ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300495; FRL–5719–3]

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 the pesticide bifenthrin in or on the raw agricultural commodity crop group, cucurbits (Crop Group 9 - cucumbers, melons, and squash), and in or on the raw agricultural commodity raspberries, in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of bifenthrin on cucurbits in California, Arizona, and Texas; and use of bifenthrin on raspberries in Oregon and Washington. This regulation establishes maximum permissible levels for residues of bifenthrin on these commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on April 30, 1998 (cucurbits) and September 30, 1997 (raspberries).

DATES: This regulation becomes effective June 6, 1997. Objections and requests for hearings must be received by EPA on August 5, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300495], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP], should be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300495]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8791, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the pesticide ((2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl) -2,2-dimethylcyclopropanecarboxylate), also referred to in this document as bifenthrin, in or on cucurbits at 1.0 ppm, and in or on raspberries at 3.0 ppm. These tolerances will expire and be revoked on April 30, 1998 (cucurbits) and September 30, 1997 (raspberries). EPA will publish documents in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) 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 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 FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. 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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Bifenthrin and FFDCA Tolerances

Bifenthrin on cucurbits. From November 1996 - January 1997, requests were received from the California Department of Pesticide Regulation, and the Arizona and Texas Departments of Agriculture, (hereafter referred to as the Applicants) for specific exemptions under FIFRA section 18 for the use of

bifenthrin to control whiteflies in cucurbits. The Applicants state that an emergency situation is present due to this recently introduced pest, its devastating effects on the cucurbit crop, and its resistance to registered alternatives. The Applicants state that this pest can have devastating effects on growers' production and revenue. After having reviewed their submission, EPA concurs that an emergency condition exists. EPA has authorized under FIFRA section 18, the use of bifenthrin on cucurbits for control of whiteflies.

Bifenthrin on raspberries. In February 1997, requests were received from the Oregon and Washington Departments of Agriculture (hereafter referred to as the Applicants) for specific exemptions under FIFRA section 18 for the use of bifenthrin to control weevils in raspberries. The Applicants state that an emergency situation is present due to these pests developing resistance to available alternatives, and the low tolerance for weevil contamination in raspberries. Rejection by the processors of contaminated raspberries can lead to significant losses in revenue for the growers. After having reviewed their submission, EPA concurs that an emergency condition exists. EPA has authorized under FIFRA section 18, the use of bifenthrin on raspberries for control of weevils.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of bifenthrin in or on cucurbits and raspberries. In doing so, EPA considered the new 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 new safety standard and with FIFRA section 18. These tolerances for bifenthrin will permit the marketing of cucurbits and raspberries treated in accordance with the provisions of the section 18 emergency exemptions. 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 under section 408(e) as provided in section 408(l)(6). Although these tolerances will expire and are revoked on April 30, 1998 (cucurbits) and September 30, 1997 (raspberries), under FFDCA section 408(l)(5), residues of bifenthrin not in excess of the amount specified in the tolerances remaining in or on cucurbits or raspberries after the dates specified above will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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.

EPA has not made any decisions about whether bifenthrin meets the requirements for registration under FIFRA section 3 for use on cucurbits and raspberries, or whether permanent tolerances for these uses would be appropriate. This action by EPA does not serve as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than those specified in this document to use this product on cucurbits or raspberries under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR 180.166. For additional information regarding the emergency exemptions, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter-term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens. lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC

exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

IV. Aggregate Risk Assessment and Determination of Safety

A. Toxicological Profile

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has evaluated the available toxicology data and considered its validity, completeness, and reliability as well as the relationship of the result 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 below.

1. *Acute risk*. The maternal NOEL of 1 mg/kg/day from the oral developmental toxicity study in rats is used for acute dietary risk estimates. The maternal LEL of this study of 2 mg/kg/day was based on tremors from day 7-17 of dosing. This acute dietary endpoint is used to determine acute dietary risks to all population subgroups.

2. *Short- and intermediate-term risk*. The maternal NOEL of 1 mg/kg/day from the oral developmental toxicity study in rats is also used for short- and intermediate-term MOE calculations (as well as acute, discussed in (1) above). The maternal LEL of this study of 2 mg/kg/day was based on tremors from day 7-17 of dosing.

3. *Chronic risk*. Based on available chronic toxicity data, the OPP has established the RfD for bifenthrin at 0.015 mg/kg/day. The RfD is based on a 1–year oral feeding study in dogs with a NOEL of 1.5 mg/kg/day and an uncertainty factor of 100, based on intermittent tremors observed at the LEL of 3 mg/kg/day.

4. *Cancer risk*. OPP classified bifenthrin as a Group C chemical (possible human carcinogen) based upon urinary bladder tumors in mice, but did not recommend assignment of a Q_*.

B. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

Tolerances for residues of bifenthrin are currently expressed as 2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl) 2,2-dimethylcyclopropanecarboxylate. Tolerances currently exist for residues on hops; strawberries; corn grain, forage and fodder; cotton seed; and livestock commodities of cattle, goats, hogs, horses, sheep, and poultry (see 40 CFR 180.442).

1. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Drinking water is also considered a component of the acute dietary exposure; however, EPA generally will not include residential or other non-dietary exposure as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary exposure could be combined with the acute total dietary exposure form food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. It is highly unlikely that, in one day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario. Thus, the Agency estimates acute risk from dietary exposure only. EPA concluded that aggregate dietary risk (food plus drinking water) would not exceed levels of concern.

2. *Short- and intermediate-term exposure.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure) plus indoor and outdoor residential exposure. The only use that could result in a residential exposure is the one registered use for bifenthrin as a termiticide. EPA evaluated information contained in a risk characterization document produced by the California Environmental Protection Agency, concerning the use of bifenthrin as a subterranean termiticide. This document characterized the risks to residents of houses treated with bifenthrin, from aggregate residential and acute dietary exposure. Exposure was calculated based on exposure data collected from indoor air monitoring data, with the absorbed dose from residential exposure converted to an oral equivalent, for comparison with the NOEL derived from an oral dosing study. Dietary exposure assessment assumed maximum anticipated residue levels resulting from the registration on cotton, and secondary meat/milk/poultry expected residue levels were extrapolated based on feeding studies. Although the California risk assessment document did not include dietary exposure resulting from bifenthrin use oin corn and hops, because of the low tolerance for corn grain (0.05 ppm) and low consumption for hops and strawberries, it is the best scientific judgment of EPA scientiest that addition of these commodities would not sufficiently lower the MOEs to levels of concern. Based on this risk characterization document produced by the California Environmental Protection Agency, aggregate short- and intermediate-term risks do not exceed EPA's level of concern.

3. *Chronic exposure.* The Agency identified chronic exposure as appropriate for aggregate risk assessment. The aggregate chronic risk is equal to the sum of the chronic risk from exposure from food + water + residential (indoor + outdoor) uses.

i. *Dietary food exposure*. For purposes of assessing the potential dietary exposure under this tolerance, EPA used tolerance level residues and 100% of crop treated to estimate the TMRC from all established food uses for bifenthrin and the proposed uses on cucurbits and raspberries. There are no cucurbit or raspberry animal feed items so no additional dietary livestock dietary burden will result from these section 18

uses. Therefore, existing meat/milk/poultry tolerances are adequate.

ii. *Drinking water exposure.* Based on the available studies used in EPA's assessment of environmental risk, bifenthrin is moderately persistent and not mobile. There is no established Maximum Concentration Level for residues of bifenthrin in drinking water. No health advisory levels for bifenthrin in drinking water have been established. The ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992) does not contain any information for bifenthrin.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's, cancer potency factors (Q*s), acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause bifenthrin to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with bifenthrin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerances are granted.

iii. *Non-dietary, non-occupational exposure.* Bifenthrin is not registered for any residential outdoor uses so no exposure from this route is expected. However, bifenthrin is registered for residential use as a termiticide, and the Agency has concluded that a chronic exposure scenario may exist with respect to this use. The Agency estimates that aggregate risk (food plus drinking water plus residential) would not exceed the RfD for bifenthrin.

C. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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, EPA has considered only risks from bifenthrin. Therefore, EPA has not assumed that bifenthrin has a common mechanism of toxicity with other substances.

D. Safety Determinations for U.S. Population

1. *Acute risk.* The acute risk assessment used anticipated residues for all commodities having bifenthrin tolerances, except for cucurbits and raspberries, for which proposed tolerance level residues were used. Additionally, the assessment assumed that 100% of the commodities for which there are tolerances, would contain residues of bifenthrin at these levels. For the most highly exposed population subgroup, children 1 - 6 years old, the high-end exposure results in a dietary (food only) MOE of 40; at the 97th percentile the MOE is 111. For infants <1 year old, the high-end exposure MOE is 50; at the 98th percentile it is 111. For the U.S. population, the high-end exposure MOE is 67; at the 99th percentile it is 111. The major portion of the estimated dietary exposure from bifenthrin is contributed through the tolerances for field corn and secondary residues in animal commodities resulting from feeding of the treated field corn. This assessment used the extremely conservative assumptin that 100% of the field corn and livestock commodities would contain residues of bifenthrin. However, available data show that of the total field corn crop grown in the U.S., only about 0.45 percent was actually treated with bifenthrin in 1994-96 (3-year average); it is expected that a similar percentage will be treated for the current year (1997), since this figure has generally remained consistent for the past three years. Therefore, it is unlikely that the actual exposure is considerably less than the conservative estimates given here; if these estimates were refined using actual percent of crop treated figures, EPA scientists believe that the MOEs would be increased to acceptable levels for the high-end consumer.

2. *Short- and intermediate-term risk.* The short- and intermediate-term risk assessment used maximum anticipated residue levels for cotton, extrapolated residue levels for meat/milk/poultry/eggs, and air monitoring data collected from 15 homes in four states. Based on this data, the MOEs for children are

calculated to be 280 for the average consumer and 250 for the high-end consumer. The MOEs for adults are calculated to be 450 for the average consumer and 390 for the high-end consumer. EPA generally has no concern for MOEs greater than 100, and thus these do not exceed EPA's level of concern.

3. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that aggregate dietary exposure to bifenthrin will utilize 25% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-Nursing Infants (<1 year old), at 58% of the RfD. This is further discussed below in the section on infants and children. EPA generally has no concern for exposure below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to bifenthrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to bifenthrin residues.

E. Determination of Safety for Infants and Children

In assessing the adequacy of the standard uncertainty factor for bifenthrin, EPA considered data from developmental toxicity studies in the rat and rabbit, and a two-generation reproductive study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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 (usually 100x for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty 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.

1. *Developmental toxicity studies*—a. *Rabbit study.* In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOEL of 4 mg/kg/day.

b. *Rat study.* In the rat developmental study, the maternal NOEL was 1 mg/kg/day, based on tremors at the LOEL of 2 mg/kg/day. The developmental (pup) NOEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOEL 2 mg/kg/day. There were 5/23 (22%) litters affected (5/141 fetuses since each litter only had one affected fetus) 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%.

c. *Pre-natal sensitivity.* 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. Based on the above, EPA concludes that reliable data support use of the standard hundredfold MOE/uncertainty factor, and that an additional MOE/uncertainty factor is not needed to protect the safety of infants and children.

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

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

3. *Acute risk.* The EPA believes that residential exposures are more appropriately included in the short-term exposure scenario, and thus estimates acute risk from dietary exposure only. EPA concluded that aggregate dietary acute risk (food plus drinking water) would not exceed levels of concern. Acute risk is discussed in detail in Units IV.B.1 and IV.D.1 of this document.

4. *Short- and intermediate-term risk.* The estimated short- and intermediate-term risk do not exceed EPA's levels of concern for children. MOEs for children are calculated to be 280 for the average consumer and 250 for the high-end consumer. This is discussed in greater detail in Units IV.B.2. and IV.D.2. of this document.

5. *Chronic risk.* EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at of below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to hyuman health. Despite the potential for exposure in drinking water, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure (including drinking water exposure) to residues of bifenthrin does not exceed 100% for any of the population subgroups. Using the conservative exposure assmuptions descibed agove, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 58% of the RfD for Non-Nursing Infants, the population subgroup with the largest percentage of the RfD occupied. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, 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 cucurbits, raspberries, and animal commodities is adequately understood for the purposes of these tolerances. The residue of concern is the parent compound only.

B. Analytical Enforcement Methodology

There is a practical analytical method for detecting and measuring levels of bifenthrin in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance (Gas Chromatography with Electron Capture Detection (GC/ECD) analytical method P–2132M, PPt0E3921, MRIDt41658601). EPA has provided information on this method to

FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Inormation and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5805.

C. Magnitude of Residues

Residues of bifenthrin are not likely to exceed 1.0 ppm in or on cucurbits, or 3.0 ppm in or on raspberries, as a result of the proposed uses. No animal feed items are associated with either use; therefore, no secondary residues in meat, milk, poultry, and eggs are expected to result.

D. Rotational Crop Restrictions

The confined rotational crop data requirements for bifenthrin have been satisfied. The following rotation instructions are required:

a. Leafy vegetables and root crops may be rotated 30 days following the final application of bifenthrin.

b. Crops for which bifenthrin tolerances exist may be rotated at any time.

c. All other crops may be rotated seven months following the final application of bifenthrin. There are no rotational crop considerations associated with raspberries.

E. International Residue Limits

There are no Codex, Canadian, or Mexican residue limits for residues of bifenthrin in or on cucurbits or raspberries.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of bifenthrin in or on cucurbits at 1.0 ppm, and raspberries at 3.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 5, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (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.

VIII. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300495] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in **ADDRESSES** at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–300495]. Electronic comments on this rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

Under Executive Order 12566 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any unfunded mandates as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with state officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**.

This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 22, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. By revising § 180.442 to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

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

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	1.0	11/15/97
Cattle, mbyp	0.10	11/15/97
Cattle, meat	0.5	11/15/97
Corn, fodder	5.0	11/15/97
Corn, forage	2.0	11/15/97
Corn, grain (field, seed, and pop)	0.05	11/15/97
Cottonseed	0.5	11/15/97
Eggs	0.05	11/15/97
Goats, fat	1.0	11/15/97
Goats, mbyp	0.10	11/15/97
Goats, meat	0.5	11/15/97
Hogs, fat	1.0	11/15/97
Hogs, mbyp	0.10	11/15/97
Hogs, meat	0.5	11/15/97
Hops, dried	10.0	11/15/97
Horses, fat	1.0	11/15/97
Horses, mbyp	0.10	11/15/97
Horses, meat	0.5	11/15/97
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0	11/15/97
Poultry, fat	0.05	11/15/97
Poultry, mbyp	0.05	11/15/97
Poultry, meat	0.05	11/15/97
Sheep, fat	1.0	11/15/97
Sheep, mbyp	0.10	11/15/97
Sheep, meat	0.5	11/15/97
Strawberries	3.00	None

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the insecticide bifenthrin ((2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl) -2,2-dimethylcyclopropanecarboxylate), in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Broccoli	0.1	1/31/98
Cauliflower	0.05	1/31/98
Raspberries	3.0	9/30/97
Vegetables, cucurbits	1.0	4/30/98

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–14721 Filed 6–5–97; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR 24

[DA 97–1152]

Personal Communications Services; Licenses in C Block (Broadband PCS)

AGENCY: Federal Communications Commission.

ACTION: Final Rule; Waiver request.

SUMMARY: On June 2, 1997, the Wireless Telecommunications Bureau of the Federal Communications Commission released a Public Notice requesting comment on several requests for waiver of the 7 percent interest rate imposed on C block broadband Personal Communications Services (PCS) installment plan notes. The Public Notice summarizes the requests for waiver and announces that comments are due on or before June 23, 1997, and