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 180.418 is revised to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cypermethrin (±)alpha cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem	2.0
Brassica, leafy	14.0
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cottonseed	0.5
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Lettuce, head	10.0
Milk	0.05
Onions, bulb	0.10
Pecans	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

(2) [Reserved]

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

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

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

[FR Doc. 97–30947 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300577; FRL–5754–8]

RIN 2070–AB78

Zeta-Cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin in or on cabbage at 2.0 parts per million (ppm); cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and the fat, meat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, and sheep at 0.05 ppm. It also removes time limitations for tolerances for residues of zeta-cypermethrin on the same commodities that expire on November 15, 1997. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

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–300577, 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–300577, 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, Crystal Mall #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. Follow the instructions in Unit VI. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

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 June 15, 1984, EPA established time-limited tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348 for residues of cypermethrin on cottonseed; fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep; and milk (49 FR 24864). As additional crop tolerances were established, they were also made time-limited. These tolerances expire on November 15, 1997. FMC Corporation, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide zeta-cypermethrin in these commodities be removed based on environmental effects data that they had submitted as a condition of the registration. FMC Corporation 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 FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 2F2623, 4F2986, 3F2824, 7F3498, and 4F3011) for tolerances by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.418 be amended by removing the time limitation for tolerances for residues of the insecticide and pyrethroid, zeta-cypermethrin in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; and pecans at 0.05 ppm. Animal commodities were not

included in the notice of filing but are being included in this final rule.

The basis for the 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, 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) of the FFDCA 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) of the FFDCA 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 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, section 408 of the FFDCA 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) of the FFDCA, 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 zeta-cypermethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for residues of zeta-cypermethrin in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and the fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 zeta-cypermethrin are discussed in this unit.

1. Acute toxicity studies with technical zeta-cypermethrin: oral LD_{50} in the rat is 134.4 milligram (mg)/kilogram (kg) for males and 86.0 mg/kg for females—Toxicity Category II.

2. Acute toxicity studies with cypermethrin bridged to zeta-cypermethrin: dermal $LD_{50} > 2460$ mg/kg in rabbits and $LD_{50} > 4920$ in rats—Toxicity Category III; inhalation (LC_{50} 2.5 mg/liter (L) for females and > 2.5 mg/L in males—Toxicity Category III; primary eye irritation— not irritating—Toxicity Category IV; primary dermal irritation, primary irritation score (PIS) 0.71 —Toxicity Category IV; dermal sensitization—moderate sensitizer in two studies, negative in other studies; delayed type neurotoxicity in hens—no evidence of delayed type neurotoxicity in hens at dose levels of 0, 2,500, 5,000, or 10,000 mg/kg; neurotoxicity screen in rats—NOEL and lowest-observed effect level (LOEL) established as < 20 mg/kg—at 20 mg/kg decreased motor activity and gait abnormalities.

3. In a 90-day feeding study, rats were dosed at 0, 10, 50, 150, 250, 500, or 900 ppm (0, 0.6, 2.7, 8.4, 13.8, 28.2, or 55.7 mg/kg/day for males and 0, 0.6, 3.3, 9.6, 16.3, 32.2, or 65.2 mg/kg/day for females). The NOEL is 250 ppm (13.9 mg/kg/day) and the LOEL is 500 ppm (28.2 mg/kg/day) based on decreases in bodyweight and bodyweight gains and food consumption at 28.2 mg/kg/day and above and deaths; clinical signs of neurotoxicity; decreases in erythrocyte and leukocyte counts, hemoglobin, and hematocrit, and increases in blood urea nitrogen (BUN) at 55.7 mg/kg/day.

4. The 21-day dermal, subchronic oral study in the dog and the 21-day inhalation studies are bridged from cypermethrin.

In a subchronic toxicity study, dogs were dosed at 0, 5, 50, 500, or 1,500 ppm (corresponding to 0, 125, 1.25, 12.5, and 37.5 mg/kg/day) for 13 weeks. The LOEL is 1,500 ppm (37.5 mg/kg/day, based on clinical signs indicating neurotoxicity). The NOEL is 500 ppm (12.5 mg/kg/day).

In a 21-day dermal toxicity study, rabbits were dosed at 2, 20, or 200 mg/kg/day with daily applications for 3 weeks for a total of 15 applications. Five/sex/group were abraded prior to application of the test material. The LOEL is 200 mg/kg/day based on liver effects. The NOEL is 20 mg/kg/day.

In a 21-day subchronic inhalation toxicity study, rats were dosed by nose only exposure at concentrations of 0, 0.01, 0.05, or 0.25 mg/L for 6 hours per day, 5 days per week for a total of 15 exposures. Additional satellite groups of five/sex were included for recovery assessment and analysis of cypermethrin in the brain. The LOEL is 0.05 mg/L based mainly on bodyweight decrease. The NOEL is 0.01 mg/L.

5. The chronic/oncogenicity studies are bridged from cypermethrin.

In a chronic toxicity study, dogs were dosed at 0, 1, 5, or 15 mg/kg/day for 52 weeks. The LOEL is 5 mg/kg/day based on gastrointestinal effects. The NOEL is 1 mg/kg/day.

In a carcinogenicity study, mice were dosed at control-1, control-2, 100, 400, and 1,600 ppm (corresponding to 0, 0, 14, 57, or 229 mg/kg/day) for 97 weeks for males and 101 weeks for females. The LOEL is 400 ppm (57 mg/kg/day) based on liver weight. The NOEL is 100 ppm (14 mg/kg/day). This study was determined to be positive for induction of benign alveologenic neoplasms. Adequacy of dosing for carcinogenicity is based upon typically 9% decreases in males and 12% in females in the first months of the study.

In a chronic toxicity/carcinogenicity study, rats were dosed at control-1, control-2, 20, 150, or 1,500 ppm (corresponding to 0, 0, 1, 7.5, or 75 mg/kg/day) for 2 years. Satellite groups of 12/sex were sacrificed after 1 year of dosing. The LOEL is 1,500 ppm (75 mg/kg/day) based on bodyweight. The NOEL is 150 ppm (7.5 mg/kg/day). Cypermethrin was not considered to be

oncogenic in this study. A possible association with increased testicular interstitial tumors was not considered definite.

6. Zeta-cypermethrin was tested in a developmental toxicity study in rats at the following dose levels: 0, 5, 12, 25, or 35 mg/kg/day. Groups of 25 females were administered the test chemical by gavage on gestation days 6 through 15 in a volume of 5 milliliter (ml)/kg bodyweight. No developmental toxicity was observed at any dose level. The maternal NOEL is 12.5 mg/kg and the maternal LOEL is 25 mg/kg based on decreases in bodyweight and bodyweight gain and food consumption and clinical signs of toxicity, particularly neurotoxicity. The developmental NOEL is 35 mg/kg/day highest dose tested (HDT). The LOEL was not established.

7. The developmental toxicity study in the rabbit is bridged from cypermethrin.

In a developmental toxicity study, rabbits were dosed at 0 (empty capsule), 0 (capsule plus corn oil), 3, 10, or 30 mg/kg/day on days 6 to 18 inclusive of gestation. There were no effects of any kind reported on the does. The maternal LOEL is > 30 mg/kg/day. The maternal NOEL is > 30 mg/kg/day. There were no treatment related effects on either the skeletal or visceral structures reported. The developmental LOEL is > 30 mg/kg/day. The developmental NOEL is > 30 mg/kg/day.

In a developmental toxicity study, rabbits were dosed at 0, 100, 450, or 700 mg/kg/day from days 7 through 19 of gestation. The does were sacrificed on day 29 of gestation. The maternal LOEL is 450 mg/kg/day, based on bodyweight gain. The maternal NOEL is 100 mg/kg/day. There were no indications of developmental toxicity. The NOEL and LOEL for developmental toxicity is > 700 mg/kg/day.

8. Zeta-cypermethrin was tested in a two-generation reproduction study in groups of 30 male and 30 female rats at the following dose levels: 0, 7.5, 25, 100, 375, or 750 ppm (0, 0.5, 1.8, 7, 27, or 45 mg/kg/day). The parental and reproductive NOELs are 7 mg/kg/day and LOELs are 27 mg/kg/day based on decreased parental and pup weight, particularly during lactation, clinical signs of toxicity, and death at 45 mg/kg/day.

9. Zeta-cypermethrin was tested in a reverse mutation assay in salmonella typhimurium strains TA1535, TA1537, TA100, TA1538, and TA98 at 0, 100, 333, 1,000, 3,333, 5,000, or 10,000 microgram (μg)/plate. It gave a very weak positive response (two-fold increase in revertants/plate) in strain TA100 at 10,000 μg/plate without S–9 activation in two-separate experiments. Doses of 3,333 and 5,000 μg/plate gave 1.5 and 1.6-fold increases in revertants/plate, respectively. Strains TA98, TA1535, TA1537, and TA1538 treated in the presence and absence of mammalian S–9 activation were not affected. Zeta-cypermethrin is therefore considered a possible weak mutagen under the conditions of the assay.

10. Zeta-cypermethrin was tested in an *in vitro* mammalian cell gene mutation assay in Chinese hamster ovary (CHO) cells ($CHO–K_1–BH_4$, subclone D_1) at the following dose levels: 0, 1, 10, 25, 50, 100, 400, 700, or 1,000 μg/ml, both in the absence and presence of S–9 activation. No evidence of increased forward mutation rate at the hypoxanthine guanine phosphoribose transferase (HGPRT) locus was observed at any dose tested under the conditions of these assays. The solubility limit of the test compound in culture media was approximately 100 μg/ml.

11. Zeta-cypermethrin was tested in an *in vivo* rat bone marrow chromosomal aberration assay. Groups of 15 male and 15 female Sprague-Dawley rats were administered single doses by gavage with 0, 31.25, 62.5, or 125 mg/kg zeta-cypermethrin in corn oil. Five rats/sex were sacrificed at 6, 18, and 30 hours-post dosing. Cyclophosphamide was used as the positive control (60 mg/kg). No evidence of structural chromosomal aberrations was demonstrated at either 6, 18, or 30 hours-post dosing.

12. Zeta-cypermethrin was tested in an unscheduled deoxyribonucleic acid (DNA) synthesis assay in male Fischer 344 rat primary hepatocyte cells. The dose levels tested were 0, 14, 45, 140, 450, 1,400, or 4,500 μg/ml. No unscheduled DNA synthesis was observed at any dose level up to 4,500 μg/ml in the primary hepatocyte cultures under the conditions of the assay. Minimal cytotoxicity was observed at the highest doses. Incomplete solubility of the test compound in culture media was observed, particularly at the higher doses. The positive control gave clear positive responses. The study is acceptable for regulatory purposes.

13. The metabolism studies are bridged from cypermethrin.

Several studies with both rats, dogs, and mice are available to support the requirement for metabolism in mammals. Some of these studies assess individual cis- and trans-radiolabeled isomers and other studies assess the metabolism of cypermethrin with the label in either the cyclopropyl of the phenoxybenzyl ring. In general the following has been demonstrated from these studies:

Cypermethrin is readily absorbed from the gastrointestinal tract and extensively metabolized. It is mostly excreted in the urine and contains several characterized metabolites derived from conjugation of the hydrolysis products of the parent compound following cleavage of the esteratic linkage site. The following three executive summaries describe the metabolism of cypermethrin in rats.

First study—First group. Six/sex rats, Wistar strain rats, were dosed with a single dose 0.61 mg/animal of labeled cis-cypermethrin isomers in 0.5 ml of corn oil. The rats were individually housed in metabolism cages and their urine and fecal matter collected daily until sacrifice. Two rats of each sex were sacrificed after 24 and 72 hours and after 8 days. Samples of the blood and selected tissues were assessed for radioactivity content.

Second group. Three/sex rats were dosed with 0.615 mg/animal of labeled trans-cypermethrin in 0.8 ml of corn oil. In addition to the urine and fecal collections, expired air was also collected from one male and one female. Total recovery was from 97.2% to 100.5%. About 70% of cis- and 80% of trans-cypermethrin was excreted in 24 hours. Essentially all was excreted in 8 days. Most of the label was excreted in the urine (> 53%) with less in the feces and (< 20%) for the trans (males and females) and cis (males only) groups and < 1% in the air for all groups. A sex difference with respect to excretion in the urine from the cis-isomer was noted for females since about equal amounts (35%) were found in both the urine and feces. Several urinary and fecal metabolites were tentatively characterized.

Second study. One group of three/sex Wistar strain rats was dosed with a single-oral dose (approximately 1.3 mg/kg) of 14*C*-cyclopropyl labeled cypermethrin in corn oil (0.8 ml). The rats were then placed in glass metabolism cages and their urine and feces were collected. Special metabolism cages for trapping any radioactivity expired through their respiratory system were used for one male and one female rat. The rats were sacrificed after 3 days and their blood and selected tissues were assessed for radioactivity, 85.5% for males and 97.2% for females of 14*C* was excreted in 72 hours. The urine (55.8% for males and 69.4% for females) was the major route of excretion with the feces containing the balance. The air contained only 0.1% or less. Tissue

retention was highest in the skin (1.2%) and liver (0.74% for males but only 0.18% for females) and fat (0.57 to 0.66%).

Third study. In a series of nine different studies, labeled cypermethrin (1 mg/kg or less) in corn oil or separated cis- or trans-cypermethrin isomers were given by gavage to single or groups of two or three Wistar strain rats. Their urine and in some cases fecal matter was collected at various intervals such as 18 hours to 3 days. In another set of experiments, labeled cypermethrin was administered to rats that were fitted with bile duct cannalulas and their bile collected for 4-5 hours while the rat was under anesthesia. Cis- and trans-14*C*-cyclopropyl labeled cypermethrin was demonstrated to form glucuronide conjugations of cis- and trans-acids and hydroxyacids. Only 1.6% or less of the total dose is excreted in the bile. Most of the cypermethrin in the feces was unmetabolized. The glucuronide conjugates in the urine were found to be unstable and subject to hydrolysis.

14. *Acute delayed type neurotoxicity-hens*. Cypermethrin was tested in the hen following a protocol similar to the series 81–7 guideline. The dose levels tested were 0, 2,500, 5,000, and 10,000 mg/kg but there was no indication of the delayed type neurotoxicity noted.

15. *Acute neurotoxicity screen-rats*. There are two acute neurotoxicity studies with cypermethrin.

First study. Rats were dosed with cypermethrin at dose levels of 0, 20, 60, or 120/100 mg/kg. The rats displayed gait, muscle effects, and choreoathetosis. Motor activity was decreased for all dose groups for males (estimated 45%, 66%, and 85% for the 20, 60, and 100 mg/kg dose group respectively) and gait abnormalities were present in the low-dose group. Body temperature was increased about 1 °C in the low-dose male group but decreased for the higher groups. Some 10 other parameters were affected at 60 mg/kg and/or above. These included: Salivation, urination, arousal, abnormal motor movement, forelimb, or hindlimb grip strength, landing foot splay, touch response, and tail pinch response. The LOEL and NOELs for neurotoxicity are < 20 mg/kg. At 20 mg/kg decreased motor activity and gait abnormalities resulted.

Second study. Rats were dosed with cypermethrin in corn oil as control, 30, 100, or 200 mg/kg. The rats were assessed at pretest, 4 hours after treatment and on days 7 and 14 for Functional Observational Battery (FOB) and motor activity. After day 14, five/sex were prepared for neurohistopathology. At 100 mg/kg, ataxia (two males and two females) and related conditions (staggered or impaired gait, decreased activity, splayed hindlimbs, and limp condition) and decreased motor activity (49%, $p < 0.001$ for males and 33%, $p < 0.01$ for females) resulted. In addition, some females had salivation, lacrimation and/or soiled fur. At 200 mg/kg, deaths resulted (one male and two females) as well as several other parameters being affected. The LEL is 100 mg/kg based primarily on ataxia and related conditions. The NOEL is 30 mg/kg.

The first study in Unit II. A.15. of this preamble is considered to define the neurotoxicity to cypermethrin because responses were noted at lower-dose levels. The second study used a variable and large dose of corn oil and a different strain of rat.

16. *Subchronic neurotoxicity screen in rats*. Rats were dosed with cypermethrin as control, 500, 1,300 or 1,700 ppm (31, 77, or 102 for males and 37, 95, or 121 for females mg/kg/day) for 90 days in a subchronic neurotoxicity study. At 1,300 ppm, females displayed ataxia (1/10), splayed hindlimbs (5/16), impaired gait (4/10), and decreased feces (4/10) as well as decreased bodyweight gain (~41%). Males had only decreased bodyweight gain (~27%) and increased landing foot splay. At 1,700 ppm, males showed ataxia (8/10) and additional related symptoms and females had decreased motor activity (~27%). The LEL is 1,300 ppm (77 mg/kg/day) based on several effects. The NOEL is 500 ppm (31 mg/kg/day).

Because the studies in Units II. A.15. and 16. of this preamble are screens, neurotoxicity studies will be required under a special Data Call-In (DCI) 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

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 0.5 mg/kg/day based on the NOEL of 1.0 mg/kg/day from the cypermethrin chronic toxicity study in dogs and a correction factor of two to account for the differences in the percentage of the biologically active isomer. The LOEL of this study of 5.0 mg/kg/day was based on gastrointestinal disturbances observed in the first week of the study.

2. *Short- and intermediate-term toxicity*. For short- and intermediate-term MOE's, EPA recommends use of a NOEL of 2.5 mg/kg/day based on neurotoxic signs in dogs starting at week 1. The inhalation NOEL is 5.0 with a correction factor of 2. Dermal absorption rate was 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 zeta-cypermethrin at 0.005 mg/kg/day. This RfD is based on gastrointestinal disturbances in dogs with an uncertainty factor of 200 to account for differences in percent biologically active isomers in enriched product.

Since insufficient data on zeta-cypermethrin are available to establish an RfD, the data from cypermethrin were used in establishing an RfD for zeta-cypermethrin. The NOELs from the cypermethrin studies were divided by 2 as a correction factor, assuming the worst case that the biologically active isomers are the ones which carry most of the toxicity. The following paragraph summarizes the decision logic for establishing the RfD for zeta-cypermethrin from the cypermethrin data base.

In general, the most sensitive species for the 10 synthetic pyrethroids appears to be the dog. For zeta-cypermethrin the Agency does not have any toxicity data on the dog that can be compared with the dog studies conducted with cypermethrin. In addition, the Agency also does not have any chronic studies on zeta-cypermethrin that can be compared with those conducted with cypermethrin. Therefore, although a comparison of the LEL's from the zeta-cypermethrin studies with the corresponding LEL's from the cypermethrin studies does not show a pronounced difference in toxicity, for risk assessment purposes, the Agency has decided to use the toxicity endpoints from cypermethrin with a two-fold correction factor to account for the differences in the percentages of the more biologically active isomers in the enriched technical product (zeta-cypermethrin). This would also apply to the inhalation endpoint because the Agency has no inhalation studies with zeta-cypermethrin. The Agency is making a conservative assumption that most of the toxicity for cypermethrin will be from the four more biologically active isomers of zeta-cypermethrin. Based on previous documentation, the Agency is assuming that the percentages of the isomers are approximately as follows:

Cypermethrin, eight isomers with percentage compositions ranging from 11–14% and zeta-cypermethrin, eight isomers with four insecticidally less active ones at a concentration of 1% each. The remaining four isomers, two

of which are regarded as being the most insecticidally active, will be present at a concentration of 24% each.

4. *Carcinogenicity.* No carcinogenicity studies are available for zeta-cypermethrin. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified cypermethrin as a weak Group C (possible human carcinogen) based on the increased incidence in lung adenomas in female CD-1 mice, but did not recommend assignment of a cancer potency factor (Q*1) for a linear quantitative cancer risk assessment. An RfD approach was recommended for human risk assessment purposes. It is assumed that zeta-cypermethrin would also test positively for lung adenomas in female CD-1 mice.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.418) for the residues of zeta-cypermethrin in or on a variety of raw agricultural commodities. Tolerances range from 0.05 ppm in animal commodities to 10.0 ppm in head lettuce. Registered uses include cabbage, cotton, head lettuce, onions, and pecans. Risk assessments were conducted by EPA to assess dietary exposures and risks from zeta-cypermethrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary exposure assessment used Monte Carlo modeling incorporating anticipated residues and percent crop treated refinements. The acute dietary MOE at the 99.9th percentile for the overall U.S. population is 126. The MOE at the 99.9th percentile for children 1–6 years of age is 105. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for zeta-cypermethrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The RfD used for the chronic dietary analysis is 0.005 mg/kg/day based on a NOEL of 1.0 mg/kg/day from the cypermethrin chronic dog study and an uncertainty factor of 200 (used to account for the differences in the percentage of the biologically active isomer). The endpoint effect of concern was based on gastrointestinal disturbances observed in the first week of the study at the LOEL of 5.0 mg/kg/day. The chronic dietary exposure assessment used anticipated residues, monitoring data, and percent of crop treated information . The chronic dietary exposure estimate for the overall U.S. population was calculated to be 0.000018 mg/kg/day (0.4% RfD utilized) and for children 1–6 years was calculated to be 0.00027 mg/kg/day (0.5% RfD utilized).

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

a. 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.

b. That the exposure estimate does not underestimate the exposure for any significant subpopulation.

c. 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 zeta-cypermethrin 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 DCI notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Laboratory and field data have demonstrated that cypermethrin is immobile in soil and will not leach into ground water. Estimates of zeta-cypermethrin drinking water concentrations were generated with the PRZM1 and EXAMS computer models. 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 0.000126 mg/kg/day (MOE of 3,982) and 0.000242 mg/kg/day (MOE of 2,069) 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 0.000005 mg/kg/day (0.1% of RfD utilized) and 0.000021 mg/kg/day (0.4% of RfD utilized) for the overall U.S. population and non-nursing infants < 1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Zeta-cypermethrin is registered for agricultural crop applications only; 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) of the FFDCA 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).

Four members of the insecticide class pyrethroids produce a common metabolite known as DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid). These insecticides are cyfluthrin, cypermethrin, zeta-cypermethrin, and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound, the toxicity of the DCVA has been assumed to be equivalent to the parent compound. However, due to the markedly different toxicological profiles of cyfluthrin, cypermethrin, zeta-cypermethrin, and permethrin, EPA does not believe that it would be appropriate to cumulate DCVA residues from these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides.

Accordingly, EPA does not have, at this time, available data to determine whether zeta-cypermethrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that zeta-cypermethrin 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 MOE calculated at the 99.9th percentile for the overall U.S. population is 122. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to zeta-cypermethrin through food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Contribution (ARC) exposure assumptions, EPA has concluded that aggregate exposure to zeta-cypermethrin from food and water will utilize 0.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest-aggregate exposure is children, ages 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. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zeta-cypermethrin 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 zeta-cypermethrin 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 zeta-cypermethrin residues.

E. Aggregate Cancer Risk for U.S. Population

No carcinogenicity studies are available for zeta-cypermethrin. However, cypermethrin has been classified as a weak Group C carcinogen with no Q*1 based on the increased incidence in lung adenomas in female CD-1 mice. Based on the recommendation that the RfD approach be used, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of cypermethrin are adequately addressed by the DRES chronic exposure analysis using the RfD. For the U.S. population, less than 1% of the RfD is occupied by aggregate chronic food and water exposure.

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 zeta-cypermethrin, 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.

Section 408 of the FFDCA provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a prenatal developmental toxicity study in rats, there was no evidence of developmental toxicity at the HDT (35 mg/kg/day). Maternal toxicity (ataxia, urine and feces stained fur, decreased bodyweight gain and food consumption) was observed at the maternal LOEL (25 mg/kg/day), and the maternal NOEL was established at 12.5 mg/kg/day. In

addition, an acceptable prenatal developmental toxicity study in rabbits conducted with cypermethrin was submitted.

iii. *Reproductive toxicity study.* In the two-generation reproduction study in rats, offspring toxicity (decreased pup weight gain during lactation) was observed at the same treatment level which resulted in parental systemic toxicity (NOEL = 100 ppm or 27 mg/kg/day; LOEL = 375 ppm or 45 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* There is no evidence of additional sensitivity to young rats following pre- or post-natal exposure to zeta-cypermethrin.

v. *Conclusion.* The data base related to pre- and post-natal sensitivity is complete. Based on the information in Unit II. F. of this preamble, 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 risk assessment takes into account exposure from food and water. The MOE calculated at the 99.9th percentile for children age 1–6 is 102. 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 has no acute aggregate concern due to exposure to zeta-cypermethrin through food and drinking water.

3. *Chronic risk.* Using conservative exposure assumptions, EPA has concluded that aggregate exposure to zeta-cypermethrin from food and water will utilize 0.6% of the RfD for children, ages 1–6 years old. 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 to infants and children from aggregate exposure to zeta-cypermethrin residues.

4. *Short- or intermediate-term risk.* Based on zeta-cypermethrin 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.

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

The metabolites found in plants and livestock also are formed in the rat. It was concluded that 3-phenoxybenzoic acid (PBA) and its conjugates are not of concern based on toxicology data for PBA. In the absence of toxicology data, the cis- and trans-isomers of DCVA are considered to be of comparable toxicity to the parent. In light of Codex Maximum Residue Limits (MRLs) including only the parent compound, the parent being recoverable by the Food and Drug Administration (FDA) multi-residue Methods I and II, and the DCVA is not likely to be measured by these methods, it was concluded that tolerances should be set in terms of cypermethrin only. Crop field trials should continue to include analyses for residues of cis- and trans-DCVA.

B. Analytical Enforcement Methodology

Adequate enforcement methodology Gas Chromatography/Electron Capture Detector (GC/ECD) is available in Pesticide Analytical Method II (PAM II) as Method I to enforce the tolerance expression.

C. Magnitude of Residues

Residue data from field trials and the FDA monitoring program (1992–1995) and the PDP monitoring program (1994) were used to estimate chronic dietary exposure. For the chronic analyses, mean residues from FDA monitoring were used for lettuce and onions (dry bulb). Residue field trial data were used for broccoli, cabbage, cotton, green onions, mustard greens, and pecans.

For acute dietary exposure analysis, field trial residue data, along with percent of crop treated data, were used in the Monte Carlo analysis.

D. International Residue Limits

Codex MRLs for cypermethrin have been established which are in harmony with the U.S. tolerances for meat and mbyp of cattle, goats, hogs, horses, and sheep (0.05 ppm); milk (0.05 ppm); and onions, bulb (0.10 ppm).

Codex MRLs have been established which exceed the U.S. tolerances for meat (fat basis) of cattle, goats, hogs, horses, and sheep (0.2 vs. 0.05 ppm).

Codex MRLs have been established which are below their U.S. counterparts for cabbage (brassica vegetables) (1.0 vs. 2.0 ppm) and lettuce, head (2.0 vs. 10.0 ppm).

No Canadian MRLs have been established for residues of cypermethrin.

Mexico has established a tolerance for residues of cypermethrin on cottonseed (0.5 ppm) which is in harmony with the U.S. tolerance.

As indicated in this unit, there are differences between the FFDCA section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculations 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 tolerances are established for residues of zeta-cypermethrin (*s*-cyano(3-phenoxyphenyl) methyl (±) cis, trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep at 0.05 ppm.

V. Objections and Hearing Requests

The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) of the FFDCA as was provided in the old section 408 and in section 409 of the FFDCA. 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 Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPP–300577 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. 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–300577. No 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.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under section 408(d) of the FFDCA 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 FR7 629, 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 section 408(d) of the FFDCA, 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 180.418 is amended by adding a new paragraph (a)(2) to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of the insecticide zeta-cypermethrin (*s*-cyano(3-phenoxyphenyl) methyl (±) cis, trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following commodities:

Commodity	Parts per million
Cabbage	2.0
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cottonseed	0.5
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Lettuce, head	10.0
Milk	0.05
Onions, bulb	0.10
Pecans	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

* * * * *

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