ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300963; FRL–6485–2]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of bifenthrin (2-methyl [1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in or on grapes and peanut nutmeats. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on grapes and peanuts. This regulation establishes maximum permissible levels for residues of bifenthrin in these food commodities. The tolerances will expire and is revoked on December 31, 2001.

DATES: This regulation is effective January 25, 2000. Objections and requests for hearings, identified by docket control number OPP–300963, must be received by EPA on or before March 27, 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 VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300963 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (703) 308–9356; and e-mail address: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	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–300963. 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

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide bifenthrin (2-methyl [1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3,-trifluoro-2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate), in or on grapes at 0.2 part per million (ppm), and in/on peanut nutmeats at 0.05 ppm. These tolerances will expire and are revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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. . . .''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has

established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Bifenthrin on Grapes and Peanuts and FFDCA Tolerances

1. *Bifenthrin on grapes*. The Applicant states that when the special local needs registration for carbofuran was canceled in 1997, the grape growers were left without adequate control for the black vine weevil, a seriously damaging pest in vineyards. Black vine weevil populations build up to damaging levels gradually, tending not to be pests in younger vineyards. Thus, this pest was generally not present at significant levels immediately following loss of carbofuran; however, the applicant states that this year, populations have been reaching damaging levels. The applicant stated that none of the available alternatives provide adequate control to avoid significant economic losses from this pest in grapes.

2. *Bifenthrin on peanuts*. The Applicant states that although spider mite infestations have affected peanut growers for some years, the infestations have exceeded economically significant levels in recent years, and applications of available pesticides did not prevent these populations from rebounding quickly. In 1999, mite populations established earlier than normal, and the registered miticides were ineffective at providing adequate control, particularly with the hot dry weather conditions which are conducive to mite outbreaks. Additionally, it is believed that the mild winter contributed to a high overwintering survival rate, thus infestations were established earlier. With the infestations beginning so early, growers had to make multiple treatments with the alternatives, and were on the verge of using up their legal number of applications of these materials. However, spider mite outbreaks were still occurring at significantly damaging levels, and the Applicant stated that the use of bifenthrin was needed to avert significant economic losses from occurring. EPA has authorized under FIFRA section 18 the uses of bifenthrin on grapes for control of black vine weevil in Washington, and on peanuts for control of spider mites in Oklahoma. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bifenthrin in or on grapes and peanut nutmeats. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on grapes and peanut nutmeats after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether bifenthrin meets EPA's registration requirements for use on grapes and peanuts or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Washington or Oklahoma to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for bifenthrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 time-limited tolerances for residues of bifenthrin (2-methyl [1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3,-trifluoro-2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) on grapes at 0.2 ppm, and on peanut nutmeats at 0.05 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 Unit II.A. of the Final Rule on Bifenthrin Pesticide Tolerances published in the **Federal Register** on June 30, 1999 (64 FR 35051) (FRL–6089–9).

B. Toxicological Endpoint

The toxicological endpoints for bifenthrin are discussed in Unit II.B. of the Final Rule on Bifenthrin Pesticide Tolerances published in the **Federal Register** on June 30, 1999.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin (2-methyl [1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3,-trifluoro-2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate), in or on a variety of raw agricultural 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 and risks 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% of the crop was treated for the following tolerances: canola, citrus, snap beans, peas, lima beans, sweet corn, cucurbits, eggplant, and Brassica vegetable. One hundred percent crop treated was also assumed for these section 18 uses for grapes and peanuts. 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 (CSFII) 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 (PCT) was used (except as indicated above) and anticipated residues for all crops.

In conducting this Dietary Exposure Evaluation Model (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 CSFII conducted in 1989 through 1992.

i. *Acute exposure and risk.* 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 (aPAD) utilized at the 99.9th percentile of exposure are 60% for the U.S. population, 75% for infants (< 1 year), and 99.7% 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 aPAD is needed to protect the safety of all population subgroups.

ii. *Chronic exposure and risk.* Dietary exposure (food only) for the most highly exposed population subgroup (children 1 - 6 years old), will utilize 8.2% of the chronic PAD (cPAD). The exposure for the U.S. population is 3% of the cPAD. A chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety or all population subgroups.

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 used PCT information as follows. It was assumed that 100% crop was treated for all crops except hops at 43%, and cottonseed-oil and cottonseed-meal at 4%.

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 underestimated. 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. *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 EPA's Pesticide Root Zone Model/Exposure Analysis Modeling Systems (PRZM/EXAMS) model using the highest application rate of 0.5 pounds/acre, which is registered for use on cotton.

i. *Acute exposure and risk.* For the purposes of this acute risk assessment, the estimated acute maximum concentration for bifenthrin in surface and ground waters is 0.10 µg/L, which was used for comparison to the back-calculated DWLOCs for the acute endpoint. The DWLOCs for various population categories are 140 µg/L for the U.S. population, 180 µg/L for females 13 years and older, and 0.3 µg/L for children 1 - 6 years old. Acute exposure to bifenthrin in drinking water is below the calculated drinking water levels of concern.

ii. *Chronic exposure and risk.* For the purposes of the 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 - 6 years old. 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 320 µg/L for the U.S. population, 270 µg/L for females 13 years and older, and 77 µg/L for children 1 - 6 years old. 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 following residential non-food sites: outdoor lawn and garden, inside households, and termiticide use. These registered uses constitute short- and/or intermediate and chronic exposure.

i. *Chronic exposure and risk.* 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 the vapor pressure of bifenthrin is extremely low.

ii. *Short- and intermediate-term exposure and risk.* 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 1,600 for adults, 610 for children (1 - 6 years), and 600 for infants (<≤ 1 year). These MOEs are well above the acceptable short-term aggregate MOE of 100.

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.'' Bifenthrin is a member of a class of chemicals commonly referred to as ''Synthetic Pyrethroids.'' Other members of the 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 more 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. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk (food plus 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 60% of the aPAD. Children 1 to 6 years are the most highly exposed population subgroup, with 99.7% of the aPAD utilized. (See discussion in Unit II.E.) An acute dietary exposure (food plus water) of 100% or less of the aPAD 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 aPAD for adults, infants and children. The estimated maximum concentration of bifenthrin in surface and ground water for acute exposure is below all DWLOCs.

2. *Chronic risk (food plus water plus residential).* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 3% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years, with 8.2% of the cPAD utilized. [See discussion in Unit II.E. in the preamble of this document]. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD 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 cPAD, the estimated maximum concentration of bifenthrin in surface and ground water for chronic exposure is very small compared to the DWLOCs. 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.

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 (non-dietary). The MOEs for food (excluding water) and residential exposures is 1,100 for adults, 420 for children 1 to 6 years, and 500 for infants < 1 year. These MOEs are all 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 (< 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 Reference Dose (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 cPAD RfD. For the U.S. population, only 3% of the cPAD 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 µg/L), EPA does not expect the aggregate exposure to exceed 100% of the cPAD 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 during 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 prenatal and postnatal toxicity and the completeness of the data base 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 MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies 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 NOAEL 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 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 2 mg/kg/day. There were 5 of 23 (22%) litters affected with each litter having only 1 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% 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 NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (HDT).

iv. *Prenatal and postnatal sensitivity—* a.*Prenatal.* 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. *Postnatal.* Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special postnatal sensitivity to infants and children in the rat reproduction study.

v. *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. Based on the completeness of the toxicity data and prenatal and postnatal toxicity of bifenthrin, no additional safety factor is needed to protect infants and children.

2. *Acute risk (food plus water.)* The percentages of the aPAD utilized at the 99.9th percentile of exposure are 75% for infants (< 1 year) and 99.7% 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 aPAD 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 aPAD for infants and children. The estimated maximum concentration of bifenthrin in surface and ground water for acute exposure is below the DWLOCs.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 8.2% of the cPAD for children (1 - 6 years old), the most highly exposed subgroup for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD 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 cPAD.

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 (< 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 (< 1 year). 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.

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.

V. 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

Residues of bifenthrin are not expected to exceed 0.2 ppm in/on grapes, and 0.05 ppm in/on peanut nutmeats, as a result of these uses. Since the use on peanuts prohibits the feeding of peanut hay to livestock, the existing tolerances for livestock commodities are considered to be adequate.

D. International Residue Limits

There are no Codex Maximum Residue Levels (MRLs) 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 7 months following the final application.

VI. 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-2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in grapes at 0.2 ppm, and in peanut, nutmeats, at 0.05 ppm.

VII. 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–300963 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 March 27, 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, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, 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, 401 M St., SW., 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, 401 M St., SW., 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 VII.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 the docket control number OPP–300963, 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 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. 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 FIFRA section 18 petition under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

IX. 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: January 7, 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), 346(a) and 371.

2. Section 180.442 is amended, by adding and alphabetically inserting the following entries to the table under paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Grapes	0.2	12/31/01
* *	* *	*
Peanuts, nutmeats	0.05	12/31/01
* *	* *	*

* * * * *

[FR Doc. 00–1667 Filed 1–24–00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE44

Endangered and Threatened Wildlife and Plants; Endangered Status for the Plant Plagiobothrys hirtus (Rough Popcornflower)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, have determined endangered status pursuant to the Endangered Species Act of 1973 (Act), as amended, for the plant *Plagiobothrys hirtus* (rough popcornflower). This species is restricted to wet swales and meadows in Douglas County, Oregon, where only 17 habitat patches exist for this species. Most populations are small with few individuals. The total