requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804, however, exempts from section 801 the following types of rules: Rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability.

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 11, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compound.

Authority: 42 U.S.C. 7401–7671q.

Dated: May 24, 2000.

Francis X. Lyons,

Regional Administrator, Region 5.

Title 40 of Code of Federal Regulations, chapter I, part 52, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Section 52.1220 is amended by adding paragraph (c)(54) to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(c) * * *

(54) On December 7, 1999, the State of Minnesota submitted to remove an Administrative Order and replace it with a federally enforceable State operating permit for Commercial Asphalt's facility located on Red Rock Road in the city of St. Paul. EPA approved a federally enforceable State operating permit (FESOP)(60 FR 21447) for the State of Minnesota on May 2, 1995.

(i) Incorporation by reference

(A) Air Emission Permit No. 12300347–002, issued by the MPCA to Commercial Asphalt CO-Plant 905, on September 10, 1999. Title I conditions only.

[FR Doc. 00–17347 Filed 7–11–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301018; FRL–6595–1]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenthrin in or on caneberry subgroup, grape, head lettuce and peppers, bell and non-bell. The Interregional Research Project (IR–4) 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 July 12, 2000. Objections and requests for hearings, identified by docket control number OPP–301018 must be received by EPA on or before September 11, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301018 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7610; and e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301018. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 22, 1999 (64 FR 71772) (FRL–6396–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) for tolerances by IR–4, New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This notice included a summary of the petitions prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.442 be amended by establishing 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-dimethylcyclopropane carboxylate, in or on the following commodities:

(1) PP 9E6016 proposed a tolerance for grape at 0.2 ppm.

(2) PP 9E6030 proposed a tolerance for peppers, bell and non-bell at 0.5 ppm.

(3) PP 9E6031 proposed a tolerance for head lettuce at 2.0 ppm, subsequently revised in this final rule to 3.0 ppm.

(4) PP 9E6034 proposed a tolerance for the caneberry at 1.0 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of bifenthrin on caneberry subgroup at 1.0 ppm, grape at 0.2 ppm, head lettuce at 3.0 ppm, and peppers, bell and non-bell at 0.5 ppm. EPA's assessment of 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 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 Type	Results
870.3700a Prenatal developmental in rodents.	Maternal NOAEL = 1 mg/kg/day LOAEL = 2 mg/kg/day based on tremors Developmental NOAEL = 1 mg/kg/day LOAEL = 24 mg/kg/day based on increased incidence of hydroureter
870.3700b Prenatal developmental in non-rodents.	Maternal NOAEL = 2.67 mg/kg/day LOAEL = 4 mg/kg/day based on head and forelimb twitching No Developmental effects observed

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

Guideline No./Study Type	Results
870.3800 Reproduction and fertility effects.	Parental/Systemic NOAEL = 3 mg/kg/day LOAEL = 5 mg/kg/day Reproductive NOAEL = 5 mg/kg/day LOAEL = no reproductive effects observed at the highest dose tested (5 mg/kg/day) Offspring NOAEL = 5 mg/kg/day LOAEL = no adverse effects observed at the highest dose tested (5 mg/kg/day)
870.4100b Chronic toxicity dogs.	NOAEL = 1.5 mg/kg/day LOAEL = 3 mg/kg/day based on increased incidence of tremors in both sexes
870.4200 Carcinogenicity rats.	NOAEL = 2.5 mg/kg/day LOAEL = 5 mg/kg/day based on increased incidence of tremors in both sexes and possible increases in organ-to-body weight ratios in males. There was no evidence of carcinogenicity.
870.4300 Carcinogenicity mice.	NOAEL = 2.5 mg/kg/day LOAEL = 10 mg/kg/day based on incidence of tremors in both sexes. Carcinogenic potential was evidenced by 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.
Gene Mutation.	A gene mutation in Salmonella (Ames) was negative.

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

Guideline No./Study Type	Results
Cytogenetics.	Chromosomal aberrations in Chinese hamster ovary and rat bone marrow cells were negative.
Other Effects.	HGPRT locus mutation in mouse lymphoma cells and unscheduled DNA synthesis in rat hepatocytes were negative.
870.7485 Metabolism and pharmacokinetics.	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.
870.7600 Dermal penetration.	Dermal absorption rate is 25%

B. Toxicological Endpoints

The dose at which 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 factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies 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.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children.	NOAEL =1.0 mg/kg/day UF = 100 ..... Acute RfD = 0.01 mg/kg/day ..... FQPA SF = 1X	aPAD = acute RfD ÷ FQPA SF = 0.01 mg/kg/day	Rat developmental LOAEL = 2 mg/kg/day based on tremors in dams during and post dosing
Chronic Dietary all populations.	NOAEL= 1.5 mg/kg/day UF = 100 ..... Chronic RfD = 0.015 mg/kg/day	cPAD = chronic RfD ÷ FQPA SF = 0.015 mg/kg/day	Dog chronic feeding LOAEL = 3 mg/kg/day based on tremors in both sexes

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Dermal (1 to 7 days) (Residential).	Oral NOAEL= 1.0 mg/kg/day (dermal absorption rate = 25%)	LOC for MOE = 100 (Residential)	Rat developmental LOAEL = 2 mg/kg/day based on tremors in dams during and post dosing
Intermediate-Term Dermal (1 week to several months) (Residential).	Oral study NOAEL = 1.0 mg/kg/day (dermal absorption rate = 25%	LOC for MOE = 100 (Residential)	Rat developmental LOAEL = 2 mg/kg/day based on tremors in dams during and post dosing
Long-Term Dermal (several months to lifetime) (Residential).	Oral study NOAEL = 1.5 mg/kg/day (dermal absorption rate = 25% when appropriate)	LOC for MOE = 100 (Residential)	Dog chronic feeding LOAEL = 3 mg/kg/day based on tremors in both sexes
Long-Term Inhalation (several months to lifetime) (Residential).	Oral study NOAEL = 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Rat developmental LOAEL = 2 mg/kg/day based on tremors in dams during and post dosing (No appropriate inhalation studies available.)
Cancer (oral, dermal, inhalation).	Dietary/Dermal/Inhalation Exposure Group C carcinogen	RfD approach	Mouse Carcinogenicity, urinary bladder tumors in male mice.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin, in or on a variety of raw agricultural commodities including tolerances on plants ranging from 0.05 ppm for corn grain (field, seed, and pop) to 10 ppm on dried hops. Tolerances are also established on animal commodities ranging from 0.05 ppm on eggs to 1.0 ppm in milk fat (reflecting 0.1 ppm in whole milk). Risk assessments were conducted by EPA to assess dietary exposures from bifenthrin in food as follows:

i. *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 1–day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: In this acute analysis, probabilistic Monte Carlo analysis (Tier 3) was used. For those foods identified by EPA as single-serving commodities, the 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 foods considered to be blended or processed, mean field trial residues were calculated. For those samples which contained residues at or below the limit of detection (LOD), ½ of the LOD was used. It was assumed that 100% of the following crops were treated with bifenthrin: artichoke, bananas, Brassica vegetable, caneberry, canola, citrus, cucurbits, eggplants, garden peas, grape, head lettuce, lima beans, peanuts, pears, peppers, potatoes, snap beans, and sweet corn. Processing factors for grapes were calculated using concentration factors (grape juice = 1.2X, raisins = 4.2X). Secondary residues for meat and milk were not affected by adding the uses on peppers, lettuce, grape, and caneberry since no animal feed items are associated with these crops.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 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. One hundred percent of crop treated was assumed for all crops except hops (43%) and cottonseed-oil and cottonseed-meal (4%). Secondary residues for meat and milk were not affected by the new proposed uses.

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 this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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 crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, 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.

2.*Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for bifenthrin 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 bifenthrin.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in ground water (SCI-GROW) model, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent of the Reference dose or percent of the population adjusted dose. 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 bifenthrin they are further discussed in the aggregate risk sections below.

Based on the GENEEC and the SCI-GROW models the EECs of bifenthrin in surface water and ground water for acute exposures are estimated to be 0.10 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.032 ppb for surface water and 0.006 ppb for ground water.

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). Bifenthrin is currently registered for use on the following residential non-dietary sites: lawns to control flea infestation, pets and as a termiticide. Registered termiticide use of bifenthrin constitutes a chronic exposure scenario, however, the exposure is considered negligible, considering the application technique of the termiticide use (buried underground) and the fact that vapor pressure of bifenthrin is extremely low. The Agency conducted a residential exposure assessment for the lawn care uses of bifenthrin. 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 (non-dietary).

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

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

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies*. See summary of developmental toxicity studies in Unit IIIA. Toxicological Profile.

iii. *Reproductive toxicity study*. See summary of reproduction toxicity studies in Unit IIIA. Toxicological profile.

iv. *Conclusion*. There is a complete toxicity data base for bifenthrin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced from 10X to 1X.

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 U.S. EPA's Office of Water are used to calculate DWLOCs: 2L/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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary (food only) exposure to bifenthrin will occupy 60% of the aPAD for the U.S. population, 40% of the aPAD for females 13 years and older, 75% of the aPAD for infants (<1 year old) and 99.7% of the aPAD for children (1 to 6 years old). In addition, there is potential for acute dietary exposure to bifenthrin in drinking water. Despite this potential and 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 aPAD.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO BIFENTHRIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.01	60	0.10	0.006	140
Females 13 years and older	0.01	40	0.10	0.006	180
children (1 to 6 years old)	0.01	99.7	0.10	0.006	0.3

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifenthrin from food will utilize 3.0% of the cPAD for the U.S. population, and 8.2% of the cPAD for children (1 to 6 years old), the subpopulation at greatest risk. Bifenthrin is also registered for residential use on outdoor lawn/gardens, inside households, pets and as a termiticide. Based on the use pattern, chronic residential exposure to residues of the bifenthrin is not expected. In addition, there is potential for chronic dietary exposure to bifenthrin in drinking water. After calculating the 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.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BIFENTHRIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.015	3.0	0.032	0.032	530

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BIFENTHRIN—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Females (13 yrs. and above)	0.015	3.0	0.032	0.032	450
children (1 to 6 years old)	0.015	3.0	0.032	0.032	140

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). Bifenthrin is currently registered for use that could result in short- and intermediate-term residential exposure. Registered termiticide use of bifenthrin constitutes a chronic exposure scenario; however, the exposure is considered negligible. The Agency has determined that it is appropriate to aggregate chronic food and water and short- and intermediate-term non-dietary exposures for bifenthrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food (water not included) and residential exposures aggregated result in aggregate MOEs of 940 for adults, 350 for children ages 1 to 6 years old, and 470 for infants less than 1 year old based on chronic food and residential use, e.g., turf representing the worst case residential exposure scenario. 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 bifenthrin 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.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BIFENTHRIN

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	940	100	0.032	0.006	320
Children 1 to 6 yrs. old	350	100	0.032	0.006	71

Applying the same exposure assumptions as above for short-term exposure, and after calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern.

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO BIFENTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
U.S. Population	940	100	0.032	0.006	480
Children 1 to 6 yrs. old	350	100	0.032	0.006	107

4. *Aggregate cancer risk for U.S. population*. A quantitative (Q_1*) 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 RfD. For the U.S. population, only 3.0% of the cPAD (cRfD) is occupied by chronic food exposure. Based on a comparison of the calculated DWLOCs and the estimated exposure to bifenthrin in drinking water (0.032 µg/L), the Agency does not expect the chronic aggregate exposure to exceed 100% of the cPAD (cRfD) for adults. Thus, EPA concludes with reasonable certainty that the carcinogenic risk is within acceptable limits.

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 bifenthrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of the regulated bifenthrin residue in plants. The data gathering method for pepper, lettuce, grapes, and caneberry is FMC method P–2132M, with a limit of quantitation of 0.05 ppm (given as 0.055 in some cases). This method is a variation of two other methods which have been submitted for inclusion in PAM II (FMC's Methods P–1031 and RAN–0140. This method has been adequately validated and is adequate for data collection. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels (MRL) have been established for residues of bifenthrin in/on bell or non-bell peppers, head lettuce, grape, or caneberries. International harmonization is therefore not an issue for these tolerances.

V. Conclusion

Therefore, the tolerances are established for residues of bifenthrin, (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate, in or on caneberry crop subgroup 13A at 1.0 ppm, grape at 0.2 ppm, head lettuce at 3.0 ppm and peppers at 0.5 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301018 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 September 11, 2000.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301018, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: June 29, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.442 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Caneberry subgroup	1.0
* * * * *	
Grape	0.2
* * * * *	
Lettuce, head	3.0
* * * * *	
Pepper, bell	0.5
Peppers, non-bell	0.5
* * * * *	

* * * * *

[FR Doc. 00–17618 Filed 7–11–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6732–8]

Delaware: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Delaware has applied to EPA for Final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The revisions cover regulatory changes adopted on August 23, 1999 to the State's authorized hazardous waste program, which include various amendments to Federal hazardous waste regulations through January 21, 1999. EPA has determined that Delaware's hazardous waste program revisions satisfy all of the requirements necessary to qualify for Final authorization, and is authorizing the state program revisions through this immediate final action. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial action and does not anticipate adverse comments. However, in the proposed rules section of this **Federal Register**, EPA is publishing a separate document that will serve as a proposal to authorize the revisions should the Agency receive adverse comment. If EPA receives comments that oppose this action or portion(s) thereof, we will publish a document in the **Federal Register** withdrawing this rule or portion(s) thereof before it takes effect, and the separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes. Unless EPA receives adverse written comments during the review and comment period, the decision to authorize Delaware's hazardous waste program revisions will take effect.

DATES: This Final authorization for Delaware will become effective without further notice on September 11, 2000, unless EPA receives adverse comments by August 11, 2000. Once again, if EPA should receive such comments on its decision, the Agency will publish a timely withdrawal informing the public that this rule will not take effect.

ADDRESSES: Send written comments to Lillie Ellerbe, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–5454. Copies of the Delaware program revision application and the materials which EPA used in evaluating the revision are available for inspection and copying from 8 a.m. to 4:30 p.m., Monday through Friday at the following addresses: Department of Natural Resources & Environmental Control, Division of Air & Waste Management, 89 Kings Highway, Dover, DE 19901, Phone number 302–739–3689 and EPA Region III, Library, 2nd Floor, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–5254.