (Crop Subgroup 6A) at 0.6 ppm; eggplant at 0.05 ppm; globe artichoke at 1.0 ppm; head and stem Brassica subgroup (Crop Subgroup 5A), except cabbage, at 0.6 ppm; rapeseed at 0.05 ppm, succulent shelled pea and bean subgroup (Crop Subgroup 6B) at 0.05 ppm; sweet corn kernel plus cob with husk removed at 0.05 ppm; and corn forage at 3.0 ppm.

V. Objections and Hearing Requests

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

However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

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

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300888] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

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

B. Executive Order 12875

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

and timely input in the development of regulatory proposals containing significant unfunded mandates.''

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

C. Executive Order 13084

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

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: June 23, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.442, by amending paragraph (a) by revising the introductory text and the tolerance level for ''corn forage'' and by alphabetically adding the following entries to the table:

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the following food commodities:

Commodity	Parts per million
Artichoke, globe	1.0
Brassica, head and stem, subgroup, excluding cabbage.	0.6
Cabbage	4.0
* * * *	* * *
Corn, forage	3.0
* * * *	* * *
Corn, sweet, kernel plus cob with husk removed.	0.05
Eggplant	0.05
* * * *	* * *
Pea and bean, succulent shelled, subgroup.	0.05
* * * *	* * *
Rapeseed	0.05
* * * *	* * *
Vegetable, cucurbit, crop group.	0.4
Vegetable, legume, edible podded, subgroup.	0.6

* * * * *

[FR Doc. 99–16575 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300887; FRL–6088–9]

RIN 2070–AB78

Cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate]; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate] in or on potatoes at 0.01 parts per million (ppm). It also removes time limitations for tolerances for residues of cyfluthrin on sweet corn, field corn, and pop corn (including forage and fodder). Bayer Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

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

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300887], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300887], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of