(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 03–10264 Filed 4–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0358; FRL–7304–4]

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenthrin in or on almond, hulls; banana; fruit, citrus, group; herb subgroup; pear; nut, tree, group; spinach; tomato; and food/feed products in food/feed handling establishments. FMC Corporation and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) , as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0358, must be received on or before June 30, 2003.

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

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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/feed or beverage manufacturer, wholesale or retailer; restaurant owner/worker; or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop producers (NAICS 111), e.g., tree fruit and nut growers, tomato growers and herb producers
- Animal producers (NAICS 112), including cattle, sheep, swine, dairy, and poultry producers
- Food and beverage manufacturers (NAICS 311), including canners, bottlers, brewers, bakers and other food and beverage processors
- Food and beverage stores (NAICS 445)
- Restaurants (NAICS 722)
- Pesticide manufacturers (NAICS 32532)

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

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0358. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

II. Background and Statutory Findings

In the **Federal Register** of February 15, 2002 (67 FR 7159–7163) (FRL–6823–3); February 14, 2001 (66 FR 10289–10292) (FRL–6768–7); and April 25, 2001 (66 FR 20811–20815) (FRL–6778–4), EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2F6390, 6F3454, 0E6216 and 1F6266) by FMC Corporation; (PP 6E4630, 0E6157, 1E6330 and 2E6402) by the Interregional Research Project Number 4 (IR-4); and (PP 1E6234) by the Taipei Economic and Cultural Representative Office. These notices included summaries of the petitions prepared by FMC Corporation, the registrant. There were no comments received in response to the notices of filing.

These 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, as follows:

1. PP 2F6390 proposed establishment of a tolerance for food products in food handling establishments at 0.01 ppm.
2. PP 6F3454 proposed establishment of a tolerance for pears at 1.0 ppm; almond hulls at 2 ppm; and tree nuts crop group at 0.05 ppm.
3. PP 0E6216 proposed establishment of a tolerance for imported bananas at 0.1 ppm.
4. PP 1F6266 proposed establishment of a tolerance for citrus whole fruits, citrus dried pulp, citrus cold pressed oil and citrus juice at 0.05 ppm.
5. PP 6E4630 proposed establishment of a tolerance for leaf petioles subgroup (4B) at 2.0 ppm.
6. PP 0E6157 proposed establishment of a tolerance for herb subgroup (19A) at 0.05 ppm.
7. PP 1E6330 proposed establishment of a tolerance for tomato at 0.15 ppm.

8. PP 2E6402 proposed establishment of a tolerance for spinach at 0.2 ppm.

9. PP 1E6234 proposed establishment of a tolerance for carambola (starfruit) at 1.0 ppm.

The residue chemistry data submitted in support of PP 6E4630 (leaf petioles subgroup) and PP 1E6234 (carambola) were determined by EPA to be insufficient to support the proposed tolerances. PP 1E6234 was subsequently withdrawn by the Taipei Economic and Cultural Representative Office. The requested tolerance for the leaf petioles subgroup (PP 6E4630) cannot be established until adequate residue chemistry data are submitted and reviewed.

Based on EPA's review, the remaining petitions described in Unit II were revised by the petitioners (FMC Corporation and IR-4) to propose tolerances for residues of bifenthrin in or on almond, hulls at 2.0 ppm; banana at 0.1 ppm; fruit, citrus, group at 0.05 ppm; herb subgroup at 0.05 ppm; pear at 0.5 ppm; nut, tree, group at 0.05 ppm; spinach at 0.2 ppm; tomato at 0.15 ppm; and food/feed products in food/feed handling establishments at 0.05 ppm. The revisions were requested for the following reasons:

EPA determined that the tolerance for pear should be set at 0.5 ppm, not 1.0 ppm as the petitioner originally proposed, based on the results of submitted field residue data, showing a maximum residue of 0.38 ppm. EPA determined that the tolerance for food/feed products in food/feed handling establishments should be set at 0.05 ppm, the limit of quantitation (LOQ) of the analytical method, rather than 0.01 ppm, the limit of detection (LOD), as the petitioner originally proposed. It is Agency policy to use the LOQ for setting tolerances when detectable residues are not found in the residue trials. No other changes to the originally proposed tolerance levels were requested; however, EPA did request minor changes in commodity terms to reflect current nomenclature practices.

Although EPA requested changes to the initial petitions, the nature of the changes is not considered significant. Therefore, EPA is issuing this as a final action.

EPA is also deleting time-limited tolerances established for residues of bifenthrin in or on citrus, dried pulp, at 0.3 ppm, citrus oil at 0.3 ppm and citrus, whole fruit, at 0.05 ppm in connection with section 18 emergency exemptions granted by EPA. With the establishment of the citrus fruit group tolerance (PP 1F6266), these tolerances are no longer needed.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of bifenthrin in or on almond, hulls at 2.0 ppm; banana at 0.1 ppm; fruit, citrus, group 10 at 0.05 ppm; herb subgroup 19A at 0.05 ppm; pear at 0.5 ppm; nut, tree, group 14 at 0.05 ppm; spinach at 0.2 ppm; tomato at 0.15 ppm; and food/feed products in food/feed handling establishments at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by bifenthrin are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline Number	Study Type	Results
870.3100	90–Day Oral Toxicity - Rat (1984)	NOAEL = 3.8 mg/kg/day (males); 4.3 mg/kg/day (females) LOAEL = 7.5 mg/kg/day (males), 8.5 mg/kg/day (females), based on increased incidence of tumors. Classification: Acceptable-Guideline
870.3150	90–Day Oral Toxicity - Dog (1984)	NOAEL = 2.21 mg/kg/day (males and females) LOAEL = 4.42 mg/kg/day (males and females) based on increased incidence of tremors. Classification: Acceptable-Guideline
870.3700	Developmental Toxicity (Gavage; corn oil vehicle) - Rat (1983)	Maternal Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. Developmental Toxicity NOAEL = not determined (fetuses not examined) LOAEL = not determined (fetuses not examined) Classification: Acceptable-Guideline

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

Guideline Number	Study Type	Results
870.3700	Developmental Toxicity (Gavage; corn oil vehicle) - Rat (1984)	Maternal Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. Developmental Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on increased fetal and litter incidence of hydroureter without nephrosis. Classification: Acceptable-Guideline
870.3700	Developmental Toxicity (Dietary) - Rat (2001)	Maternal Toxicity NOAEL = 7.1 mg/kg/day LOAEL = 15.5 mg/kg/day based clinical signs and decreased food consumption, body weight gains, and body weight gains adjusted for gravid uterine weight. Developmental Toxicity NOAEL = 15.5 mg/kg/day LOAEL = not observed. Classification: Acceptable-Guideline
870.3700	Developmental Toxicity - Rabbit (1984)	Maternal Toxicity NOAEL = 2.36 mg/kg/day LOAEL = 3.5 mg/kg/day based on treatment-related head and forelimb twitching. Developmental Toxicity NOAEL = greater than 7 mg/kg/day LOAEL = not observed Classification: Acceptable-Guideline
870.3800	Multigeneration Reproductive Toxicity - Rat (1986)	Parental/Systemic Toxicity NOAEL = 3.0 mg/kg/day for females and 5.0 mg/kg/day for males LOAEL = 5.0 mg/kg/day for females, based on tremors and decreased body weight; not observed for males. Reproductive/offspring Toxicity NOAEL = not observed. LOAEL = not observed. Classification: Acceptable-Guideline
870.4100	Chronic Toxicity - Dog (1985)	NOAEL = 1.3 mg/kg/day (males and females) LOAEL = 2.7 mg/kg/day (males and females) based on increased incidence of tremors. Classification: Acceptable-Guideline
870.4300	Combined Chronic Toxicity/ Carcinogenicity - Rat (1986)	NOAEL = 3.0 mg/kg/day (females); 4.7 mg/kg/day (males) LOAEL = 6.1 mg/kg/day (females), based on increased incidence of tremors; 9.7 mg/kg/day (males), based on increased incidence of tremors. Carcinogenicity - No conclusive evidence of carcinogenic potential. Classification: Acceptable-Guideline
870.4200	Carcinogenicity - Mice (1986)	NOAEL = 6.7 mg/kg/day (males); 8.8 mg/kg/day (females) LOAEL = 25.6 mg/kg/day (males) and 32.7 mg/kg/day (females), based on increased incidence of tremors. Carcinogenicity - carcinogenic potential was evidenced by a dose-related increased in the incidence of leiomyosarcomas in the urinary bladder, 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. Classification: Acceptable-Guideline
870.6200	Acute Neurotoxicity - Rat	NOAEL = 35 mg/kg (32.8 mg ai/kg/day). LOAEL = 75 mg/kg (70.3 mg ai/kg/day) based on mortality (females only), clinical and functional operational battery (FOB) findings and differences in motor activity. Classification: Acceptable-Guideline
870.6200	Subchronic Neurotoxicity - Rat	NOAEL = 50 ppm (equivalent to 2.9 mg/kg/day in males and 3.7 mg/kg/day in females). LOAEL =100 ppm (equivalent to 6.0 mg/kg/day in males and 7.2 mg/kg/day in females) based on neuromuscular findings (tremors, changes in grip strength and landing footsplay). Classification: Acceptable-Guideline
870.3200	Dermal Toxicity - Rabbit	NOAEL = 88 mg ai/kg/day (males and females) LOAEL = 442 mg ai/kg/day (males and females), based on loss of muscle coordination and increased incidence of tremors.

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

Guideline Number	Study Type	Results
870.3200	Dermal Toxicity - Rat	NOAEL = 47 mg ai/kg/day (males and females) LOAEL = 93 mg ai/kg/day (males and females), based on loss of muscle coordination and increased incidence of tremors.
870.7485	Metabolism - Rat	Very little of the administered radioactive dose was expired as $^{14}C\text{-}CO_2$ (0.028% for males and 0.053% for females). The majority (about 70%) of the administered radioactivity was found in the feces with about 20% in the urine. A complication of this study is that males were administered a radioactive dose with the label in the acid position, while females were administered a radioactive dose with the label in the alcohol position. This could make comparisons between males and females difficult. Despite the difference in ^{14}C-labeling position in the bifenthrin administered to males and females, the study is acceptable. This conclusion is based on the fact that most (>90%) of the radioactivity was eliminated via the urine and feces, with no significant differences between the sexes in this respect. Further, there were no significant differences between dosage groups in percentages excreted. This suggests that most of the compound is excreted with little or no change, or in a form incorporating both of the labeled sites. The results also show that females retained slightly more radioactivity in their bodies (particularly in adipose tissue) than did males, particularly at the high-dose. Labeling of the material given to the females was in the biphenyl group, and, given a splitting of the molecule between the two labeling sites, this would have tended to give a more lipophilic radiolabeled residue. Classification: Acceptable-Guideline
870.7485	Metabolism - Rat	Plasma radioactivity in the low-dose (4 mg/kg) animals after dosing slowly rose, indicating a slow rate of absorption from the gastrointestinal tract. The half-life of absorption was calculated to be about 1.5 hours, with a lag-time of 0.5 hours following first order kinetics. Radioactivity peaked in plasma for low-dose animals in 4 hours. The elimination of ^{14}C-bifenthrin from the plasma was equally slow, with significant radioactivity still remaining in blood at 72 hours. Plasma radioactivity in the high-dose (35 mg/kg) animals appeared to follow a similar course as seen in the low-dose animals. The peak radioactivity for the high-dose group appeared to be somewhat delayed, peaking at about 6 hours. Significant radioactivity still remained after 72 hours in the high-dose animals. Classification: Acceptable-Guideline
870.7485	Metabolism - Rat	The major metabolic route of radiolabeled bifenthrin appeared to be hydrolysis of the ester linkage with oxidation of the resulting alcohol to the acid. Protein binding of radioactive components or metabolites appears to increase with time. Classification: Acceptable-Guideline
870.7485	Metabolism - Rat	Fat and skin half-lives were the longest with half-lives of 51 and 50 days, respectively. The half-lives for ovaries, liver, kidneys and sciatic nerve were 37.4, 19.0, 28.5, and 42 days, respectively. Radioactive components were measured in fat at numerous time intervals, before and after daily dosing. The major component in fat is parent compound with a half-life of 47.5 days. Other unidentified components included a somewhat polar (R_f = 0.65) compound and two other relatively minor components. Classification: Acceptable-Guideline
870.7485	Metabolism - Rat	Within 7 days, nearly all bifenthrin and/or metabolites were excreted in either urine or feces. The majority of radioactivity was excreted in the feces within 48 hours. Tissues that retained bifenthrin and/or metabolites beyond 7 days included fat and skin in males and females, and gonads in females. Classification: Unacceptable-Guideline. Although the number of animals/group in this study was 3, and not 5/sex/group as recommended by guidelines, and a quality assurance statement was lacking, the results of this study provide useful information.

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

Guideline Number	Study Type	Results
870.7485	Metabolism - Rat	Results showed minimal breakage of the ester linkage of the parent compound in the material eliminated via the feces in the period of 0–48 hours after dosage, when most of the administered radioactivity is identifiable as coming from unmodified parent compound. However, the material was subsequently eliminated, although a relatively small proportion of the administered dose appears to have undergone more modification. Since a greater proportion of the radioactivity was eliminated via the feces in the period of 48–168 hours in the form of 2-Methyl-3-phenylbenzyl alcohol and 2-Methyl-3-phenylbenzoic acid than the parent compound, this is evidence that extensive breakage of the ester linkage does occur, either in the material retained in the intestines for more than 46 hours, or in the material absorbed and subsequently eliminated via the feces. Classification: Unacceptable-Guideline. While this study is limited, it dose provide some insight into the incomplete absorption of bifenthrin from the intestine, and the lack of modification of most of the unabsorbed material, particularly that eliminated via the feces during the period of 0–48 hours. However, the metabolism of the absorbed compound (radioactivity primarily excreted via the urine, despite differences in labeling) is less clear.
870.7485	Metabolism - Rat	The results of the study demonstrated that the majority of radioactivity excreted in the feces was the parent compound and its intact hydroxylated metabolites. Much of the radioactivity excreted in urine was hydrolytic and hydrolytic/oxidative degradation products of the parent compound. Classification: Unacceptable-Guideline.
870.7600	Dermal Penetration - Rats	For animals in group A, means of 4.6, 14.2, 12.8 and 14.7% total dose were recovered from the skin at 0, 4, 10 and 24 hours post-dose; corresponding percentages in the wash were 94.6, 80.8, 78.6 and 70%. For animals in group B, means of 20.0, 37.9, 42.0 and 41.2% remained (and were recovered from) the skin at 0, 4, 10 and 24 hours post-dose; corresponding percentages in the wash were 73.9, 50.6, 41.3 and 37.7% respectively. This dermal absorption study is classified as acceptable. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.
870.7600	Dermal Penetration - Rats	Means of 96.83, 84.75, 76.86 and 72.88% of the radioactivity were recovered in the skin wash at 0, 4, 10 and 24 hours post dosage, respectively. By the time the 4–hour post-dose and later skin samples were collected the emulsifying solvents had evaporated. Means of 4.04, 12.00, 16.55 and 19.44% total dose were recovered from the washed skin of the application site at 0, 4, 10 and 24 hours respectively; corresponding mean percentages recovered from the carcass were 0.09, 0.87, 0.85 and 1.67%. Mean percentages recovered in urine and feces were 0, 0.14, 0.43 and 3.23%. This dermal absorption study is classified as acceptable. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.
870.7600	Dermal Penetration - Rats	In general, only very small amounts of radioactivity were present in blood, excrement, and carcasses, with almost all (approximately 99%) of the absorbed radioactivity localized in skin at the application site, and in the skin adjacent to the application site. Average percentages of FMC 54800 dosages absorbed at 10 hours were 55.8%, 54.1%, and 37.5% for the 49.2, 514 and 5253 μg/rat groups respectively. Corresponding percentages for the 3 groups at the 0.5 hour sacrifice were 54.6%, 56.4%, and 52.5%, so the percentage absorption of FMC 54800 did not seem to depend on time-to-sacrifice. At 10 hours and the lowest dose level, the percentages present were as follows: excreta: <0.44%; carcass: <1.8%; skin at application site: 50.3%; skin adjacent to application site: 5.5%. At 10 hours and the highest dose level, the percentages of total dose present were as follows: excreta: 0.07%; carcass: 0.5%; skin at application site: 34.6%; skin adjacent to application site: 2.7%. Classification: This dermal absorption study is classified as acceptable. However, by itself, does not satisfy the guideline requirement for a dermal penetration study in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.

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

Guideline Number	Study Type	Results
870.7600	Dermal Penetration - Rats	The report states that at 24 hours postdose, 5.11% of the dose was absorbed (application-site skin + carcass + urine + feces) in this second trial. However, it is noted that there was poor recovery (68% of the total dose) from one of the rats (C32545) sacrificed at 24 hours in the second trial; disregarding the findings from this one animal then the mean value of the dose that was absorbed was 5.88%, and this can be taken as a reasonable estimate of the dermal absorption at this dose level. This dermal absorption study is classified as acceptable. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. In this case, EPA has determined that an additional 10X data base uncertainty factor (UF_{DB}) is needed to account for the lack of a developmental neurotoxicity (DNT) study when assessing acute (single dose) exposure scenarios. EPA has further determined that for repeated dose exposure scenarios (i.e., chronic dietary; short- and intermediate-term incidental oral; and short-, intermediate-, and long-term dermal and inhalation scenarios) a 3X UF_{DB} is adequate to account for the lack of the DNT study. The factors which EPA considered in making these determinations are discussed in detail below in Unit III.D.3.

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

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. In this case, since 300 is the appropriate UF for repeated dose exposure scenarios (10X to account for interspecies differences;10X for intraspecies differences and 3X for data base uncertainty) the LOC is 300. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

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

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 = 32.8 mg ai/kg UF = 1,000 Acute RfD = 0.033 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.033 mg/kg/day	Acute Neurotoxicity Study in Rats LOAEL = 70.3 mg/kg/day based on observations of mortality (females only), clinical and functional operational battery (FOB) findings and differences in motor activity.
Chronic Dietary (All populations)	NOAEL = 1.3 mg/kg/day UF = 300 Chronic RfD = 0.004 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.004 mg/kg/day	1–Year Oral Study in Dogs LOAEL = 2.7 mg/kg/day based on observations of increased incidence of 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
Incidental Oral Short-Term (1 – 30 Days) Residential Only	NOAEL = 2.21 mg ai/kg/day UF = 300	FQPA SF = 1X LOC for MOE = 300	90–Day Oral Study in Dogs LOAEL = 4.42 mg ai/kg/day based on observations of increased incidence of tremors in both sexes.
Incidental Oral Intermediate-Term (1 – 6 Months) Residential Only	NOAEL = 2.21 mg ai/kg/day UF = 300	FQPA SF = 1X LOC for MOE = 300	90–Day Oral Study in Dogs LOAEL = 4.42 mg ai/kg/day based on observations of increased incidence of tremors in both sexes.
Short-Term Dermal (1 to 30 days) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21–Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Intermediate-Term Dermal (1 to 6 months) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21–Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Long-Term Dermal (several months to lifetime) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21–Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Short-Term Inhalation (1 to 30 days) (Residential)	oral study NOAEL = 2.21 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	90–Day Oral Study in Dogs LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Intermediate-Term Inhalation (1 to 6 months) (Residential)	oral study NOAEL = 2.21 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	90–Day Oral Study in Dogs LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Long-Term Inhalation (several months to lifetime) (Residential)	oral study NOAEL = 1.3 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	1–Year Oral Study in Dogs LOAEL = 2.7 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Cancer (oral, dermal, inhalation)	EPA's Carcinogenicity Peer Review Committee (CPRC) has characterized bifenthrin as a Category C (possible human) carcinogen, primarily on the basis of the mouse carcinogenicity study in which the high-dose males (81.3 mg/kg/day) showed a highly significant increased incidence of urinary bladder tumors. Other findings in the mouse study included a dose-related trend of increased combined incidences of adenoma and adenocarcinoma of the liver (males only), and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females at some, but not all, doses relative to their controls. The Agency did not recommend assignment of a Q1* but has determined that the reference dose (RfD) approach should be used for quantification of human risk.		

*The reference to the FQPA SF refers to any additional SF 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. Tolerances have been established on plant commodities ranging from 0.05 ppm for corn grain, peas, beans and eggplant to 10 ppm for dried hops and on animal commodities ranging from 0.01 ppm for meat byproducts to 1.0 ppm for milk fat and fat of cattle, goats, hogs, horses, and sheep. 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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: A probabilistic dietary exposure assessment was conducted for the general U.S. population and all population subgroups, including infants and children. The highly refined assessment incorporated the most recent USDA Pesticide Data Program (PDP) monitoring data, field trial data and processing factor data (for grapes and pending uses). It assumed 100% crop treated for the new and existing uses.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the

individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A highly refined chronic exposure assessment was conducted which incorporated the most recent PDP monitoring data, field trial data and processing factor data (for grapes and pending uses). It assumed 100% crop treated for the new and existing uses.

iii. *Cancer*. Bifenthrin has been classified as a Category C (possible human) carcinogen. The Agency has determined that the reference dose (RfD) approach should be used for quantification of human risk. For further discussion of the weight-of-the-evidence considered by EPA in making this determination, see the proposed rule for Bifenthrin tolerances (59 FR 9167, February 25, 1994) (FRL–4756–1). Under this approach, chronic dietary exposures that are less than the RfD (or cPAD) are assumed to be protective for cancer dietary exposure as well. Therefore, a separate cancer dietary risk assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA 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) of the FFDCA, 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) of the FFDCA 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 PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency did not use percent crop treated information for assessing dietary risk from bifenthrin.

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

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

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

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of bifenthrin for acute exposures are estimated to be 0.1 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.1 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: ornamental gardens, lawns, turf, and general insect control in, around and on buildings, structures, and immediate surroundings. There are also uses for spot treatments and crack and crevice treatments for insects in, on, and around homes, buildings, and other structures and for subsoil treatment around structures for control of termites (termiticide use). The risk assessment was conducted using the following residential exposure assumptions: Adults and children are potentially exposed to bifenthrin residues after application of bifenthrin products in residential settings. Short- and intermediate-term post-application dermal exposures for adults, and short- and intermediate-term post-application dermal and incidental oral exposures for children are anticipated. Risk estimates were generated for potential contact with lawn, soil, and treated indoor surfaces using EPA's Draft Standard Operating Procedures for Residential Exposure Assessment; and for the lawn exposure scenarios, dissipation data from a chemical specific turf transferable residue (TTR) study. Indoor surface residues in homes were based on crack and crevice data collected for bifenthrin and another insecticide, malathion. These estimates are considered conservative screening level estimates, since the study data were adjusted to reflect maximum application rates.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA

requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether bifenthrin has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to bifenthrin and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. EPA concluded that there is not a concern for pre- and/or postnatal toxicity resulting from exposure to bifenthrin. There was no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to Bifenthrin in developmental toxicity studies and no quantitative or qualitative evidence of increased susceptibility of neonates (as compared to adults) to bifenthrin in a 2-generation reproduction study in rats. In addition, there are no concerns or residual uncertainties for pre and/or post-natal toxicity following exposure to Bifenthrin.

3. *Conclusion*. No special FQPA safety factor is needed based on concerns for pre- and/or postnatal toxicity to bifenthrin. However, EPA has concluded that in light of the lack of the DNT study there is no reliable basis for removing the additional FQPA 10X safety factor when assessing acute (single dose) exposure scenarios. The following points were considered in this determination:

i. It is assumed that the DNT study will be conducted at dose levels similar to those used in the rat reproduction study with Bifenthrin wherein the offspring NOAEL was 5.0 mg/kg/day, the highest dose tested (no effects were observed in offspring at this dose); but that the DNT study would not be conducted at dose levels higher than 10 mg/kg/day since a range-finding study indicates excessive fetotoxicity occurred at this dose (all pups from 2 of the 4 litters at 10 mg/kg/day died within 14 days of birth).

ii. The DNT study may impact the currently selected acute regulatory dose since the NOAEL used to establish the acute Reference dose for dietary risk assessment is 33 mg/kg/day, a level which is more than 5–fold higher than the offspring NOAEL in the rat reproduction study of 5.0 mg/kg/day (a level which is similar to dose levels likely to be used in the DNT study).

EPA has further determined that for repeated dose exposure scenarios a 3X UF_{DB} is adequate to account for the lack of the DNT study. Repeated dose exposure scenarios include chronic dietary exposure; short-term (repeated exposure up to 30 days) and intermediate-term (repeated exposure from 1 to 6 months) incidental oral exposure; and short-term, intermediate-term, and long-term (several months to lifetime) dermal and inhalation exposure scenarios. EPA's determination that a 3X UF_{DB} is adequate for repeated dose exposure scenarios is based on the following considerations:

a. As stated above, the DNT study will likely be conducted at dose levels similar to the rat reproduction study.

b. The results of the DNT study are not expected to impact the current regulatory doses selected for repeated exposure scenarios since the NOAELs used for these risk assessment endpoints (e.g., 1.3 mg/kg/day from the chronic dog study for chronic RfD) are approximately 4–fold lower than the offspring NOAEL (5.0 mg/kg/day) in the rat reproduction study conducted with Bifenthrin. Although the results of the DNT are not expected to impact the current regulatory dose given the 4–fold difference observed in the rat and dog studies, EPA does not have sufficient reliable data to apply no additional FQPA safety factor. Rather, EPA believes that the 4X difference between the offspring NOAEL in the rat reproduction study and the NOAELs used for risk assessment endpoints provides reliable data supporting a 3X UF for repeated dose exposure scenarios. The use of a 3X provides roughly a 10–fold difference between the NOAEL associated with the identified effects in the rat necessitating the DNT study and the NOAELs used for setting regulatory doses. Therefore, a UF_{DB} of 3X will be applied as a FQPA safety factor to repeated dose exposure scenarios to account for the lack of the DNT study with Bifenthrin.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Actual 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 ground water 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 exposure from food to bifenthrin will occupy 32% of the aPAD for the U.S. population, 19% of the aPAD for females 13 to 50 years old, 52% of the aPAD for infants less than 1 year old and 38% of the aPAD for children 1 to 6 years old. In addition, there is potential for acute dietary exposure to bifenthrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

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	0.033	32	0.1	0.006	780
All Infants (<1 year old)	0.033	52	0.1	0.006	160
Children (1–6 years old)	0.033	38	0.1	0.006	200
Females (13–50 years old)	0.033	19	0.1	0.006	800

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 12% of the cPAD for the U.S. population, 13% of the cPAD for infants less than 1 year old and 24% of the cPAD for children 1 to 6 years old. Based on the use pattern, chronic residential exposure to residues of bifenthrin is not expected. In addition, there is potential for chronic dietary exposure to bifenthrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC 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	0.004	12	0.1	0.006	120
All Infants (<1 year old)	0.004	13	0.1	0.006	35
Children (1–6 years old)	0.004	24	0.1	0.006	30

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-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for bifenthrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 544 to 1,070 for adult male and female homeowners applying bifenthrin to turf, treating structural wood or making crack and crevice applications indoors. EPA has further concluded that food and residential exposures aggregated result in aggregate MOEs of 354 for children (toddlers) with post-application exposure outdoors and 694 for children (toddlers) with post-application exposure following indoor crack and crevice treatments. 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, as shown in Table 5 of this unit:

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)
Adult Female: Structural Wood Treatment	544	300	0.1	0.006	100
Adult Male: Structural Wood Treatment	546	300	0.1	0.006	120
Adult Female: Indoor Crack and Crevice Treatment	855	300	0.1	0.006	140
Adult Male: Indoor Crack and Crevice Treatment	858	300	0.1	0.006	170
Children (Toddler): Outdoor Post-application Exposure	354	300	0.1	0.006	11
Children (Toddler): Indoor Post-application Exposure	694	300	0.1	0.006	42

4. *Intermediate-term risk.* Intermediate-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(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for bifenthrin. However, since short-term risk estimates for residential handler and post-application exposures to bifenthrin represent worst-case risk estimates for intermediate-term scenarios, separate intermediate-term aggregate risks were not estimated. Short-term risk estimates are considered to represent worst-case risk estimates for intermediate-term scenarios for the following reasons.

The toxic endpoints used to estimate risks for intermediate-term dermal, incidental oral, and inhalation exposures for bifenthrin are the same as those used to estimate risks from short-term exposures. In addition, EPA used the same residue data from outdoor (turf) and indoor (hard-surface) studies to estimate short and intermediate-term exposures. Any differences in the exposure estimates are a result of the assumptions used for activity patterns, which may differ for short versus intermediate-term exposure depending on the scenario assessed. As a result of these differences, exposure estimates for intermediate-term exposure scenarios are either equal to or lower than exposure estimates for short-term scenarios. Consequently, risk estimates (MOEs) for intermediate-term exposures are equal to or greater than MOEs for short-term exposures. Since short-term risk estimates are below levels of concern, intermediate-term risk estimates are also below levels of concern.

5. *Aggregate cancer risk for U.S. population.* Bifenthrin has been classified as a Category C (possible human) carcinogen. The Agency has determined that the reference dose (RfD) approach should be used for quantification of human risk. Therefore, the chronic aggregate risk assessment described above in Unit III.E.2. also encompasses chronic aggregate cancer risk from bifenthrin.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of the regulated bifenthrin residue in plants. Crop field trial samples were analyzed for residues of bifenthrin using FMC Methods P–1073, P–1089, P–1645M, P–2132M, P–3133, or P–3346. These methods are variations of two other methods which have been submitted for inclusion in PAM II (FMC's Methods P–1031 and RAN–0140). These methods have been adequately validated and are adequate for data collection.

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

B. International Residue Limits

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of bifenthrin in/on various commodities. The Codex MRLs are expressed in terms of bifenthrin per se. The Codex MRL and the U.S. tolerance expressions are compatible.

Of the new commodities for which tolerances are being established, Codex MRLS exist only for pear, grapefruit, lemon and orange. The Codex MRLs of 0.5 ppm for pear and 0.05 ppm for grapefruit, lemon and orange are compatible with the new U.S. tolerances for pear (0.5 ppm) and citrus fruit (0.05 ppm). Codex MRLs have not been established for bananas, herbs, tomatoes, spinach or tree nuts.

The following conclusions can be made regarding efforts to harmonize existing (i.e., previously established) U.S. tolerances with Codex MRLs: (i) Compatibility between the U.S. tolerances and Codex MRLs exists for maize and chicken commodities except eggs; (ii) incompatibility of the U.S. tolerances and Codex MRLs remains for maize forage and fodder, strawberry, eggs, and cattle commodities because of differences in agricultural practices and/or method limits of quantitation. No questions of compatibility exist with respect to commodities where Codex MRLs have been established but U.S. tolerances do not exist.

There are no Canadian MRLs established for bifenthrin. Mexican MRLs have been established for bifentrin at 0.5 ppm for cottonseed, 0.05 ppm for maize, and 3 ppm for strawberry. These levels are compatible with the U.S. tolerance levels.

V. Conclusion

Therefore, 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 almond, hulls at 2.0 ppm; banana at 0.1 ppm; fruit, citrus, group 10 at 0.05 ppm; herb subgroup 19A at 0.05 ppm; pear at 0.5 ppm; nut, tree, group 14 at 0.05 ppm; spinach at 0.2 ppm; tomato at 0.15 ppm; and food/feed products in food/feed handling establishments at 0.05 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0358 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 June 30, 2003.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0358, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since

tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 16, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.442 is amended in paragraph (a) by designating the text following the paragraph heading as paragraph (a)(1); by adding alphabetically commodities to the table in newly designated paragraph (a)(1), by adding paragraph (a)(2), and in the table to paragraph (b) by deleting the entries for ''Citrus;'' ''Citrus, dried pulp;'' and ''Citrus, oil.''.

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Almond, hulls	2.0
* * * *	*
Banana[1]	0.1
* * * *	*
Fruit, citrus, group 10	0.05
* * * *	*
Herb subgroup 19A	0.05
* * * *	*
Nut, tree, group 14	0.05
* * * *	*
Pear	0.5
* * * *	*
Spinach	0.2
* * * *	*
Tomato	0.15
* * * *	*

[1] There are no U.S. registrations as of April 30, 2003.

(2) A tolerance of 0.05 ppm is established for residues of the insecticide bifenthrin, (2-methyl[1,1′-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate, as follows:

(i) In or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments.

(ii) The insecticide may be present as a residue from application of bifenthrin in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries, feed handling establishments including feed manufacturing and processing establishments, in accordance with the following prescribed conditions:

(A) Application shall be limited to general surface and spot and/or crack and crevice treatment in food/feed handling establishments where food/feed and food/feed products are held, processed, prepared and served. General surface application may be used only when the facility is not in operation provided exposed food/feed has been covered or removed from the area being treated. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed food/feed is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of food/feed or food/feed contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labeling.

* * * * *

[FR Doc. 03–10400 Filed 4–29–03; 8:45 am]

BILLING CODE 6560–50–S