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Environmental Protection Specialist.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300576; FRL–5754–9]

RIN 2070–AB78

Tefluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of tefluthrin and its metabolite in or on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 parts per million (ppm). It also removes time limitations for tolerances for residues of tefluthrin on the same commodities that expire on November 15, 1997. Zeneca Ag Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act 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–300576], 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–300576], 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–300576]. 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: Beth Edwards, 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) 305-5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On February 1, 1989 (54 FR 5080), EPA established time limited tolerances under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of tefluthrin on corn, grain, field, and pop; corn, forage and fodder, field and pop. As additional crop tolerances were established, they were also made time-limited. These tolerances expire on November 15, 1997. Zeneca Ag Products, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide tefluthrin in the corn commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of the registration. Zeneca Ag Products also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petitions (PP 7F3521 and 4F4406) for tolerances by Zeneca Ag Products, P.O. Box 15458, Wilmington, DE, 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.440 be amended by removing the time-limitation for tolerances for combined residues of the insecticide and pyrethroid tefluthrin and its metabolite (*Z*)-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid, in or on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 part per million (ppm).

The basis for the time-limited tolerances that expire November 15, 1997, was given in the **Federal Register** of October 20, 1993 (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 rationale 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, and 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% 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 3 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 ground water 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% 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 tefluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for combined residues of tefluthrin and its metabolite on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 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 tefluthrin are discussed below.

1. Acute toxicity studies with the technical grade of the active ingredient tefluthrin: oral LD_{50} in the rat is 21.8 milligrams/kilogram (mg/kg) for males and 34.6 mg/kg for females - Toxicity Category I; dermal LD_{50} in the rat is 316 mg/kg in males and 177 mg/kg in females - Toxicity Category I; acute inhalation LC_{50} in the rat is 0.037 mg/l and 0.049 mg/l in male and female rats, respectively - Toxicity Category I; the primary eye irritation study in the rabbit was an invalid study; primary dermal irritation study in the rabbit showed slight irritation - Toxicity Category IV; dermal sensitization study in the guinea pig showed no skin sensitization; and the acute delayed neurotoxicity study did not show acute delayed neurotoxicity.

2. In an oral toxicity study, rats were dosed at 0, 25, 100, or 400 ppm (1.25, 5, or 20 milligrans/kilogram/day) (mg/kg/day) for 21 days. The LOEL for females for this 21-day oral toxicity study is 400 ppm (equivalent to approximately 20 mg/kg/day) based on decreased body weight gain, decreased platelet counts, and increased WBC and lymphocytes in the high-dose females. The NOEL for females is 100 ppm (equivalent to approximately 5 mg/kg/day). The NOEL in males was not observed.

3. In a subchronic oral toxicity study, rats were dosed at 0, 50, 150, or 350 ppm (2.5, 7.5, or 17.5 mg/kg/day) for 90 days. The LOEL for this 90-day feeding study is 150 ppm (equivalent to approximately 7.5 mg/kg/day) based on changes in hemoglobin, cholesterol, and liver weight in the mid-dose animals. The NOEL is 50 ppm (equivalent to approximately 2.5 mg/kg/day).

4. In a subchronic oral toxicity study, dogs were dosed at 0, 0.1, 0.5, or 1.5 mg/kg/day for 90 days. The LOEL for this 90-day oral toxicity study is 1.5 mg/kg/day based on thyroid changes, and increased levels of plasma triglycerides and aspartate transaminase observed at the high-dose. The NOEL is 0.5 mg/kg/day.

5. In an oral toxicity study, mice were dosed at 0, 25, 75, 200, or 400 ppm (0, 3.75, 11.3, 30.0, or 60.0 mg/kg/day) for 28 days. The LOEL is 400 ppm (equivalent to approximately 60 mg/kg/day) based on decreased body weight gains in both sexes and final body weights in females. The NOEL is 200 ppm (equivalent to approximately 30 mg/kg/day).

6. In a dermal toxicity study, rats were dosed at 0, 0.1, 1.0, or 50 mg/kg. The LOEL for skin effects for this 21-day dermal toxicity study is 50.0 mg/kg based on acanthosis, necrosis epidermis, and inflammatory cell infiltrate dermis observed in the high-dose animals. The NOEL for skin effects is 1.0 mg/kg). The NOEL for neurological effects (the observed postural effects) may be between 0.025 and 0.1 mg/kg.

7. In a chronic/oncogenicity study, mice were dosed at 0, 25, 100, or 400 ppm (actual dose levels were equivalent to 3.4, 13.5, or 54.4 mg/kg/day) for 104 weeks. The chronic LOEL is 13.5 mg/kg based on hemangiomatous changes of the uterus and liver necrosis observed in the mid- and high-dose females. The chronic NOEL is 3.4 mg/kg. Under the conditions of this study, there was no evidence of carcinogenic potential.

8. In a chronic toxicity study, dogs were dosed at dose levels of 0, 0.1, 0.5, and 2 mg/kg/day for 12 months. The LOEL for this chronic study is 2.0 mg/kg/day based on the increased incidence of ataxia in both sexes at the high-dose. The NOEL is 0.5 mg/kg/day.

9. In a chronic/oncogenicity study, rats were dosed for 24 months at 0, 25, 100, or 400 ppm (actual dose levels were equivalent to 1.1, 4.6, or 18.2 mg/kg/day). The chronic LOEL is 4.6 mg/kg/day based on decreased body weights, and neurotoxicity and clinical chemistry changes in the mid- and high-dose animals. The chronic NOEL is 1.1 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

10. In a developmental toxicity study, rats were dosed at 0, 1, 3, or 5 mg/kg/day from days 7 through 16 of gestation. The maternal LOEL is 3 mg/kg/day, based on treatment-related decrease body weight gains during dosing. The maternal NOEL is 1 mg/kg/day. Developmental toxicity was demonstrated at 5 mg/kg/day as an increase in the fetal incidence of bilaterally unossified calcanea (92.9% vs. 87.5% in controls, $p<0.05$; litter incidence was not shown) and a slight increase in the pes score (3.05 vs. 2.96 in controls) indicating slight inhibition of ossification at these sites. There were no treatment-related effects on the number, growth, and survival of the young in utero. In addition, the inter-group differences in the mean numbers of corpora lutea, implantations, pre- and post- implantation deaths, live fetuses, proportion of male fetuses, and fetal weights were not remarkable. The developmental LOEL is 5 mg/kg/day, based on inhibited ossification. The developmental NOEL is 3 mg/kg/day.

11. In a developmental toxicity study, rabbits were dosed at 0, 3, 6, or 12 mg/kg/day from days 7 through 19 of gestation. The maternal LOEL is 3 mg/kg/day, based on treatment-related clinical signs of toxicity (tremors). The maternal NOEL is <3 mg/kg/day. There was no developmental toxicity demonstrated at any dose level. There were no treatment-related effects on in utero survival and growth or on litter size and sex ratio of the fetuses. The skeletal variant data showed significant ($p<0.01$ or 0.05) increases in incidence of extra thoracic ribs and 27 pre-sacral vertebrae among fetuses in the dosed groups; however, when the litter was used as the unit for comparison, the incidences of these respective variants were comparable between all groups. The incidences of these variants were not biologically significant. The NOEL for developmental toxicity is 12 mg/kg/day. The developmental LOEL was not observed.

12. In a multi-generation reproduction study, rats were dosed at 0, 15, 50, or 250 ppm (0, 0.75, 2.5, or 12.5 mg/kg/day). The LOEL for parental toxicity is 12.5 mg/kg/day, based on lowered body

weight gains, and the NOEL is 2.5 mg/kg/day. The LOEL for neurotoxic effects is 2.5 mg/kg/day, based on abnormal, splayed, or high-stepping gait. The NOEL for neurotoxic effects is 0.75 mg/kg/day. Reproductive toxicity was demonstrated at the high-dose as lowered pup body weight gain throughout the study in all generations and in both sexes. Additionally, total litter weight was decreased on day 29 in all of the high-dose groups. The LOEL for reproductive toxicity is 12.5 mg/kg/day, based on lowered pup body weight gains. The reproductive NOEL is 2.5 mg/kg/day.

13. Mutagenicity. There is no mutagenicity concern. The submitted studies satisfy the pre-1991 mutagenicity test battery and the new mutagenicity testing requirements. There are seven acceptable studies: one dominant lethal study in mice; reverse mutation assay (*Salmonella typhimurium*); one forward mutation assay in mammalian cells; one mouse lymphoma assay, one *in vivo* chromosomal aberration assay, *in vitro* chromosome aberration study; one UDS assay in primary rat hepatocytes. All these studies were negative.

14. Metabolism. In both rats and dogs, when given either 1 or 10 mg/kg, most of the radioactivity was found in the feces unchanged and most urinary metabolites were conjugated. Approximately 30% of the administered dose was absorbed and excreted in the urine in both species. Single doses in both rats and dogs were excreted within 48 hours, 50–65% in feces and 20–30% in the urine. In rats, a biliary fistula experiment suggested that the radioactivity measured in the feces may be partially due to biliary excretion. Studies also suggest that oxidation precedes the ester body cleavage. In rats, the halflife in the liver is 4.8 days, in the fat is 13.3 days and in the blood is 10.6 days. In a study with rat fat, half of the radioactive residues could be attributed to the parent and the remaining residues consisted of a mixture of fatty acid esters of hydroxylated parent metabolites.

15. Neurotoxicity. No acceptable mammalian neurotoxicity studies are available. In a supplementary study, 10 animals/sex/group were given either vehicle, 2,5-hexanedione or 5 mg/kg or 15 mg/kg tefluthrin. The positive control, 2,5-hexanedione, elicited the appropriate neurotoxicological response. No consistent effects on motor or sensory nerve electrophysiology or function or clinical signs of neurotoxicity were evident in animals treated with either 5 or 15 mg/kg tefluthrin. A slight but significant increase in pull-up time was observed on day 12 in males which was accompanied by a significant decrease in both SNCV and the amplitude of the SNAP. Both quickly returned to values similar to control values, and did not decrease again.

Neurotoxicity 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 toxicity data to support these tolerances and these additional studies are not expected to significantly change the risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 0.5 mg/kg/day based on increased incidence of tremors and ataxia in both sexes of dogs at 2.0 mg/kg/day (LOEL) on day 1 of the study from the 1 year oral chronic toxicity study in dogs.

2. *Short - and intermediate - term toxicity.* For short- and intermediate term MOE's, EPA recommends use of a NOEL of 0.5 mg/kg/day based on increased incidence of tremors and ataxia in both sexes of dogs at 2.0 mg/kg/day (LOEL) from the one year oral toxicity study in dogs and use of a dermal absorption rate of 25%. A dermal absorption rate of 25% was recommended based on the weight-of-the-evidence available for structurally related pyrethroids.

3. *Chronic toxicity*. EPA has established the RfD for tefluthrin at 0.005 milligrams/kilogram/day (mg/kg/day). This RfD is based on increased incidence of tremors and ataxia in both sexes of dogs in a chronic toxicity study and an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. No evidence of carcinogenicity was demonstrated in studies conducted with mice or rats.

C. Exposures and Risks

1. *From food and feed uses.*Tolerances have been established (40 CFR 180.440) for the combined residues of tefluthrin and its metabolite, in or on corn. Risk assessments were conducted by EPA to assess dietary exposures and risks from tefluthrin 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 one day or single exposure. Percent of crop treated data and tolerance values were used in conjunction with Monte Carlo. The acute dietary MOE at the 99.9th percentile for the most highly exposed population subgroup (non-nursing infants <1 year old) is 691. The MOE at the 99.9th percentile for the general U.S. population is 1,469. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for tefluthrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The chronic dietary exposure assessment used tolerance values and percent crop treated information. The RfD used for the chronic dietary analysis is 0.005 mg/kg/day. The risk assessment resulted in use of less than one percent (0.1%) of the RfD for the U.S. population. The percent of the RfD used for the most highly exposed population subgroup (children ages one to six) is 0.3%.

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 tolerance levels and percent of crop treated refinements. The chronic dietary risk assessments used tolerance levels and percent crop treated information.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe 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 and; (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 tefluthrin were derived from federal and market survey data. EPA considers these data 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 crop treated, the Agency is reasonably certain that exposure is not underestimate for any significant subpopulation. 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 Data 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.* Tefluthrin is immobile in soil and, therefore, will not leach into ground water. Additionally, due to the insolubility and lipophilic nature of tefluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water.

A screening evaluation of leaching potential of a typical synthetic pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM). Based on this screening assessment, potential concentrations of a pyrethroid in ground water at depths of 1 to 2 meters are essentially zero (<0.001 ppb). Surface water concentrations for pyrethroids were estimated using PRZM1 and Exposure Analysis Modeling Systems (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulation 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 0.000040 mg/kg/day (MOE of 12,362) and 0.000078 mg/kg/day (MOE of 6,439) for the overall U.S. population and non-nursing infants <1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water exposure and risk estimates are 0.000000 mg/kg/day (0.0% of RfD utilized) and 0.000002 mg/kg/day (0.0% of RfD utilized) for the overall U.S. population and non-nursing infants <1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Tefluthrin is currently not registered for use on residential non-food sites; therefore, no non-occupational non-dietary exposure is expected.

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 tefluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tefluthrin 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 tefluthrin 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 overall U.S. population is 1,316. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger. Therefore, the Agency concludes that there is reasonable certainty that no harm will result from acute aggregate exposure to tefluthrin residues in food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Concentration (ARC) exposure assumptions described above, EPA has concluded that aggregate exposure to tefluthrin from food and water will utilize 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children age 1-6 years (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tefluthrin 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. Based on tefluthrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not

exceed levels of concern (MOE less than 100), and that there is reasonable certainty that no harm will result from aggregate exposure to tefluthrin residues.

E. Aggregate Cancer Risk for U.S. Population

No evidence of carcinogenicity was demonstrated in studies conducted mice or rats.

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 tefluthrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-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 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 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 tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the prenatal developmental toxicity studies in rats and rabbits, the developmental NOEL was greater than the maternal NOEL, indicating a lack of sensitivity to in utero exposure. In rats, the maternal NOEL (1 mg/kg/day), based on body weight decreases at the LOEL of 3 mg/kg/day, which was based on ossification reductions in the extremities at 5 mg/kg/day. In the rabbit study, maternal pyrethroid toxicity was observed at all dose levels (maternal NOEL <3 mg/kg/day), but no developmental toxicity was observed (developmental NOEL >12 mg/kg/day).

iii. *Reproductive toxicity study.* In the two-generation reproduction study in rats, offspring toxicity (reduced mean pup weight gain) was observed only at the highest dose level tested (250 ppm; 12.5 mg/kg/day), while evidence of neurotoxicity in parental animals was observed at the systemic LOEL of 50 ppm (2.5 mg/kg/day). The offspring toxicity NOEL was 50 ppm (2.5 mg/kg/day) and the parental systemic NOEL was 15 ppm (0.75 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* The data demonstrated no indication of increased sensitivity of rats or to in utero and/or postnatal exposure with tefluthrin.

v. *Conclusion.* The data base related to pre- and post-natal sensitivity 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. *Acute risk.* The acute aggregate MOE calculated at the 99.9th percentile for non-nursing infants <1 year old is 623. EPA concluded that aggregate dietary acute risk (food plus water) would not exceed levels of concern. Therefore, the Agency has no acute aggregate concern due to exposure to tefluthrin through food and drinking water.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to tefluthrin from food and water will utilize 0.3% of the RfD for children age 1-6 years. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk.* Based on tefluthrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tefluthrin residues.

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.

G. Endocrine Disrupter Effects

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

Plant metabolism studies indicate that tefluthrin *per se* is not translocated to plants but is degraded in soil to two principal metabolites that are capable of being taken up by plants. The metabolites are the products of the cleavage of the ester to the free acid (*Z*)-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylic acid (Metabolite Ia) and to 2,3,5,6-tetrafluoro-4-hydroxymethylbenzoic acid (Metabolite VI). The Agency concluded that Metabolite VI need not be regulated.

In animals, dosing with radioactive tefluthrin at level equivalent to 11 ppm in feed resulted in identifiable residues of tefluthrin and its metabolites in tissues but at levels below those capable of detection by proposed enforcement methods.

B. Analytical Enforcement Methodology

Validated enforcement analytical methods are available for tefluthrin parent (Method PPRAM No. 85/1, The Determination of Residues of Tefluthrin in Crops and Soil-A Gas-Liquid Chromatographic Method) and for Metabolite Ia (Method GRAM-028 A Gas Chromatography Method for the

Determination of Residues of the Tefluthrin Metabolite PP890 in Crops of High and Low Moisture Content). The limits of quantitation of these methods are 0.01 ppm for tefluthrin and 0.05 ppm for Metabolite Ia.

C. Magnitude of Residues

1. *Plant commodities— Field trial studies.* No residues were detected in field trials conducted at maximum label rates and minimum PHIs. Tolerances were established at the limit of quantitation of the analytical method (0.06 ppm). The 0.06 ppm tolerances were used to estimate chronic and acute dietary exposure to potential residues of tefluthrin.

2. *Animal commodities.* Studies conducted indicate that no residues are detected in animal tissues, milk, and eggs and therefore secondary residues would not be a concern. For that reason, no tolerances have been established on meat, milk, and eggs. Secondary residues were therefore not considered in these analyses.

D. International Residue Limits

There are no Codex Maximum Residue Levels established for tefluthrin. No Canadian MRLs have been established for residues of tefluthrin on corn commodities. Mexico has established a tolerance for residues of tefluthrin on corn grain (0.06 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, the tolerance is established for combined residues of tefluthrin and its metabolite in corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 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 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 Docket

EPA has established a record for this rulemaking under docket control number [OPP–300576] (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 Hwy., 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 a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). 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 and exemptions that 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 180.440 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]

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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