ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180

[OPP–300484; FRL–5715–6]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes time-limited tolerances with an expiration date of November 15, 1997 for residues of the pyrethroid cyfluthrin in or on the food commodities group citrus fruit and a maximum residue limit for cyfluthrin on citrus oil and dried pulp. A petition was submitted by Bayer Corporation to EPA under the Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance. This tolerance will expire and is revoked on November 15, 1997.

DATES: This regulation becomes effective May 9, 1997. Written objections and requests for hearings must be received by July 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300484], 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–300484], should be submitted to: Public Response and Program Resources Branch, Field Operations 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.

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 number [OPP–300484]. 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: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the July 13, 1994 **Federal Register** (59 FR 35717)(FRL–4871–5), which announced that Miles Corporation had submitted a pesticide petition (4F4313) to EPA and a food/feed additive petition (FAP) 4H5687 to EPA. Pesticide petition 4F4313 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug an Cosmetic Act, 21 U.S.C. 346a(d), amend 40 CFR 180.436 to establish tolerances for residues of the insecticide cyfluthrin, ([cyano-[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dicloroethenyl]-2,2-dimethylcyclopropanecarboxylate]; CAS No. 68359–37–5; EPA Chemical No. 128831) in or on the food commodities group citrus, fruits at 0.2 parts per million (ppm). Food/feed additive petition 4H5687 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348), amend 40 CFR parts 185 and 186 by establishing a food/feed additive regulation for cyfluthrin in or on the process commodities citrus oil and citrus dried pulp at 0.3 ppm. The Agency was unable to publish a final rule prior to the enactment of the Food Quality and Protection Act (FQPA) of 1996. Because of new procedures under FQPA Bayer Corporation was required to submit a new notice of filing requesting issuance of these tolerances in compliance with FQPA.

In the **Federal Register** of March 14, 1997 (62 FR 12182)(FRL–5990–2) EPA issued a second notice of filing to bring the notice into conformity with the FQPA. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and assessments to support its conclusion that the petition complied with FQPA.

There were no comments received in response to the notices of filing.

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 Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. 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.

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, 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 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level.

II. 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 (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 significant 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.

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 margin of exposure 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, FQPA 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. 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 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.

Consistent with sections 408(b)(2)(C)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for cyfluthrin its evaluation of application for registration on citrus. EPA has sufficient data to assess the hazards of cyfluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting time-limited tolerances for residues of cyfluthrin on citrus at 0.2 ppm, and citrus oil and dried pulp at 0.3 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing these tolerances follows:

A. Toxicology Database

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 cyfluthrin are discussed below.

1. *Acute studies*. A battery of acute toxicity studies placing technical cyfluthrin in toxicity category II.

2. *Chronic studies*. i. A 12–month chronic feeding study in dogs with a no-observed effect level (NOEL) of 4 milligram per kilogram per day (mg/kg/day). The lowest effect level (LEL) for this study is established at 16 mg/kg/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

ii. A 24–month chronic feeding/carcinogenicity study in rats with a NOEL of 2.5 mg/kg/day and LEL of 6.2 mg/kg/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

iii. A 24–month carcinogenicity study in mice. There were no carcinogenic effects observed under the conditions of the study.

3. *Developmental and reproductive effects studies*. i. An oral rat developmental toxicity study, the maternal (systemic) NOEL is 3 mg/kg/day. The maternal (systemic) lowest observed effect level (LOEL) of 10 mg/kg/day was based on behavioral changes in gait and coordination. The developmental (fetal) NOEL is 30 mg/kg/day (highest dose tested). No developmental effects were noted.

ii. An oral rat developmental toxicity study, the maternal (systemic) NOEL is 10 mg/kg/day (highest dose tested). The developmental (fetal) NOEL is 10 mg/kg/day (highest dose tested). No developmental effects were noted.

iii. A rat inhalation developmental toxicity study, the maternal (systemic) NOEL is 0.46 mg/m^3. The maternal (systemic) LOEL 2.55 mg/m^3 was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) NOEL is 0.46 mg/m^3. The developmental (fetal) LOEL of 2.55 mg/m^3 is based on reduced fetal and placental weight, reduced ossification in the phalanges, metacarpals and vertebrae.

iv. An oral rabbit developmental toxicity study, the maternal (systemic) NOEL is 20 mg/kg/day. The maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption during the dosing period. The developmental (fetal) NOEL is 20 mg/kg/day. The developmental (fetal) LOEL is 60 mg/kg/day based on statistically significant increase in the numbers of resorptions and statistically significant post-implantation loss.

v. An oral 3-generation reproduction study, the systemic NOEL is 1.5 mg/kg/day. The systemic LOEL of 4.5 mg/kg/day was based on body weight decrease in pups. The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

4. *Other studies.* i. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary(CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

ii. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed. The NOEL for dermal and systemic toxicity was 1,000 mg/kg/day (limit dose). New Zealand White strain rabbits were given 15 dermal applications at 0, 100, 500, or 1,000 mg/kg/day for 21 days. Under the conditions of the test, there was no evidence of treatment-related toxicity from dermal application at doses up to 1,000 mg/kg/day.

The toxicity database for cyfluthrin is essentially complete. Data lacking but desirable are a new 21–day subchronic dermal study, an acute neurotoxicity study in rats, a 90–day neurotoxicity study in rats, and a dermal sensitization study on the end-use product, Baythroid 2. These studies have been submitted to the Agency and are currently under review, with the exception of the acute and 90–day neurotoxicity studies. Bayer Corporation has committed to submit the results of these neurotoxicity studies to the Agency by July 1997. Although these data are lacking, the Agency believes it has sufficient toxicity data to support the proposed tolerance and these additional studies will not significantly change its risk assessment.

B. Toxicological Profile

1. *Toxicity endpoints for dietary exposure*— i. *acute*. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits. This risk assessment will evaluate acute dietary risk to females 13+ years and older.

ii. *Chronic*. A reference dose (RfD) of 0.025 mg/kg/day has been estimated by the Agency. The RfD was established based on the rat chronic feeding/carcinogenicity study with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100.

iii. *Carcinogenicity*. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

2. *Toxicity endpoints for non-dietary exposure—i. short and intermediate term residential dermal and/or inhalation exposure.* For short-and intermediate term dermal exposure, the agency used the dermal toxicity NOEL of 250 mg/kg/day (highest dose tested) from the 21–day dermal rabbit toxicity study. For short- and intermediate-term inhalation exposure, the Agency used the inhalation developmental study in rats, where the maternal threshold NOEL was 0.00046 based on decreased body weight gain and reduced relative food efficiency at the LOEL of 0.0025 milligrams per liter (mg/L). The developmental NOEL of 0.00046 mg/l was based on reduced fetal weights, reduced placental weights, and reduced ossification in the phalanx, metacarpals and vertebrae at the LOEL of 0.0025 mg/L (0.46 mg/kg/day).

ii. *Chronic residential exposure.* Based upon the registered indoor/outdoor uses of cyfluthrin, exposure from these uses are expected to be from inhalation and/or dermal contact. EPA has no quantitative data on dermal absorption for the formulations of this pesticide, nor does it have reliable data for indoor/outdoor exposures. Estimations of outdoor residential exposure have been required for cyfluthrin in a data call-in issued in 1995. These data are being generated by the Outdoor Residential Exposure Task Force. Without these data EPA cannot determine the risk to the public exposed by the non-dietary uses of this pesticide. For this reason EPA is using a maximum default assumption of 20% of the RfD (0.025 mg/kg/day) as the exposure for these uses.

iii. *Dermal penetration*. The default value of 100% is being used for dermal penetration in the absence of actual data.

C. Aggregate Exposure

1. *From food and feed uses.* The primary source of human exposure to cyfluthrin will be from ingestion of both raw and processed food commodities treated with cyfluthrin. These commodities include the current citrus fruit group plus citrus oil and dried pulp and other commodities listed in 40 CFR 180.436, 185.1250 and 186.1250. Any secondary residues occurring in cattle meat, meat byproducts, milk and fat from the addition of the feed items citrus dried pulp will be covered by existing tolerances. There is no reasonable expectation of finite residues in poultry and swine, therefore the necessity or adequacy of tolerances for these commodities is not an issue relevant to the use on citrus.

The Agency has requested additional confirmatory animal feeding study data on levels of the metabolite DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) in animal commodities.

2. *From potable (drinking) water.* There is no established Maximum Concentration Level for residues of cyfluthrin in drinking water. Although data indicate little potential for soil mobility or leaching, cyfluthrin is moderately persistent. 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 indoor/outdoor residential sites.

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 or 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 below the level that would cause cyfluthrin to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with cyfluthrin 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 tolerance is granted.

3. *From non-dietary uses.* Cyfluthrin is registered for use on non-food sites including golf courses, lawns, ornamental shrubs, indoor foggers, and wood surfaces. Upon considering the registered uses, formulation types, persistence, and toxicological endpoints, and in accordance with the Agency's Interim Decision Logic (PR

97–1, Jaunary 31, 1997), EPA has determined that, in the absence of exposure data, the registered non-dietary, non-occupational uses of cyfluthrin should be assigned a default value of 20% of the acceptable aggregate chronic; and short- and intermediate-term risk.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Cyfluthrin is a member of the synthetic pyrethroid class of pesticides. 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).

Although cyfluthrin is structurally similar to other members of the synthetic pyrethroid class of insecticides, EPA does not have, at this time, available data to determine whether cyfluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that cyfluthrin has a common mechanism of toxicity with other substances.

D. Aggregate Risk Assessment

1. *Acute aggregate risk.* The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated. Thus, this acute dietary exposure estimate is considered conservative; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate. A Monte Carlo analysis is a probabilistic risk assessment methodology in which a distribution of expected residues (also consumption estimates) is considered, instead of a single value such as the tolerance level. The estimated acute dietary risk, using a high-end exposure of 0.03 mg/kg/day, resulted in an MOE = 666 for the population of concern (females, 13+ years).

The acute aggregate risk assessment takes into account exposure from dietary food only. As indicated above, although EPA has not identified a water exposure figure based upon available environmental data, cyfluthrin is not expected to be mobile in soil or water environments and poses relatively little threat to drinking water. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from 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 1 day exposure is a reasonably probable event. It is highly unlikely that, in 1 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.

An acute dietary MOE of greater than 100 would not be of concern to EPA. As indicated above, the MOE for females 13+ years was calculated to be 666. Under any bounding assumption EPA is considering for exposure from drinking water, this MOE would not be reduced to less than 100. Therefore, EPA has no acute aggregate concern due to exposure to cyfluthrin through food and drinking water.

2. *Short- and intermediate term aggregate risk.* In the absence of exposure data, EPA is reserving a default value of 20% for residential exposures. However, as non-quantifiable exposures can not be included in MOE calculations, the short-term MOE will include only dietary exposure. Since the short term NOEL is based on a 21 day dermal exposure toxicity, the dermal exposure will be adjusted for a dietary endpoint (from the developmental study). The NOEL from the developmental study (20 mg/kg/day) is 12.5-fold lower than that of the 21–day dermal study (250 mg/kg/day). The adjusted chronic dietary exposure is thus 0.339 mg/kg/day (TMRC of 0.0271 mg/kg/day multiplied by 12.5). As the calculated MOE for children (1 to 6 years old) is 737 (short term NOEL of 250 mg/kg/day divided by adjusted dietary exposure of 0.339 mg/kg/day), the addition of any bounding assumption EPA is considering for exposures from dietary water and residential sources is unlikely to result in a MOE of <100. EPA thus considers the short- and intermediate term risk to be acceptable for the purposes of establishing the proposed tolerances.

3. *Chronic aggregate risk.* The chronic dietary (food only) risk assessment used anticipated residues and percent crop treated for certain crops. Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using the 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, to pesticide residues. The resulting exposure

estimates should therefore be viewed as partially refined. Further refinement using anticipated residues and percent crop treated for all commodities would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the population subgroup with the largest percentage of the RfD occupied is children (non-nursing infants, <1 years old) at 13% of the RfD.

Section 408 (b)(2)(E) requires that, if EPA relies upon anticipated residue levels in setting a tolerance, EPA must require that data be submitted 5 years after approval of the tolerance on whether the anticipated residue level remains accurate. Because this tolerance is limited to less than 1 year, data are not being required at this time.

The aggregated chronic risk is equal to the sum of the chronic risk for food, drinking water, and indoor and outdoor residential exposures. For cyfluthrin, residential exposure data are lacking although the potential for exposure does exist. Therefore, residential exposure was also aggregated with dietary exposure in the chronic risk assessment. The aggregated chronic risk for the population subgroup non-nursing infants less than 1 year old from combined sources is 33% of the RfD (dietary = 13% + non-occupational = 20%). Under any bounding assumptions EPA is considering for exposure from drinking water, exposure to cyfluthrin would not exceed the RfD. EPA therefore concludes that there is reasonable certainty that no harm will result to consumers, including infants and children, from aggregate exposure to cyfluthrin residues.

4. *Determination of safety for infants and children.* 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 margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/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 margin/factor.

In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, EPA considered data from oral developmental toxicity studies in the rat and rabbit, as well data from 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 the mothers. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

5. *Pre-natal effects.* In the oral rat developmental toxicity studies, maternal (systemic) effects consisting of behavioral changes in gait and coordination were the basis of the maternal LOEL of 10 mg/kg/day. No developmental (fetal) effects were noted in doses up to 30 mg/kg/day (highest dose tested). In the oral rabbit developmental study, no developmental toxicity was observed at doses where maternal toxicity was noted. The maternal (systemic) NOEL is 20 mg/kg/day and the maternal (systemic) LOEL of 60 mg/kg/day was based on decreased body weight gain and food consumption. The developmental (fetal) NOEL is 20 mg/kg/day and the developmental (fetal) LOEL of 60 mg/kg/day was based on increases in the numbers of resorptions and post-implantation loss.

In an inhalation developmental toxicity study, the maternal (systemic) and developmental (fetal) NOELs are 0.46 mg/m^3 and the maternal (systemic) and developmental (fetal) LOELs are 2.55 mg/m^3. The maternal (systemic) LOEL was based on decreased body weight gain and reduced food efficiency. The developmental (fetal) LOEL was based on reduced fetal and placental weight and reduced ossification. The weight of the evidence from this study would suggest that cyfluthrin exposure caused developmental toxicity indirectly through bradypnea (abnormal slowness of breathing) in the dams.

6. *Post-natal effects.* In the rat 2-generation reproduction study, parental toxicity was observed at 4.5 mg/kg/day based on body weight decrease in pups (weaned for the next generation). The reproductive (fetal) NOEL is 4.5 mg/kg/day. The reproductive (fetal) LOEL is 7.5 mg/kg/day based on decreased pup viability.

These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or post-natal sensitivity. Therefore, EPA concludes that reliable data support use of a hundredfold safety factor, and an additional tenfold safety factor is not needed to protect the safety of infants and children.

E. Other Considerations

1. *Endocrine effects.* No evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that cyfluthrin causes endocrine effects.

2. *Metabolism and nature of the residue.* The nature of the residue in plants and animals is adequately understood. The residue of concern is parent cyfluthrin. Any secondary residues occurring in cattle meat, meat by-products, milk and fat from the consumption of cyfluthrin treated citrus will be covered by the existing tolerances for these commodities.

3. *Analytical methodology.* Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. EPA has provided information on this method to the Food and Drug Adminstration. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations 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.

4. *International tolerances.* There are no Codex, Canadian or Mexican maximum residue limits (MRLs) for residues of cyfluthrin in/on citrus.

F. Summary of Findings

Tolerances are time-limited to allow for development and review of supplemental toxicity data; animal feeding data for a metabolite of cyfluthrin; and residential, water and cumulative exposure data. These tolerances will expire and be revoked by EPA on November 15, 1997. After that November 15, 1997, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

EPA concludes that the time-limited tolerances will be safe. Therefore the tolerances are established as set forth.

III. 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 the new section 408(d) 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 given 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 its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 8, 1997, 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 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.

IV. 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–300484 (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–300484. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

V. Regulatory Assessment Requirements

Under Executive Order 12866 (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 mandate 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), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. 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 recordkeeping requirements.

Dated: April 30, 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 for part 180 continues to read as follows:

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

2. Section 180.436 is amended by revising the introductory text to paragraph (a), by revising the column headings to the table in paragraph (a), and by alphabetically adding entries for citrus crop group; citrus oil; and citrus dried pulp.

§ 180.436 Cyfluthrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 68359–37–5) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation date
* * *	* * *	* * *
Citrus crop group.	0.2	Nov. 15, 1997

Commodity	Parts per million	Expiration/ Revocation date
Citrus dried pulp.	0.3	Do.
Citrus oil	0.3	Do.
*	* *	* *

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[FR Doc. 97–12195 Filed 5–8–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 180

[OPP–30113; FRL–5714–1]

Tolerance Processing Fees

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This rule increases fees charged for processing tolerance petitions for pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). The change in fees reflects a 3.33 percent increase in locality pay for civilian Federal General Schedule (GS) employees working in the Washington, DC/Baltimore, MD metropolitan area in 1997.

EFFECTIVE DATE: June 9, 1997.

FOR FURTHER INFORMATION CONTACT: For information concerning this rule: By mail: Edward Setren, Immediate Office, Resources Management Staff (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 700–I, CM#2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–5927), e-mail:setren.Edward@epamail.epa.gov. For further information concerning tolerance petitions and individual fees contact: Sonya Brooks at the same address, telephone (703) 308–6428, e-mail: brooks.sonya@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The EPA is charged with administration of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 authorizes the Agency to establish tolerance levels and exemptions from the requirements for tolerances for food commodities. Section 408(o) requires that the Agency collect fees as will, in the aggregate, be sufficient to cover the costs of processing petitions for pesticide products, i.e., that the tolerance process be as self-supporting as possible.

The current fee schedule for tolerance petitions (40 CFR 180.33) was published in the **Federal Register** on May 3, 1996 (61 FR 19850)(FRL–5365–2) and became effective on June 3, 1996. At that time the fees were increased 2.54 percent in accordance with a provision in the regulation that provides for automatic annual adjustments to the fees based on annual percentage changes in Federal salaries. The specific language in the regulation is contained in paragraph (o) of § 180.33 and reads in part as follows:

(o) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale.... When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the **Federal Register** as a final rule to become effective 30 days or more after publication, as specified in the rule.

The Federal Employees Pay Comparability Act of 1990 (FEPCA) initiated locality-based comparability pay, known as ''locality pay''. The intent of the legislation is to make Federal pay more responsive to local labor market conditions by adjusting General Schedule salaries on the basis of a comparison with non-Federal rates on a geographic, locality basis.

The processing and review of tolerance petitions is conducted by EPA employees working in the Washington, DC/ Baltimore, MD pay area. The pay raise in 1997 for Federal General Schedule employees working in the Washington, DC/Baltimore, MD metropolitan pay area is 3.33 percent; therefore, the tolerance petition fees are being increased 3.33 percent. The entire fee schedule, § 180.33, is presented for the reader's convenience. (All fees have been rounded to the nearest $25.00.)

List of Subjects in 40 CFR Part 180

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

Dated: April 30, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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 180.33 is revised to read as follows:

§ 180.33 Fees.

(a) Each petition or request for the establishment of a new tolerance or a tolerance higher than already established, shall be accompanied by a fee of $64,025, plus $1,600 for each food commodity more than nine on which the establishment of a tolerance is requested, except as provided in paragraphs (b), (d), and (h) of this section.

(b) Each petition or request for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the same pesticide chemical, or for the establishment of a tolerance on additional food commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a fee of $14,650 plus $975 for each food commodity on which a tolerance is requested.

(c) Each petition or request for an exemption from the requirement of a tolerance or repeal of an exemption shall be accompanied by a fee of $11,800.

(d) Each petition or request for a temporary tolerance or a temporary exemption from the requirement of a tolerance shall be accompanied by a fee of $25,575 except as provided in paragraph (e) of this section. A petition or request to renew or extend such temporary tolerance or temporary exemption shall be accompanied by a fee of $3,625.

(e) A petition or request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level or a higher numerical level shall be accompanied by a fee of $12,750 plus $975 for each food commodity on which the temporary tolerance is sought.

(f) Each petition or request for repeal of a tolerance shall be accompanied by a fee of $8,000. Such fee is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be repealed and a fee is paid as required by paragraph (a) of this section.

(g) If a petition or a request is not accepted for processing because it is technically incomplete, the fee, less $1,600 for handling and initial review, shall be returned. If a petition is withdrawn by the petitioner after initial processing, but before significant Agency scientific review has begun, the fee, less $1,600 for handling and initial review, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were being submitted for the first time.

(h) Each petition or request for a crop group tolerance, regardless of the number of food commodities involved, shall be accompanied by a fee equal to