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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300584; FRL–5756–2]

RIN 2070–AB78

Deltamethrin and Tralomethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin and tralomethrin in or on: deltamethrin--cottonseed at 0.04 parts per million (ppm) and cottonseed oil at 0.2 ppm; and tralomethrin--broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm. It also removes time limitations for tolerances for residues of deltamethrin and tralomethrin on the same commodities that expire on November 15, 1997. AgrEvo USA Company requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104-170). These tolerances were established under petition numbers PP 2F4055, PP 6F3436, PP 4F2993, and PP 6F3309.

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–300584, 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–300584, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300584. 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: John Hebert, 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) 308–3068, e-mail: hebert.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 16, 1995 and September 15, 1985, 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 deltamethrin (60 FR 42455) (FRL–4966–3) and tralomethrin (50 FR 37851) respectively, on cottonseed. These tolerances expire on November 15, 1997. AgrEvo USA Company, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticides deltamethrin on cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm; and tralomethrin on broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm, be removed based on ecological and environmental effects data that they had submitted as a condition of the registration and time-limited tolerances. AgrEvo USA Company 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–5848–2), 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 petition (PP) for a tolerance by AgrEvo USA Company. This notice included a summary of the petition prepared by AgrEvo USA Company (acting as registered US agent for Hoechst Schering AgrEvo, S. A., Little Falls Centre, 2711 Centerville Road, Wilmington, DE 19808, the registrant. There were no comments received in response to the notice of filing.

The basis for time limited tolerances that expire November 15, 1997, was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The 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, 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.

Deltamethrin and tralomethrin are being combined for analysis under FQPA because tralomethrin is rapidly metabolized by animals to deltamethrin as a result of debromination. Results of the rat metabolism study supports this action.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes

exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects*. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed effect level'' or ''NOEL'').

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

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

2. *Differences in toxic effect due to exposure duration*. The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

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

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

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in 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.

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 this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

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 deltamethrin and tralomethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), to remove the time limitation for a tolerances for residues of deltamethrin--cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm; and tralomethrin--broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 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 deltamethrin and tralomethrin are discussed below.

Deltamethrin

1. A battery of acute toxicity studies places technical deltamethrin in Toxicity Category III for acute dermal (LD_{50} > 2,000 milligrams/kilograms (mg/kg)), acute inhalation (LC_{50} = 2.2 mg/l) and primary eye irritation; Category IV for acute oral (LD_{50} > 5,000 mg/kg) and primary dermal (non-irritating). Deltamethrin is a non-sensitizer. The NOEL for acute delayed neurotoxicity is greater than 5,000 mg/kg.

2. In a subchronic oral toxicity study deltamethrin was administered to 20 Sprague-Dawley rats/sex/dose in polyethylene glycol 200 by gavage at dose levels of 0, 0.1, 1.0, 2.5, or 10.0 milligrams/kilograms/day (mg/kg/day) for 13 weeks. The lowest observed effect level (LOEL) for males is 2.5 mg/kg/day, based on depressed body weights and body weight gains. The LOEL for females is 10 mg/kg/day, based on some hypersensitivity observed during neurotoxicity testing. The NOEL for males and females is 1.0 and 2.5 mg/kg/day, respectively. This subchronic oral toxicity study in rats is classified as core minimum.

3. In a subchronic oral toxicity study deltamethrin was administered to 3-5 beagle dogs/sex/dose in polyethylene glycol in gelatine capsules at dose levels of 0, 0.1, 1.0, 2.5, or 10 mg/kg/day for 13 weeks. The LOEL is 2.5 mg/kg/day, based on gastro-intestinal disturbance and stimulation of the nervous system as noted in the clinical signs of toxicity for both sexes. The NOEL is 1.0 mg/kg/day. This subchronic oral toxicity study in dogs is classified as core minimum. A NOEL of 1.0 mg/kg/day is supported. At higher levels stimulation of the nervous system is noted (the LOEL is set at 2.5 mg/kg/day, but effects were more definite at 10 mg/kg/day).

4. In a 21–day subchronic dermal toxicity study five Sprague-Dawley rats/sex/dose were dermally exposed to 6 ml/kg of deltamethrin for 6 hours/day at dose levels of 0, 100, 300, or 1,000 mg/kg/day (limit test). The LOEL for males is 300 mg/kg/day, based on slightly decreased body weight gain supported by marginally decreased food consumption. The NOEL for males is 100 mg/kg/day. The LOEL for females was not observed. The NOEL for females is >1,000 mg/kg/day (limit dose).

5. In a 3-week inhalation toxicity study deltamethrin was administered to eight CD rats/sex/dose at concentrations of 0.003, 0.0096, or 0.0563 mg/l for 6 hours/day for 5 days/week (14 exposures total). The LOEL is 0.0096 mg/l, based on signs of irritation (nerve stimulation) and reduced body weight gains in males and elevated Na+ levels in both males and females. The NOEL is 0.003 mg/l.

6. In a chronic toxicity study deltamethrin was administered to eight beagle dogs/sex/dose in the diet at dose levels of 0, 0.026, 0.261, or 1.134 mg/kg/day for males and 0, 0.024, 0.271, or 1.061 mg/kg/day for females for 24 months. The NOEL is ≥40 ppm (equivalent to 1.134 mg/kg/day for males and 1.061 mg/kg/day for females). A LOEL was not observed. Sufficient data to support a NOEL of >40 ppm have been generated.

7. In a chronic toxicity study deltamethrin was administered to 80 Charles River CD-1 mice/sex/dose in the diet at dose levels of 0, 0.12, 0.61, 3.1, or 12 mg/kg/day for males and 0, 0.15, 0.76, 3.8, or 15 mg/kg/day for females. The NOEL is ≥12 mg/kg/day for males or ≥15 mg/kg/day for females. A LOEL was not observed.

8. In a chronic toxicity study deltamethrin was administered to 90 Charles River CD rats/sex/dose in the diet at dose levels of 0, 0.1, 1.0, or 2.5 mg/kg/day. The LOEL is 2.5 mg/kg/day based on decreased body weight gains noted in both sexes. The NOEL is 1.0 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

9. In a developmental toxicity study deltamethrin was administered to 16 New Zealand White rabbits/dose in 0.5% carboxymethylcellulose by gavage at dose levels of 0, 10, 25, or 100 mg/kg/day from days 7 through 19 of gestation. The maternal LOEL is 25 mg/kg/day, based on treatment-related clinical findings (decreased defecation). The maternal NOEL is 10 mg/kg/day. The developmental LOEL is 100 mg/kg/day, based on treatment-related increases in the fetal incidence of several skeletal variations and a positive trend for litter incidence of two of these variations (unossified pubic and tail bones). The developmental NOEL is 25 mg/kg/day. The developmental toxicity study in the rabbit is classified core minimum.

10. In a developmental toxicity study deltamethrin was administered to 25 Charles River Crl:CD VAF/Plus rats/dose in corn oil by gavage at dose levels of 0, 1.0, 3.3, or 11 mg/kg/day from days 6 through 15 of gestation. Because of excessive toxicity at 11 mg/kg/day, an additional group of 25 rats dosed at 7 mg/kg/day was added. The maternal

LOEL is 7 mg/kg/day, based on treatment-related increases in mortality, clinical findings (increased salivation), and decreased body weight gains during dosing. The maternal NOEL is 3.3 mg/kg/day. There were no treatment-related effects on fetal deaths or resorptions, altered growth, or developmental malformations or variations (external, visceral, and skeletal) noted at any dose level. The developmental NOEL is ≥11 mg/kg/day. A developmental LOEL was not observed.

11. In three different developmental toxicity studies deltamethrin was administered to mice, rats, and rabbits. *Mice:* Mice were dosed at 0, 0.1, 1.0, or 10 mg/kg/day on gestational days 6-17 and were sacrificed on day 18. The maternal NOEL is ≥10 mg/kg/day. There was no maternal LOEL observed. The developmental LOEL is 1.0 mg/kg/day based on increase incidence (fetal and/or litter) of delayed ossification of the sternebrae and paws together with decreased fetal body weights. The developmental NOEL is 0.1 mg/kg/day.

Rats: Rats were dosed at 0, 0.1, 1.0, or 10 mg/kg/day on days 6-18 of gestation and were sacrificed on day 21. The maternal LOEL is 10 mg/kg/day based on slightly reduced body weights. The maternal NOEL is 1.0 mg/kg/day. The developmental LOEL is equivocally set at 10 mg/kg/day, based only on a statistically significant increased incidence (fetal and/or litter) of delayed ossification of the sternebrae. The developmental NOEL is 1.0 mg/kg/day.

Rabbits: Rabbits were dosed at 0, 1, 4, or 16 mg/kg/day on days 6-19 of gestation and were sacrificed on day 28; two separate groups of rabbits received 16 mg/kg/day. The maternal NOEL is ≥16 mg/kg/day. There was no maternal LOEL observed. The developmental LOEL is 16 mg/kg/day based on increased fetal losses and decreased fetal weights. The developmental NOEL is 4 mg/kg/day.

12. In a 3-generation reproduction study deltamethrin was administered to 10 male and 20 female Charles River CD rats/dose in the diet at doses of 0, 0.1, 1.0, or 2.5 mg/kg/day. Parental toxicity was not demonstrated at any dose level. The NOEL for systemic toxicity is ≥2.5 mg/kg/day. The LOEL for systemic toxicity was not observed. Reproductive toxicity was not demonstrated at any dose level. The NOEL for reproductive toxicity is ≥2.5 mg/kg/day. The reproductive LOEL was not observed.

13. There is no mutagenicity concern. There are three acceptable studies: one reverse mutation assay; one *in vitro* chromosome aberration study; one UDS assay in primary rat hepatocytes. All these studies were negative. A dominant lethal study is also available but has not been officially reviewed. A quick assessment indicated that it is also negative.

14. Studies on metabolism: Deltamethrin ^{14}C-labeled at either the benzyl (BD) or the dimethyl (DMD) portion of the molecule was relatively well absorbed. Urine and fecal excretions were almost complete at 48 hours post-dosing. Seven days after dosing, 31-56% of the radioactivity administered was recovered in the urine, 36-59% recovered in the feces, < 0.2% recovered in tissues (fat was highest) and < 1.2% recovered in carcass. Fecal extracts contained mostly unabsorbed, unchanged deltamethrin (17-46% of BD dose and 21-35% of DMD dose).

15. Studies on neurotoxicity: With the exception of the acute delayed neurotoxicity study, no neurotoxicity studies are available.

16. The following studies are considered data gaps in the toxicology data base: 2-generation reproduction study and acute, chronic and developmental mammalian neurotoxicity. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

Tralomethrin

1. A battery of acute toxicity studies places technical tralomethrin in Toxicity Category II for acute oral (LD_{50} in males = 84.9 mg/kg; LD_{50} in females = 95.4 mg/kg), acute inhalation (LC_{50} > 2,000 mg/kg) and primary eye irritation (corneal opacity which reversed within 14 days); Category III for acute dermal (LD_{50} > 2,000 mg/kg); Category IV for primary dermal irritation (non-irritating). Tralomethrin is not a sensitizer. The NOEL for Acute Delayed Neurotoxicity is greater than 6,000 mg/kg.

2. In a rat oral toxicity study, tralomethrin was administered to 20 CD rats/sex/dose via gavage at dose levels of 0, 1, 6, or 18 mg/kg/day for 13 weeks (91 days). The LOEL for this 13-week rat oral toxicity study is 6 mg/kg/day based on decreased liver weights. The NOEL is 1 mg/kg/day.

3. In a 13-week dog feeding study, tralomethrin in polyethylene glycol was administered to 5 beagle dogs/sex/group via capsule at dose levels of 0, 0.1, 1.0, or 10 mg/kg/day. The LOEL for this 13-week dog feeding study is 10 mg/kg/day based on neurological and hematological effects. The NOEL is 1 mg/kg/day.

4. In a 1-year dog feeding study, tralomethrin in corn oil was administered to eight beagle dogs/sex/group by capsule at dose levels of 0.75, 3.0, and 10.0 mg/kg/day. The high dose level was excessively toxic and was reduced to 8.0 mg/kg/day at 4 weeks and to 6.0 mg/kg/day on week 14. The low dose level was increased from 0.75 to 1.0 mg/kg/day during week 14. The LOEL in this 1-year dog feeding study is 3.0 mg/kg/day, based on reduced body weight gain, tremors, and ptyalism. The NOEL is 0.75/1.0 mg/kg/day.

5. In a mouse oncogenicity study, tralomethrin in corn oil was administered to 80 CD-1 mice/sex/dose by gavage at dose levels of 0.75, 3.0, or 10.0 mg/kg/day for up to 2 years. The systemic LOEL in this mouse oncogenicity study is 3 mg/kg/day, based on skin lesions in male and female mice. The systemic NOEL is 0.75 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

6. In a rat chronic toxicity/oncogenicity study, tralomethrin in corn oil was administered to 80 CD rats/sex/dose by gavage at dose levels of 0.75, 3.0, or 12.0 mg/kg/day for up to 2 years. The LOEL is 3.0 mg/kg/day in male and female rats based on decreased body weight gain in males and decreased food and water consumption in males and females at 3.0 mg/kg/day. The NOEL is 0.75 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

7. In a rat developmental study, tralomethrin in corn oil was administered to 25 female Sprague-Dawley CD rats per group at 0, 2, 6, or 18 mg/kg/day via gavage on days 6-17 of gestation. On day 21 the rats were sacrificed and pups delivered by cesarean section. The maternal LOEL 18 mg/kg/day based on one treatment-related death at this dose level. The maternal NOEL is 6 mg/kg/day. There was no developmental toxicity noted at any dose level. There were no treatment-related increases in malformations or variations found upon external, internal, and skeletal examination of the fetuses. A developmental LOEL was not observed. The developmental NOEL is ≥18 mg/kg/day.

8. In a developmental study, tralomethrin in corn oil was administered to 15 female New Zealand white rabbits per group at 0, 2, 8, or 32 mg/kg/day via gavage on days 6-18 of gestation. There was no maternal toxicity noted at any dose level. In a

developmental study, tralomethrin (purity not indicated) in corn oil was administered to 15 female New Zealand white rabbits per group at 0, 2, 8, or 32 mg/kg/day via gavage on days 6-18 of gestation. On day 28 the dams were sacrificed and pups delivered. A maternal LOEL was not observed. The maternal NOEL is ≥32 mg/kg/day. There was no developmental toxicity noted at any dose level. A developmental LOEL was not observed. The developmental NOEL is ≥32 mg/kg/day.

9. In a two-generation rat reproductive toxicity study, tralomethrin in corn oil was administered to COBS CD rats by gavage at dose levels of 0, 0.75, 3.0, or 12.0 mg/kg/day. The LOEL for parental toxicity is 3.0 mg/kg/day, based on decreased body weight gains. The NOEL for parental toxicity is 0.75 mg/kg/day. Reproductive toxicity was demonstrated at the mid- and high-doses. The LOEL for reproductive toxicity is 0.75 mg/kg/day, based on litters with smaller than normal pups. A reproductive NOEL was not observed.

10. There does not appear to be a concern for mutagenicity, however, all studies should be revisited, particularly, the mouse lymphoma. There are three reviewed studies that are not classified for acceptability: one mouse lymphoma assay (Accession No. 072115; one *in vitro* chromosome aberration study in CHO cells and one UDS assay in primary rat hepatocytes (MRID 41138803). The mouse lymphoma assay tested negatively without activation and was moderately positive with activation. The other two assays tested negatively.

11. The metabolism studies indicate that tralomethrin is rapidly debrominated to deltamethrin. It is then further metabolized to alcohols, carboxylic acids, glucuronides, glycine and sulfate conjugates.

12. No mammalian neurotoxicity studies are available. The acute delayed neurotoxicity study in the hen is summarized in section one.

13. The following studies are considered data gaps in the toxicology data base: acute, chronic and developmental mammalian neurotoxicity. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

Tralomethrin is rapidly metabolized to deltamethrin. The toxicology data bases for deltamethrin and tralomethrin were combined in order to determine appropriate endpoints for risk assessment. Results of the rat metabolism study support this action.

1. *Acute toxicity*. EPA has established an NOEL of 1.0 mg/kg/day based on combined acute dietary dog studies with a combined deltamethrin/tralomethrin data base. This NOEL is based on an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

2. *Short - and intermediate-term toxicity*. There is no concern for short- and intermediate-term toxicity. There is no dermal or systemic toxicity at 1,000 mg/kg/day in 21–day dermal study in rats.

3. *Chronic toxicity*. EPA has established the RfD for deltamethrin and tralomethrin at 0.01 (mg/kg/day). This RfD is based on a NOEL of 0.75/1.0 mg/kg/day from a 1 year toxicity study in dogs. The NOEL is based on decreased body weight gain, tremors, and ptyalism. This RfD is based on an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in either rats or mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.422 and 180.435) for the residues of tralomethrin and deltamethrin in or on a variety of raw agricultural commodities. For purposes of the risk assessment the data bases for deltamethrin and tralomethrin have been combined. EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA's June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. Field trial data and FDA monitoring data were used to generate anticipated residues or residue distribution for Monte Carlo analyses. Chronic dietary risk assessments used anticipated residues and percent crop treated refinements. Risk assessments were conducted by EPA to assess dietary exposures and risks from deltamethrin and tralomethrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The NOEL used for the acute dietary exposure was 1.0 mg/kg/day. Potential acute exposures from food commodities were estimated using a Tier 3 acute dietary risk assessment (Monte Carlo Analysis). The MOE's (99.9th percentile) for the U.S. population based on an acute dietary exposure of 0.000728 mg/kg/day are 1,373. For children 1-6 years old (most highly exposed population), the MOE's based on an acute dietary exposure of 0.001855 mg/kg/day are 539. The Agency has no cause for concern if total exposure calculated for the 99.9th percentile yields an MOE of 100 or larger.

ii. *Chronic exposure and risk*. Potential chronic exposures were estimated using NOVIGEN's DEEM (Dietary Exposure Evaluation Model). The RfD used for the chronic dietary analysis is 0.01 mg/kg/day. Using tolerance values and anticipated residues discussed above, the risk assessment resulted in use of 0.2% of the RfD for the general U.S. population and 0.5% of the RfD for children 1-6 years.

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 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate.

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 deltamethrin and tralomethrin 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 underestimated 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 FIFRA.

2. *From drinking water*. Deltamethrin and tralomethrin are immobile in soil and will not leach into ground water. Additionally, due to their insolubility and lipophilic nature, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment. A screening evaluation of leaching potential of a typical potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM1). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at depths of 1 and 2 meters are essentially zero (much less than 0.001 ppb). Therefore, EPA concludes that residues are not expected to occur in drinking water.

i. *Acute exposure and risk*. Acute drinking water exposure is estimated for the U.S. population to be 0.000014 mg/kg/day with an MOE of 69,093. For Non-nursing infants less than 1 year old the exposure is 0.000028 with and MOE of 35,895.

ii. *Chronic exposure and risk*. Chronic drinking water exposure is estimated for the U.S. population to be zero and for the non-nursing infants 0.000001 mg/kg/day. Zero percent of the RfD is occupied by both population groups.

3. *From non-dietary exposure*. Deltamethrin and tralomethrin are broad spectrum insecticides registered for use on a variety of food and non-food agricultural commodities. Non-agricultural registered uses include turf and lawn care treatments, broadcast carpet treatments, indoor fogger, spot, crack and crevice treatment, insect baits, lawn and garden sprays and indoor and outdoor residential, industrial, and food/feed handling establishments.

To evaluate non-dietary exposure, the ''flea infestation control'' scenario was chosen to represent a plausible but worst-case non-dietary (indoor and outdoor) non-occupational exposure. This scenario provides a situation where deltamethrin and/or tralomethrin is commonly used and they can be used concurrently for a multitude of uses, e.g., spot and/or broadcast treatment of infested indoor surfaces such as carpets and rugs, treatment of pets and treatment of the lawn. This hypothetical situation provides a very conservative, upper bound estimate of potential non-dietary exposures. Consequently, if health risks are acceptable under these conditions, the potential risks associated with other more likely scenarios would also be acceptable.

Because tralomethrin is rapidly metabolized to deltamethrin, and the toxicology profiles of deltamethrin and tralomethrin are virtually identical, a non-dietary and aggregate (non-dietary + chronic dietary) exposure/risk assessment has been conducted for the combination of both active ingredients. The total exposure to both materials was expressed as ''deltamethrin equivalents'' and these were compared to the toxicology endpoints identified from the combined deltamethrin/tralomethrin toxicology data base.

The total aggregate non-dietary exposure including lawn, carpet, and pet uses (in mg/kg/day) are: 0.00002 for adults; 0.000503 for children aged 1-6 years; and 0.000543 for infants less than 1 year old.

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).

Although deltamethrin and tralomethrin are similar to other members of the synthetic pyrethroid class of insecticides, EPA does not have, at this time, available data to determine whether deltamethrin and tralomethrin have common methods 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, deltamethrin and tralomethrin do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that deltamethrin and tralomethrin have 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 drinking water. The potential acute exposure from food and water to the US population for deltamethrin and tralomethrin is 0.000742 mg/kg/day with an MOE of 1,348. This acute dietary exposure estimate is considered conservative, using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis.

2. *Chronic risk*. Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to deltamethrin and tralomethrin from food and drinking water will utilize 0.2% of the RfD for the U.S. population. The major

identifiable subgroup with the highest aggregate exposure are children 1-6 years old (discussed in Unit II.F. of this preamble). 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.

3. *Short- and intermediate-term risk*. Short- and intermediate aggregate exposure takes into account chronic dietary food and drinking water (considered to be a background exposure level) plus indoor and outdoor residential exposure. The potential short- and intermediate-term aggregate risk for the U.S. population is an exposure 0.000042 mg/kg/day with an MOE of 49,000.

EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to deltamethrin and tralomethrin residues.

E. Aggregate Cancer Risk for U.S. Population

Deltamethrin and tralomethrin do not yet have carcinogenicity classification; however, there is no evidence of carcinogenicity in any of the chronic studies. Therefore, a carcinogenicity risk analysis is not required.

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 deltamethrin and tralomethrin, 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*. See toxicological profile in Unit II.A. of this preamble.

iii. *Reproductive toxicity study*. See toxicological profile in Unit II.A. of this preamble.

iv. *Pre- and post-natal sensitivity*. There is no evidence of additional sensitivity to young rats or rabbits following prenatal exposure to deltamethrin or tralomethrin.

v. *Conclusion*. 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 potential acute exposure from food and drinking water to the most sensitive population subgroup, children 1-6 years old is 0.001867 mg/kg/day with an MOE of 535. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to deltamethrin and tralomethrin from food will utilize 0.5% of the RfD for infants and children. 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*. EPA has concluded that potential short- or intermediate-term aggregate exposure of deltamethrin or tralomethrin from chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure to infants (less than 1 year old) is 0.000057 mg/kg/day with an MOE of 1,800. For children (1-6 years old) the exposure is 0.000055 mg/kg/day with and MOE of 2,700.

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.

EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to deltamethrin and tralomethrin.

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

The absorption of deltamethrin appears to be highly dependent upon the route and vehicle of administration. Once absorbed, deltamethrin is rapidly and extensively metabolized and excreted through urine and feces, almost completed within the first 48 hours. Tralomethrin is rapidly metabolized to deltamethrin after debromination. The metabolic pattern of the debrominated tralomethrin is exactly the same as that of the metabolic pattern of deltamethrin.

B. Analytical Enforcement Methodology

The analytical method designated HRAV-7B is adequate for enforcement purposes. Multi residue methods data for tralomethrin, deltamethrin, and trans-deltamethrin have been sent to the Food and Drug Administration.

C. Magnitude of Residues

Based on the low level of deltamethrin residues expected in the diet of cattle from the use on cotton, the ruminant metabolism study, and an available cattle feeding study, measurable residues are not expected in the milk or meat of ruminants. A poultry metabolism or feeding study is not required because cottonseed meal is

not a major poultry feed item and deltamethrin residues are predicted to be non-detectable. For dietary exposure analyses, field trial data and FDA monitoring data were used to generate the appropriate anticipated residues or residue distribution for Monte Carlo analysis.

D. International Residue Limits

No CODEX maximum residue levels (MRL) are established for deltamethrin and tralomethrin tolerances addressed in this document. For deltamethrin on cottonseed, Mexico has an established tolerance of 0.1 ppm (vs. U.S. tolerance of 0.04 ppm). For tralomethrin on broccoli and soybeans Mexico has established tolerances of 0.02 ppm (vs. U.S. tolerance of 0.50) and 0.05 ppm (vs. U.S tolerance of 0.05ppm) respectively. As indicated above, there are small differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculation of animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerance is established for residues of deltamethrin in cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm and tralomethrin broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm.

In addition to the tolerances being established, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerance for cottonseed oil that now appears in § 185.1580 with the tolerances that appear in §180.435.

V. Objections and Hearing Requests

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

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number OPP–300584 (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

VII. Regulatory Assessment Requirements

This final rule removes time limitations for 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

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests. 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. In part 180:

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

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

b. By revising § 180.422 to read as follows:

§ 180.422 Tralomethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pesticide chemical tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate calculated as the parent in or on the following agricultural commodities:

Commodity	Parts per million
Broccoli	0.5
Cottonseed	0.02
Cottonseed oil	0.20
Lettuce, head	1.00
Lettuce, leaf	3.00
Soybeans	0.05
Sunflower seed	0.05

(2) A food additive tolerance of 0.02 part per million is established for the combined residues of the insecticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(RS)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate) and its metabolites *cis*-deltamethrin [(*S*-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-[2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and trans-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] as follows:

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

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

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

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

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

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

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

c. By revising § 180.435 to read as follows:

§ 180.435 Deltamethrin, tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the pesticide chemical deltamethrin [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (*S*)-*alpha*-cyano-3-phenoxybenzyl ester and its major metabolites, *trans* deltamethrin [(*S*)-*alpha*-cyano-*m*-phenoxybenzyl(1R,3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *alpha-R*-deltamethrin [(*R*)-*alpha*-cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on the following agricultural commodities:

Commodity	Parts per million
Cottonseed	0.04
Cottonseed oil	0.2
Tomatoes	0.2
Tomato (products) concentrated.	1.0

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

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

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1580 [Removed]

b. By removing § 185.1580.

§ 185.5450 [Removed]

c. By removing § 185.5450.

[FR Doc. 97–31103 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300581; FRL–5755–5]

RIN 2070–AB78

Lambda-Cyhalothrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of the pyrethroid lambda-cyhalothrin and its epimer in or on broccoli, cabbage, corn (grain, fodder and forage), corn (sweet), cottonseed, dry bulb onion, garlic, lettuce, head, peanuts, rice, soybeans, sorghum, sunflower, tomatoes, wheat, sunflower, and livestock commodities. It also removes time limitations for tolerances for residues of lambda-cyhalothrin on the same commodities that expire on November 15, 1997. The Zeneca Ag Products requested these tolerances under the Federal Food, Drug and Cosmetic Act, 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 28, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300581], 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–300581], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300581]. 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) 308–6100, e-mail: heyward.adam@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On May 24, 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 lambda-cyhalothrin and its epimer on cottonseed (53 FR 18558). As additional crops tolerances were established, they were also made time-limited. These tolerance expire on November 15, 1997. Zeneca Ag Products, on September 15, 1997, requested that the time limitation for tolerances for residues of the insecticide lambda-cyhalothrin and its epimer in or on the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of 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 Friday, 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 pesticide petitions (PP 6F3318, 7F3560, 7H5543, 7F3488, 1F3952, 1H5607, 1F3992, 2F4109, 2F4100, 2F4114, 1F3985, 9F3770 and 6F4769) for tolerances by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, Delaware 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 180.438 be amended by removing time limitatioins for tolerances for the combined residue of the insecticide, lambda-cyhalothrin and its epimer in or on the following crops and commodities: broccoli at 0.4 parts per millions (ppm); cabbage at 0.4 ppm; cattle, fat at 3.0 ppm; cattle, meat at 0.2 ppm; cattle, meat and meat by-products (mbyp) at 0.2 ppm; corn, grain (field and pop) at 0.05 ppm; corn, fodder at 1.0 ppm; corn, forage at 6.0 ppm; corn, sweet (k+kwhr) at 0.05 ppm; cottonseed at 0.05 ppm; dry bulb onion at 0.1 ppm; eggs at 0.01 ppm; garlic at 0.1 ppm; goats, fat at 3.0 ppm; goats, meat at 0.2 ppm; goats, mbyp at 0.2 ppm, hogs, fat at 3.0 ppm; hogs, meat at 0.2 ppm; hogs, mbyp at 0.2 ppm; horses, fat at 3.0 ppm; horses, meat at 0.2 ppm; horses, mbyp at 0.2 ppm; lettuce, head at 2.0 ppm; milk, fat (reflecting 0.2 ppm in whole milk) at 5.0 ppm; peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, mbyp at 0.01 ppm; rice, grain at 1.0 ppm; rice, hulls at 5.0 ppm; rice, straw at 1.8 ppm; sheep, fat at 3.0 ppm; sheep, meat at 0.2 ppm; sheep, mbyp at 0.2 ppm; soybeans at 0.01 ppm; sorghum, grain at 0.02 ppm; sorghum, grain dust at 1.5 ppm; sunflower, seeds at 0.2 ppm; sunflower, forage at 0.2 ppm; tomatoes at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, forage at 2.0 ppm; wheat, hay at 2.0 ppm; wheat, straw at 2.0 ppm; wheat, grain dust at 2.0 ppm; corn, grain flour at 0.15 ppm; sunflower, oil at 0.30 ppm; sunflower, hulls at 0.50 ppm; tomato pomace (dry or wet) at 6.0 ppm; and wheat, bran at 0.2 ppm.

In the Notice of Filing the established tolerance level for sorghum grain was inadvertently listed as 0.02 ppm. The correct tolerance level for this commodity if 0.2 ppm. The correct tolerance was considered by EPA for risk assessment purposes. In the latest CFR, 40 CFR 180.438 (revised as of July 1, 1997), the tolerance for garlic was incorrectly listed as 0.02 ppm. The correct level if 0.1 ppm. This error occurred when the CFR was updated. The 0.1 ppm level was considered by EPA for risk assessment.

The basis for time limited tolerances that expire November 15, 1997 was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional