raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 14, 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. Section 180.440 is revised to read as follows:

§ 180.440 Tefluthrin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide tefluthrin (2,3,5,6 tetrafluroro-4-methylphenyl)methyl-(1 alpha, 3 alpha)-(*Z*)-(±)-3(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-diemthylcyclopropanecarboxylate) and its metabolite (*Z*)-3-(2-chloro-3,3,3-trifluroro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid in or on the following commodities:

Commodity	Parts per million
Corn, field, fodder and forage, pop and sweet	0.06
Corn, fresh (including sweet K and corn with husk removed (CWHR)	0.06
Corn, field, grain and pop	0.06

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

[FR Doc. 97–30946 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300579; FRL–5754–7]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide bifenthrin ((2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate), in or on the raw agricultural commodities (RAC) cottonseed at 0.5 parts per million (ppm); corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and meat by-products (mbyp) of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk) at 1.0 ppm; poultry, fat, meat, and mbyp at 0.05 ppm. It also removes time limitations for tolerances for residues of bifenthrin on the same commodities that expire on November 15, 1997. These tolerances were requested under pesticide petitions (PP) 6F3453, 7F3546, and OE3921. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300579], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300579], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 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–300579]. 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: Adam Heyward, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5418, e-mail: heyward.adam@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 15, 1988, EPA established a time-limited tolerance under section 408 of the FFDCA, 21 U.S.C. 346 a(d) and 348 for residues of bifenthrin on cottonseed (53 FR 30678). As additional crops were approved tolerances were also made time-limited. These tolerances will expire on November 15, 1997. FMC Corporation, on September 15, 1997, requested that the time limitations for

tolerances for residues of the insecticide bifenthrin in or on the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of registration. FMC Corporation also submitted a summary of its petition as required under the FFDCA as amended by the FQPA of 1996 (Pub. L. 104–170).

In the **Federal Register** of Friday, September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F3453, 7F3546, and 0E3921) for tolerances by the FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and from the Interregional Research Project No. 4 (IR–4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This notice included a summary of the petitions prepared by the FMC Corporation and the Interregional Research Project No. 4 (IR–4), the registrants. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.442 be amended by removing the time limitation for tolerances of the insecticide bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the raw agricultural commodities cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and mbyp of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk) at 1.0 ppm, poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.05 ppm. Tolerances for corn (forage and fodder) and livestock commodities were inadvertently not listed in the proposal paragraph of the notice of filing but were included in the discussion under Aggregate Exposure of the notice. These tolerances were considered by EPA for risk assessment purposes.

The basis for time-limited tolerances that expire November 15, 1997, was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rational for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal 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 percent 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 100-fold MOE is based on the same rationale as the 100-fold 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.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure

that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate-term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure and high-end residential exposure are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g., frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e. the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. Toxicity results at lower levels when the dosing duration is increased.

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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, residues in 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. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. 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 percent 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.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of bifenthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), on cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and mbyp of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.10 ppm. EPA's assessment of the dietary 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 below.

1. Acute toxicity. Acute toxicity studies with the technical grade of the active ingredient bifenthrin: Oral LD_{50} in the rats of 70.1 milligram/kilogram (mg/kg) (male) and 53.8 mg/kg (female): Toxic category II, dermal LD_{50} in the rats of > 2000 mg/kg (male and female): Toxic category II, primary dermal and eye showed no irritation: Toxic category IV. Bifenthrin is not a dermal senstizer.

2. Mutagenicity. The following genotoxicity tests were all negative: A *Salmonella typhimurium* reverse gene mutation assay, a mouse lymphoma forward gene mutation assay (HGPRT locus), a mouse lymphoma $TO^{\pm}$ assay, a CHO/HGPRT assay, an *in vitro* chromosomal aberration assay in CHO cells, a rat bone marrow cytogenetic assay, and 2 unscheduled DNA synthesis assays in primary rat hepatocytes. Bifenthrin tests positively both with and without metabolic activation in the mouse lymphoma forward gene mutation assay ($TO^{\pm}$). There is also presumptive evidence that bifenthrin is mutagenic with metabolic activation in the CHO gene mutation assay. However, this study appears to be unacceptable at this time. All the other studies tested negatively. The submitted studies satisfies both the pre 1991 and new mutagenicity test batteries. No further testing is required at this time.

3. A 13-week feeding study in dogs (by capsule) of doses at nominal dose levels of 0, 2.5, 5, 10, or 20 milligram/kilogram/day (mg/kg/day) (equivalent to 2.21, 4.42, 8.84, and 17.7 mg/kg/day, based on percent active ingredient (a.i.)) for 13 weeks. There was no mortality during the study. There were no treatment-related changes noted in food consumption, hematology, clinical chemistry, organ weight, gross or microscopic parameters. In addition,

there were no treatment-related ophthalmological changes. Tremors were noted in 3 dogs/sex at 4.42 mg/kg/day and in 4 dogs/sex at 8.84 and 17.7 mg/kg/day. Ataxia was noted in 4 dogs/sex at 8.84 and 17.7 mg/kg/day and in one female at 4.42 mg/kg/day. Languidness occurred primarily at 17.7 mg/kg/day in both sexes, but also occasionally at 8.84 mg/kg/day. All of these symptoms occurred more frequently during the last 3 weeks of the study. Other dose-related clinical signs included blinking, mydriasis, nystagmus, lacrimation, and polypnea. One high-dose female appeared thin and/or dehydrated during the final weeks of the study. A non-statistically significant, but possibly treatment-related reduction in body weight (bwt) gain was noted in females at 17.7 mg/kg/day (0.6 kilogram (kg)) relative to the controls (1.3 kg). None of the females at 8.84 or 17.7 mg/kg/day showed cyclic activity or signs of estrus, but cyclic activity was observed in 2, 2, and 1 female at 0, 2.21, and 4.42 mg/kg/day, respectively and 4/5 showed signs of estrus. The lowest observed effect level (LOEL) for this 13-week study is 4.42 mg/kg/day based on the increased incidence of tremors in both sexes. The NOEL is 2.21 mg/kg/day.

4. A 90-day feeding study in rats fed at doses of 0, 12, 50, 100, and 200 ppm (0, 0.6, 2.5, 5, or 10 mg/kg/day) with a NOEL of 2.5 mg/kg/day and LOEL of 5 mg/kg/day based on the increased incidence of tremors in both sexes.

5. A 21-day study in rabbits exposed dermally to doses of 0, 25, 50, 100, or 500 mg/kg/day for 21 days with a systemic NOEL of 100 mg/kg/day. Systemic LOEL is 500 mg/kg/day based on the loss of muscle coordination in both sexes.

6. A 1-year chronic/carcinogenicity study in dogs was administered in the diet at dose levels of 0, 0.75, 1.5, 3, or 5 mg/kg/day. No mortality occurred during the study and there were no treatment-related effects on bwt, food consumption, organ weights, and grossor microscopic pathology. In addition, there were no treatment-related ophthalmological changes. Tremors were noted in all males and females at 5 mg/kg/day during weeks 15–29 and in 1/4 males and 3/4 females at 3 mg/kg/day during weeks 16–23. A significant increase in platelets was noted at 52 weeks in 5 mg/kg/day males. Serum sodium levels were significantly increased in males at 3 and 5 mg/kg/day and serum chloride was increased in males at 5mg/kg/day. The LOEL for this 52-week study is 3 mg/kg/day based on the increased incidence of tremors in both sexes. The NOEL is 1.5 mg/kg/day.

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

8. Chronic/carcinogenicity study in rats was administered for in the diet at doses of 0, 12, 50, 100, or 200 ppm (0, 0.6, 2.5, 5, or 10 mg/kg/day). Chronic LOEL is 5 mg/kg/day based on the increased incidence of tremors in both sexes and possible increases in organ-to-body weight ratios in males. Chronic NOEL is 2.5 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

9. In a pilot developmental study in rats bifenthrin was administered in the diet at dose levels of 0, 0.5, 1.0, 2.0, or 2.5 mg/kg/day during days 6–15 of gestation. Three of 10 rats at 2.5 mg/kg/day died on days 14–15. Tremors were noted in all 10 rats at 2.5 mg/kg/day and in 9/10 at 2.0 mg/kg/day. Mean bwt gains were depressed at 2.5 mg/kg/day throughout the study, and food consumption was 20 percent lower at this dose level during days 6–13. There were no differences in mean bwt gains or food consumption in the lower dose groups with respect to the controls. There were no treatment-related differences from controls in the number of implantations or litter size. The mean number of resorptions was similar in the lower dose groups; at 2.5 mg/kg/day it was somewhat higher, but this was attributable to an excessive number of resorptions in a single rat. The maternal LOEL is 2.0 mg/kg/day based on sporadic tremors (gestation days 7–18) and 30 percent mortality at 2.5 mg/kg/day. The maternal NOEL is 1.0 mg/kg/day. The developmental LOEL and NOEL were not determined; fetuses were not examined.

10. A developmental study in rats given gavage doses of 0, 0.5, 1.0, or 2.0 mg/kg/day was administered. Developmental toxicity was noted at 2.0 mg/kg/day and was characterized as an increased fetal and litter incidence of hydroureter. Although not statistically significant, the incidence of hydroureter was double that of the vehicle control and the lower dose groups. Developmental LOEL is 2.0 mg/kg/day based on the increased fetal and litter incidence of hydroureter. Developmental NOEL is 1.0 mg/kg/day. Maternal toxicity NOEL was 1.0 mg/kg/day based on tremors at LOEL of 2.0 mg/kg/day.

11. A developmental study in rabbits given gavage doses of 0, 2.67, 4.0, or 8.0 mg/kg/day or with 3.0 gram/kilogram/day (g/kg/day) resulted in no developmental toxicity observed under the conditions of the study. The maternal NOEL is 2.67 mg/kg/day, based on head and forelimb twitching at LOEL of 4.0 mg/kg/day. The developmental NOEL is ≥ 8.0 mg/kg/day, the highest dose tested.

12. A 2-generation reproduction study in rats fed diets containing doses of 0, 30, 60, or 100 ppm (0, 1.5, 3 or 5 mg/kg/day). Systemic LOEL is 5 mg/kg/day based on the incidence of tremors and marginally lower bwts in P and F_1 generation females during gestation and lactation. Systemic NOEL is 3 mg/kg/day. A reproductive LOEL was not observed. The reproductive NOEL is 5 mg/kg/day.

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

14. In a dermal absorption study, the following doses of ^{14}C bifenthrin were administered dermally in aqueous suspension: 49.2, 514, or 5253 µg/rat. Bifenthrin is rapidly absorbed into and through the skin, with a direct correlation between the doses applied and the amount absorbed. Most of the label was recovered within the skin at the application site. Average amounts of activity absorbed at the skin site for each of the doses at the 0.5 hour sacrifice were 54.47 percent, 56.42 percent, and 52.54 percent; and at the 24-hour sacrifice were 71.34 percent, 45.33 percent, and 53.63 percent.

15. No neurotoxicity studies are available. These studies will be required under a special data call-in letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient data to support these tolerances and these additional studies will not significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For the purposes of assessing acute dietary risk, EPA has

used the maternal NOEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats. The maternal lowest effect level (LEL) of this study is 2.0 mg/kg/day, which 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 toxicity*. The maternal NOEL of 1.0 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 Unit II.B.1. of this preamble). The maternal LEL of this study of 2.0 mg/kg/day was based on tremors from day 7–17 of dosing, which was observed at this dose level in the pilot study. In comparison to the other studies, tremors were observed at the earliest time period with the lowest dose level in this study. A dermal absorption rate of 25 percent was recommended based on the weight of the evidence for structurally related pyrethroids. Although a 21-day dermal study in the rabbit is available it was not used because the rat is considered to be more sensitive than the rabbit based on comparison of the maternal NOELs and LELs in the developmental studies.

For the inhalation endpoint, no appropriate studies were available. EPA determined that the risk assessment should be inclusive of oral and inhalation exposure components assuming 100 percent absorption via the inhalation route. An aggregate oral and inhalation risk assessment is appropriate due to the similarity in the toxicity endpoint (neurotoxicity) seen in rats via these routes. The inhalation study used for comparison purposes was an acute toxicity study in rats on the 25.1 percent formulation where tremors, convulsions, and loss of hindlimb motor control was observed among other clinical signs of toxicity.

3. *Chronic toxicity*. EPA has established the RfD for bifenthrin at 0.015 mg/kg/day. This RfD is based on a 1-year oral feeding study in dogs with a NOEL of 1.5 mg/kg/day, based on intermittent tremors observed at the LOEL of 3.0 mg/kg/day; an uncertainty factor of 100 is used.

For chronic dermal occupational and residential exposure, EPA recommended the NOEL of 1.5 mg/kg/day from the chronic oral study in the dog with a dermal absorption rate of 25 percent. The LEL for the dog study was 3.0 mg/kg/day based on intermittent tremors. The recommended MOE is 100.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified bifenthrin as a Group C chemical, possible human carcinogen, based on urinary bladder tumors in mice, but did not recommend assignment of a cancer potency factor Q* (Q star) for a linear quantitative cancer risk assessment, instead, the CPRC recommended the RfD approach. Based on CPRC's recommendation that the RfD approach be used to assess dietary cancer risk, a quantitative linear dietary cancer risk assessment was not performed. Human health risk concerns due to long term consumption of bifenthrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of bifenthrin on corn (grain, forage, and fodder), cottonseed, hops, and livestock commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from bifenthrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute risk assessment used Monte Carlo modeling incorporating anticipated residue and percent crop treated refinements. The acute dietary (food only) MOE calculated at the 99.9th percentile for the most highly exposed population subgroup (children 1–6 years old) is 193. The MOE calculated at the 99.9th percentile for the general U.S. population is 466. EPA concludes that there is a reasonable certainty of no harm for MOE of 100 or greater. Therefore, the acute dietary risk assessment for bifenthrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk*. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The risk assessment resulted in use of 0.2 percent of the RfD for the U.S. population and 0.3 percent of the most highly exposed population subgroup (children 1–6 years old).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. The chronic dietary risk assessment used percent crop treated information and anticipated residues.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the antipicated residue levels of pesticide chemicals that have been measure 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, and a demonstration must be made to show 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. Section 408 (b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

(1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

(2) That the exposure estimate does not underestimate the exposure for any significant subpopulation.

(3) Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for bifenthrin were derived from Federal and market survey data. EPA considers these reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Date Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water*. Laboratory and field data have demonstrated that bifenthrin is immobile in soil and will

not leach into ground water. Other data show that bifenthrin is virtually insoluble in water and extremely lipophilic. As a result, EPA concludes that residues reaching surface waters from field runoff will quickly absorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM). Based on this screening assessment, the potential concentrations of a pyrethroid in groundwater at depths of 1 and 2 meters are essentially zero (<< 0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM2 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 0.052 ppb. Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived from surface water would normally be treated before consumption. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk*. The acute drinking water exposure and risk estimates are 0.000060 mg/kg/day (MOE 16,664) and 0.000115 mg/kg/day (MOE 8,658) for the overall population and non-nursing infants < 1 year old respectively.

ii. *Chronic exposure and risk*. The chronic drinking water exposure and risk estimates are 0.000001 mg/kg/day (0.0 percent RfD utilized) and 0.000002 mg/kg/day (0.0 percent of RfD utilized) for the overall population and non-nursing infants < 1 year old respectively.

3. *From non-dietary exposure*. Bifenthrin is currently registered for use on the following residential non-food sites: General indoor/outdoor pest control, termiticide, ornamental plants and lawns around homes, park, recreation areas and athletic fields, and golf courses turf. Application of this pesticide in and around these sites is mainly limited to commercial applicators. Analyses were conducted which included an evaluation of potential non-dietary (residential) applicator, post-application and chronic dietary aggregate exposures associated with bifenthrin products used for residential flea infestation control and agricultural/commercial applications. The aggregate analysis conservatively assumes that a person is concurrently exposed to the same active ingredient via the use of consumer or professional flea infestation control products and to chronic level residues in the diet.

In the case of potential non-dietary health risks, conservative point estimates of non-dietary exposures, expressed as total systemic absorbed dose (summed across inhalation and incidental ingestion routes) for each relevant product use category (i.e. lawn care) and receptor subpopulation (i.e. adults, children 1–6 years old and infants < 1 year old) are compared to the systemic absorbed dose NOEL for bifenthrin to provide estimates of the MOEs. Based on the toxicity endpoints selected by EPA for bifenthrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOEL for estimating MOEs.

In the case of potential aggregate health risks, the above-mentioned conservative point estimates of inhalation and incidental ingestion non-dietary exposure (expressed as systemic absorbed dose) are combined with estimates (arithmetic mean values) of chronic average dietary (oral) absorbed doses. These aggregate absorbed dose estimates are also provided for adults, children 1–6 years old and infants < 1 year old. The combined or aggregated absorbed dose estimates (summed across non-dietary and chronic dietary) are then compared with the systemic absorbed dose NOEL to provide estimates of aggregate MOEs.

The short and intermediate-term non-dietary and aggregate (non-dietary + chronic dietary (food and water) MOEs for bifenthrin indicate a substantial degree of safety. The total non-dietary (inhalation + incidental ingestion + dermal) MOEs for post-application exposure for the lawn care product evaluated was estimated to be > 51,000 for adults, 1,900 for children 1–6 years old and 1,800 for infants < 1 year. The aggregate MOE (inhalation + incidental oral + dermal + chronic dietary, summed across all product use categories) was estimated to be 417 for adults, 196 for children 1–6 years old and 200 for infants (< 1 year old).

It can be concluded that the potential non-dietary and aggregate (non-dietary + chronic dietary) exposures for bifenthrin are associated with substantial margins of safety.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' 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 acumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, bifenthrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this

tolerance action, therefore, EPA has not assumed that bifenthrin has a common mechanism of toxicity with other substances.

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

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the U.S. population is 453. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or large. Therefore, the Agency has no acute aggregate concern due to exposure to bifenthrin through food and drinking water.

2. *Chronic risk*. Using the Anticipated Residue Concentrations (ARC) exposure assumptions described in Unit II.C.1.ii. of this preamble, EPA has concluded that aggregate exposure to bifenthrin from food and water will utilize 0.2 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1–6 year old (discussed in Unit II.F. of this preamble). EPA generally has no concern for exposures below 100 percent 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. Therefore, EPA does not expect the aggregate exposure to exceed 100 percent of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to bifenthrin residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. As indicated above the non-dietary and chronic dietary MOEs was estimated to be 417 for adults.

E. Aggregate Cancer Risk for U.S. Population

As indicated in Unit II.B.4. of this preamble, based on EPA's recommendation that the RfD approach be used, a quantitative dietary cancer risk assessment was not performed. Human health risk concerns due to long term consumption of bifenthrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

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

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of bifenthrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from 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 10-fold 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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOEL of 4 mg/kg/day. 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 percent) 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 percent with a maximum incidence of 90 percent.

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

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

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

v. *Conclusion*. The toxicological data base related to pre- and post-natal sensistivity is complete. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Aggregate acute risk*. The aggregate acute MOE calculated at the 99.9th percentile for children age 1–6 is 191. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to bifenthrin through food and drinking water.

3. *Aggregate chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 0.3 percent of the RfD for children 1–6 years old. EPA generally has no concern for exposures below 100 percent 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.

4. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. As indicated above the non-dietary and chronic dietary MOEs was

estimated to be 196 for children 1–6 year old and 200 for infants (1 year old).

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to bifenthrin residues.

G. Endocrine Disruption

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

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of bifenthrin in plants and animals is adequately understood. Studies have been conducted to delineate the metabolism of radio labelled bifenthrin in various crops and animals all showing similar results. The residue of concern is the parent compound only.

B. Nature of the Residue

Nature of the residue studies in corn, ruminants and poultry for bifenthrin have been adequately defined. The EPA Health Effect Division (HED) Metabolism Committee concluded that only the parent compound should appear in the tolerance expression for corn grain, forage, fodder, ruminant, and poultry commodities. No special concern was expressed about the principal metabolite in corn, 4′-hydroxy bifenthrin. The metabolite typically is found in corn forage or fodder at about 1/10 the concentration of parent and is also a rat metabolite of bifenthrin. Similarly, no concern was raised over biphenyl alcohol, the only metabolite predicted to be present in ruminant tissue in detectable concentrations. EPA estimated that the maximum concentration of this metabolite in ruminant tissue would be 0.04 ppm in fat. Neither bifenthrin nor its metabolites are likely to be present in poultry and eggs in detectable concentrations.

C. Analytical Enforcement Methodology

An enforcement method Gas Chromatography/Electron Capture Detector (GC/ECD) for the determination of residues of bifenthrin in cottonseed has been sent to the FDA for inclusion in Pesticide Analytical Method II (PAM II). Additionally, EPA has recently concluded that another method (Method P–2550M, GC/ECD large bore fused silica column) is suitable as an enforcement method for the determination of bifenthrin residues in corn matrices.

D. Magnitude of Residues

Crop field trial residue data from studies conducted at the maximum label rates for cotton, corn (field, seed, pop), strawberries, and hops show that the established bifenthrin tolerances on cottonseed of 0.5 ppm, corn, grain (field, seed, and pop) of 0.05 ppm, corn, fodder of 5.0 ppm, corn, forage of 2.0 ppm, strawberries of 3.0 ppm, and hops, dried of 10.0 ppm will not be exceeded when the bifenthrin products labeled for these uses are used as directed.

F. International Residue Limits

Codex Maximum Residue Levels (MRLs) for bifenthrin have been established which are in harmony with the U.S. tolerances for cattle meat (0.5 ppm), corn grain (0.05 ppm), poultry fat (0.05 ppm), poultry meat (0.05 ppm), and poultry meat byproducts (0.05 ppm). Codex MRLs have been established which exceed the U.S. tolerances for horse fat (10.0 vs. 1.0 ppm). Codex MRLs have been established which are below their U.S. counterparts for cattle fat (0.5 vs 1.0 ppm), cattle meat byproducts (0.05 vs. 0.10 ppm), corn forage (0.05 vs. 2.0 ppm), corn fodder (0.2 vs. 5.0 ppm), eggs (0.01 vs.0.05 ppm), and whole milk (0.05 vs. 0.1 ppm).

As indicated above there are differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods used to establish tolerances, calculate animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

No Canadian MRLs have been established for residues of bifenthrin. Mexico has established a tolerance for residues of bifenthrin on cottonseed (0.5 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, tolerances are established for bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and meat by-products (mbyp) of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.10 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300579] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may 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.

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

VII. Regulatory Assessment Requirements

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

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

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 14, 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. Section 180.442 is amended by revising paragraph (a) and removing the entire entry for ''Raspberries'' in the table in paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* 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-dimethylcyclopropanecarboxylate in or on the raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, mbyp	0.10
Cattle, meat	0.5
Corn, fodder	5.0
Corn, forage	2.0
Corn, grain (field, seed, and pop)	0.05
Cottonseed	0.5
Eggs	0.05
Goats, fat	1.0
Goats, mbyp	0.10
Goats, meat	0.5
Hogs, fat	1.0
Hogs, mbyp	0.10
Hogs, meat	0.5
Hops, dried	10.0
Horses, fat	1.0
Horses, mby	0.10

Commodity	Parts per million
Horses, meat	0.5
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	1.0
Sheep, mbyp	0.1
Sheep, meat	0.5
Strawberries	3.0

* * * * *

[FR Doc. 97–30948 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300587; FRL–5757–4]

RIN 2070–AB78

Fipronil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]4-[(trifloumethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on field corn grain, stover, and forage; milk fat, (reflecting residues in whole milk); eggs; poultry fat, meat, and meat byproducts; hog fat, meat, meat byproducts, and liver; and liver, fat, meat, and meat byproducts of cattle, goat, horse, and sheep. In petition number 5F4426 Rhone Poulenc AG, Inc. requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300587], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300587], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300587]. 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: Marion Johnson, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6788, e-mail: johnson.marion@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 1997 (62 FR 33641)(FRL–5723–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of a pesticide petition for a tolerance (PP 5F4426) by Rhone Poulenc AG Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by Rhone Poulenc, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on the following items: corn, field, grain — 0.02 ppm; corn, field, stover — 0.30 ppm; corn, field, forage — 0.15 ppm; Milk, fat (reflecting 0.05 ppm in whole milk) — 1.50 ppm; Liver of cattle, goat, horse and sheep — 0.10 ppm; eggs — 0.03 ppm; Fat of cattle, goat, horse and sheep — 0.40 ppm; poultry fat — 0.05 ppm; meat of cattle, goat, horse and sheep — 0.04 ppm; poultry meat — 0.02 ppm; meat byproducts (except liver) of cattle, goat, horse and sheep — 0.04 ppm; poultry meat byproducts — 0.02 ppm; hog fat — 0.04 ppm; hog liver — 0.02 ppm; hog meat byproducts (except liver) — 0.01 ppm; hog meat — 0.01 ppm.

I. Risk Assessment and Statutory Findings

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and