Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 6, 2001

Peter Caulkins,

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. 321(q), 346(a) and 371.

2. Section 180.458 is amended by revising the section heading, the introductory text paragraph (a)(3), and alphabetically adding commodities to the table in paragraph (a)(3) to read as follows:

§ 180.458 Clethodim; tolerances for residues.

(a) * * *

(3) Tolerances are established for the combined residues of the herbicide clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim tolerance residues for the following commodities.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup	3.0
Canola, meal	1.0
Canola, seed	0.50
* * * * *	
Flax, meal	1.0
Flax, seed	0.50
* * * * *	
Lettuce, leaf	2.0
* * * * *	
Mustard, seed	0.50
* * * * *	
Onion, green	2.0
* * * * *	

* * * * *

[FR Doc. 01–23086 Filed 9–14–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301171; FRL–6801–1]

RIN 2070–AB78

Zeta-cypermethrin and its Inactive R-isomers; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin and its inactive R-isomers in or on alfalfa, hay at 15 parts per million (ppm), alfalfa, forage at 5.0 ppm, alfalfa, seed at 0.5 ppm; beets, sugar, roots at 0.05 ppm, beets, sugar, tops at 0.20 ppm; corn, field, grain at 0.05 ppm, corn, pop, grain at 0.05 ppm, corn, field, forage at 0.20 ppm, corn, field, stover at 3.0 ppm, corn, pop, stover at 3.0 ppm, corn, sweet, (K + CWHR) at 0.05 ppm, corn, sweet, forage at 15 ppm, corn, sweet, stover at 15 ppm; onions, green at 3.0 ppm; leafy vegetables except Brassica at 10 ppm, head and stem Brassica at 2.0 ppm, leafy Brassica at 14 ppm; sugarcane at 0.6 ppm; rice, grain at 1.5 ppm, rice, straw at 2.0 ppm, rice, hulls at 6.0 ppm; fat of cattle, goat, horse, sheep, hogs at 1.0 ppm, meat of cattle, goat, horse, sheep, hogs at 0.1 ppm, milk, fat at 2.50 ppm (reflecting 0.10 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, poultry, meat by-products at 0.05 ppm, and eggs at 0.05 ppm. FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 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 September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301171, must be received by EPA on or before November 16, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301171 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda A. DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460; telephone number: (703) 305–5428; e-mail address: deluise.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301171. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 23, 1998 (63 FR 34176) (FRL–5795–1), and September 8, 1999 (64 FR 48829) FRL–6097–6), EPA issued notices under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a announcing the filing of pesticide petitions (PP) (PF 813 and PF 888) for tolerances by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103.

These notices included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to these notices of filing.

The petitions requested that 40 CFR 180.418 be amended by establishing a tolerance for residues of the insecticide zeta-cypermethrin, in or on the following raw agricultural commodities:

1. PP 9F6040 proposed a tolerance for rice, grain at 1.2 parts per million (ppm), rice, straw at 2.0 ppm and rice, hulls at 16.0 ppm. Based on EPA's review of processing studies, the petition was revised by the petitioner to propose a tolerance of 1.5 ppm on rice grain and 6.0 ppm on rice hulls.

2. PP 8F4970 proposed a tolerance for leafy vegetables (except Brassica vegetables) group (Crop Group 4) at 10.0 ppm, Brassica, head and stem (Crop Group 5A) at 2.0 ppm and Brassica, leafy (Crop Group 5B) at 14.0 ppm. These tolerances as proposed are adequate.

3. PP 9F3067 proposed a tolerance for sugar beets, roots at 0.05 ppm, and sugar beets, tops at 0.20 ppm; sugarcane at 0.60 ppm; corn, grain (field, seed and pop) at 0.05 ppm; green onions at 6.0 ppm; alfalfa seed at 0.5 ppm, alfalfa forage at 10.0 ppm, and alfalfa hay at 30.0 ppm; and corn, sweet (K + CWHR) at 0.1 ppm, corn, forage and corn, fodder at 30.0 ppm; poultry, meat at 0.05 ppm, poultry, meat by-products at 0.05 ppm, poultry, fat at 0.05 ppm and eggs at 0.05 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.3 ppm; fat of cattle, goats, hogs, horses, and sheep at 2.0 ppm; and milk, fat at 1.0 ppm (reflecting 0.2 ppm in whole milk). Based on EPA's review of the field residue and animal feeding data the petition was revised by the petitioner to:

a. Propose tolerances of 0.05 ppm for sweet corn (K + CWHR) and 15 ppm for sweet corn forage and stover. (Note that stover is the correct term instead of fodder).

b. Propose separate tolerance for field corn grain and pop corn grain at 0.05 ppm.

c. Delete the proposed seed corn tolerance since it is covered by field corn.

d. Propose separate tolerances for field corn stover and pop corn stover at 3.0 ppm and field corn forage at 0.20 ppm.

e. Reduce the proposed 6.0 ppm tolerance on green onion to 3.0 ppm.

f. Propose the following livestock commodity tolerances as a result of the increased dietary burden: animal (cattle, goat, hog, horse, sheep) meat at 0.1 ppm; fat at 1.0 ppm; and milk fat at 2.5 ppm (reflecting 0.10 ppm in whole milk).

g. Propose tolerances for alfalfa seed, forage and hay, respectively at 0.5 ppm, 5 ppm, and 15 ppm.

Based upon the isomer composition of zeta-cypermethrin with four insecticidally less active ones at a concentration of 1% each, EPA is proposing the current tolerance expression be revised by adding the phrase and its inactive R-isomers after the chemical name.

Although EPA had requested a number of changes to the initial petitions and Notice of Filings, the nature of the changes, i.e. reduction in tolerance levels, clarification and correction of commodity terms are not considered significant nor do they alter the risk assessment. Therefore EPA is issuing this as a final action.

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. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of zeta-cypermethrin and its inactive R-isomers in or on alfalfa, hay at 15 parts per million (ppm), alfalfa, forage at 5.0 ppm, alfalfa, seed at 0.5 ppm; beets, sugar, roots at 0.05 ppm, beets, sugar, tops at 0.20 ppm; corn, field, grain at 0.05 ppm, corn, pop, grain at 0.05 ppm, corn, field, forage at 0.20 ppm, corn, field, stover at 3.0 ppm, corn, pop, stover at 3.0 ppm, corn, sweet, (K + CWHR) at 0.05 ppm, corn, sweet, forage at 15 ppm, corn, sweet, stover at 15 ppm; onions, green at 3.0 ppm; leafy vegetables except Brassica at 10 ppm, head and stem Brassica at 2.0 ppm, leafy Brassica at 14 ppm; sugarcane at 0.6 ppm; rice, grain at 1.5 ppm, rice, hulls at 6.0 ppm; rice, straw at 2.0 ppp; fat of cattle, goat, horse, sheep, hogs at 1.0 ppm, meat of cattle, goat, horse, sheep, hogs 0.1 ppm, milk, fat at 2.5 ppm (reflecting 0.10 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, poultry, meat by-products at 0.05 ppm; and eggs at 0.05 ppm. EPA's assessment of 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 zeta-cypermethrin and its inactive R-isomers are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed. Zeta-cypermethrin is an enriched isomer of cypermethrin. In order to select toxicity endpoints for the purposes of risk assessment, bridging data on zeta-cypermethrin were submitted so that the toxicity of zeta-cypermethrin could be compared with that of cypermethrin and the data bases could be combined to form one complete data base for both chemicals. In the selection of toxicity endpoints, studies conducted with zeta-cypermethrin were used wherever possible. When an endpoint was selected using a study conducted with cypermethrin, a rationale was provided on why this particular endpoint was protective for exposure to zeta-cypermethrin.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY ZETA-CYPERMETHRIN AND CYPERMETHRIN TECHNICAL*

Guideline No.	Study Type	Results	Toxicity Category
870.1000	Acute oral - rat - zeta-cypermethrin	LD_{50} (M): 134.4 mg/kg (F): 86.0 mg/kg Clinical signs of neurotoxicity observed.	II
870.1000	Acute oral - cypermethrin	LD_{50} (M): 247 mg/kg (F): 309 mg/kg females Deaths: ≥150 mg/kg, usually in first day. Clinical signs of neurotoxicity, gait abnormalities; some persisting to 14 days.	II
870.1100	Acute Dermal Rats - cypermethrin Rabbits - cypermethrin	LD_{50} >4,920 mg/kg/day. Clinical signs of neurotoxicity. Abraded skin: LD_{50} >2,460 mg/kg. Lacrimation, discharge from the eye and nervous and shaking	III III
870.1200	Acute inhalation - rat - cypermethrin	LC_{50}: male (not calculated but higher than female) LC_{50}: female 2.5 (1.6-3.4) mg/L. Clinical signs of neurotoxicity. MMAD ranged from 2.22 to 2.62 μm	IV
870.2400	Primary eye irritation - rabbit cypermethrin	Slight redness of conjunctivae, chemosis and discharge. Persisted to day 7.	III

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY ZETA-CYPERMETHRIN AND CYPERMETHRIN TECHNICAL*—Continued

Guideline No.	Study Type	Results	Toxicity Category
870.2500	Primary skin irritation rabbit - cypermethrin	Slight to mild erythema on intact and abraded skin. Reversed by 48 hours. Primary Irritation Index: 0.71	IV
870.2600	Dermal sensitization - cypermethrin	Not a sensitizer in Buehler assay. Moderate sensitizer in Magnusson Kligman Maximization method.	N/A

TABLE 2.—TOXICITY PROFILES OF ZETA-CYPERMETHRIN TECHNICAL AND CYPERMETHRIN TECHNICAL*

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity - rat: zeta-cypermethrin	NOAEL = M = 13.8 (M), 16.3 (F) mg/kg/day LOAEL = 28.2 mg/kg/day (M) based on decreased body weight, body weight gain and food consumption; at 55.7 mg/kg/day, mortality as well as decreased RBC, WBC, HGB and HCT plus increase in BUN. 32.2 mg/kg/day (F) based on decreased body weight, body weight gain and food consumption as well as interference with estrous cycle and decreased glucose; mortality at 65.2 mg/kg/day.
870.3100	90-Day oral toxicity - rat: cypermethrin	NOAEL = 7.5 mg/kg/day LOAEL = 75 mg/kg/day based on decreased body weight in both sexes.
870.3150	90-Day oral toxicity in dogs (feeding): cypermethrin	NOAEL = 24.6 (M), 34.3 (F) mg/kg/day LOAEL = 37.0 (M), 45.2 (F) mg/kg/day based on tremors as well as decreased body weight and body weight gains in both sexes.
870.3150	90-Day oral toxicity in dogs (feeding): cypermethrin	NOAEL = 12.5 mg/kg/day LOAEL = 37.5 mg/kg/day based on clinical signs (whole body tremors, exaggerated gait, ataxia, incoordination, hyperaesthesia, licking and chewing of paws; diarrhea, anorexia) and decreased body weight
870.3200	21-Day dermal toxicity - rat: zeta-cypermethrin	NOAEL = Systemic: 1,000 mg/kg/day. Dermal: <100 mg/kg/day LOAEL = Systemic: >1,000 mg/kg/day (Limit Dose) Dermal: 100 mg/kg/day, based on erythema and/or eschar 1/10 M and 6/10 F; desquamation 0/10 M and 2/10 F (no effects in any M or F controls).
870.3200	21-Day dermal toxicity - rabbit: cypermethrin	NOAEL = Systemic nonabraded animals: 200 mg/kg/day (HDT) Dermal: 20 mg/kg/day LOAEL = Systemic nonabraded animals: >200 mg/kg/day (HDT) Dermal: 200 mg/kg/day based on signs of dermal irritation
870.3465	21-Day inhalation toxicity - cypermethrin	NOAEL = 0.01 mg/L (2.7 mg/kg/day) LOAEL = 0.05 mg/L based on decreases in body weight
870.3700	Prenatal developmental in rats - zeta-cypermethrin	*Maternal* NOAEL = 12.5 mg/kg/day LOAEL = 25 mg/kg/day, based on ataxia, urine-stained abdominal fur, fecal-stained perineal fur, decreased food consumption and decreased body weight gain. *Developmental* NOAEL ≥ 35 mg/kg/day LOAEL = > 35 mg/kg/day

TABLE 2.—TOXICITY PROFILES OF ZETA-CYPERMETHRIN TECHNICAL AND CYPERMETHRIN TECHNICAL*—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in rats - cypermethrin	*Maternal* NOAEL = 17.5 mg/kg/day LOAEL = 35 mg/kg/day based on decreased body weight gain; at 70 mg/kg/day, splayed limbs, spasms and hypersensitivity to noise and convulsions. *Developmental* NOAEL = 70 mg/kg/day (HDT) LOAEL = >70 mg/kg/day
870.3700	Prenatal developmental in rabbits - cypermethrin	*Maternal* NOAEL = 100 mg/kg/day LOAEL = 450 mg/kg/day based on decreased body weight gain; anorexia, abdomino-genital staining, decreased feces and red or pink material in the pan (few does). At 700, anorexia, abdomino-genital staining, decreased feces and red or pink material in the pan were observed. *Developmental* NOAEL = 700 mg/kg/day LOAEL = >700 mg/kg/day (highest dose tested)
870.3700	Prenatal developmental in rabbits - cypermethrin	*Maternal* NOAEL = 30 mg/kg/day LOAEL > 30 mg/kg/day (HDT) *Developmental* NOAEL = 30 mg/kg/day LOAEL = > 30 mg/kg/day (highest dose tested)
870.3800	Reproduction and fertility effects - zeta-cypermethrin	*Parental/Systemic* NOAEL = 7 mg/kg/day LOAEL = 27 mg/kg/day based on decreased body weight gain (most noticeable during lactation) and increased relative brain weights M and F; at 45 mg/kg/day, some neurotoxic clinical signs in a few animals (some mortality) . *Reproductive* NOAEL = 45 mg/kg/day LOAEL >45 mg/kg/day (highest dose tested). *Offspring* NOAEL = 7 mg/kg/day LOAEL = 27 mg/kg/day, based on decreased body weight gain during lactation; at 45 mg/kg/day, pup mortality.
870.3800	Reproduction and fertility effects - cypermethrin	*Parental/Offspring* NOAEL = 7.5 mg/kg/day LOAEL = 50/37.5 mg/kg/day based on decreased body weight gain in both sexes and decreased mean litter weight gain during lactation.
870.3800	Reproduction and fertility effects - cypermethrin	*Parental/Systemic* NOAEL = 5 mg/kg/day LOAEL = 25: based on decreased body weight gain. *Offspring* NOAEL = 5 mg/kg/day LOAEL = 25: based on decreased body weight gain (lactation day 21).
870.4100	Chronic toxicity rats - cypermethrin	NOAEL = 7.5 mg/kg/day LOAEL = 75 mg/kg/day based on decreases in body weight gain (both sexes)
870.4100	Chronic toxicity dogs (capsule) - cypermethrin	NOAEL = 1 mg/kg/day LOAEL = 5 mg/kg/day based on gastrointestinal effects (liquid stool); at 15 mg/kg/day, body tremors, gait abnormalities, in coordination, disorientation and hypersensitivity to noise plus decrease in body weight.
870.4100	Chronic toxicity dogs (feeding) - cypermethrin	NOAEL = 6 mg/kg/day (M), 5.7 mg/kg/day (F) LOAEL = 20.4 mg/kg/day (M) based on abnormal clinical signs (tremors, excessive salivation, irregular gait); at 33.9 mg/kg/day, mortality. 18.1 mg/kg/day (F) based on decreased body weight and weight gains.

TABLE 2.—TOXICITY PROFILES OF ZETA-CYPERMETHRIN TECHNICAL AND CYPERMETHRIN TECHNICAL*—Continued

Guideline No.	Study Type	Results
870.4200	Carcinogenicity rats - cypermethrin	NOAEL = 7.5 mg/kg/day LOAEL = 75 mg/kg/day based on decreases in body weight gain (both sexes). No evidence of carcinogenicity
870.4300	Carcinogenicity mice - cypermethrin	NOAEL = 14 mg/kg/day LOAEL = 57 mg/kg/day (M) based on increased absolute (20%) liver weights Females, there was a 15% increase in relative liver weights only at 229 mg/kg/day. Cancer: positive for induction of benign alveologenic neoplasms.
870.5265	*Salmonella typhimurium* reverse mutation assay - zeta-cypermethrin	Very weak positive response (2-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. Zeta-cypermethrin considered a possible weak mutagen under the conditions of the assay.
870.5265	*Salmonella typhimurium* and *S. cerevisiae* reverse mutation assay - cypermethrin	Negative up to doses of 2,500 μg/plate
870.5300	Gene mutation in mammalian cells in culture zeta-cypermethrin	CHO-K1-BH_4, subclone D1 cells. No evidence of increased forward mutation rate at the HGPRT locus at any dose tested up to and beyond solubility limit.
870.5300	Gene mutation in mammalian cells in culture cypermethrin	CHO-K1-BH_4, subclone D1 cells. No evidence of increased forward mutation rate at the HGPRT locus at any dose tested up to and beyond solubility limit.
870.5375	*In vitro* cytogenetics zeta-cypermethrin	The study demonstrates that zeta-cypermethrin is not mutagenic in the mouse lymphoma assay (L5178Y cell line) at the above doses with or without metabolic activation.
870.5380	*In vivo* cytogenetics zeta-cypermethrin	No evidence of structural chromosomal aberrations in rat bone marrow at either 6, 18, or 30 hours post dosing.
870.5380	*In vivo* cytogenetics cypermethrin	No evidence of structural chromosomal aberrations in rat bone marrow at 20 or 40 mg/kg.
870.5550	Unscheduled DNA synthesis in mammalian cells in culture zeta-cypermethrin	No unscheduled DNA synthesis was observed at any dose level up to 4,500 μg/mL in male rat (Fischer 344) liver primary hepatocyte cultures under the conditions of this assay. Minimal cytotoxicity was observed at the highest doses. Incomplete solubility of the test compound in culture media was observed, particularly at higher doses.
870.5550	Unscheduled DNA synthesis in mammalian cells in culture cypermethrin	No unscheduled DNA synthesis was observed at any dose level up to 200 mg/kg in corn oil in Alpk:APfSD strain rats (males) assessed 4 and 12 hours post dosing. 200 mg/kg dose was considered near the MTD.
870.5450	Dominant lethal assay in the rodent cypermethrin	No evidence of dominant lethal activity in CD-1 strain mice up to 10 mg/kg/day for 5 consecutive days.
870.6200	Acute neurotoxicity screening battery - zeta-cypermethrin	NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on clinical signs (abdominogenital staining, oral discharge, splayed hindlimbs, staggered gait and tremors); FOB findings (abnormal mobile posture, splayed hindlimbs, soiled fur and unable to walk); at 250, more severe findings.
870.6200	Acute neurotoxicity screening battery - cypermethrin	NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg based primarily on ataxia and related conditions (staggered or impaired gait, decreased activity, splayed hindlimbs and limp conditions, in addition to decreased motor activity in males and females on days 0, 1, or 2).
870.6200	Acute neurotoxicity screening battery - cypermethrin	NOAEL = < 20 mg/kg/day LOAEL = 20 mg/kg based on decreased motor activity and gait abnormalities.

TABLE 2.—TOXICITY PROFILES OF ZETA-CYPERMETHRIN TECHNICAL AND CYPERMETHRIN TECHNICAL*—Continued

Guideline No.	Study Type	Results
870.6200	Subchronic neurotoxicity screening battery - zeta-cypermethrin	NOAEL = 5.0 mg/kg/day (M); 31.5 mg/kg/day (F) LOAEL = 26.3 mg/kg/day (M) based on decreased motor activity, increased landing foot splay, and decreased body weights, body weight gains, and food consumption 55.6 mg/kg/day (F) based on decreased body weights, body weight gains, and food consumption.
870.6200	Subchronic neurotoxicity screening battery - cypermethrin	NOAEL = 31 mg/kg/day LOAEL = 77 mg/kg/day based on the following: Males: decreased body weight gain and increased landing foot splay; Females: ataxia, splayed hindlimbs, impaired gait and decreased feces as well as decreased body weight gain.
870.7485	Metabolism and pharmacokinetics	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* radiolabelled 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 mostly excreted in the urine that contains several characterized metabolites derived from conjugation of the hydrolysis products of the parent compound following cleavage of the esteratic linkage site.
870.7600	Dermal penetration	No study is available.

*Zeta-cypermethrin is bridged to data base with cypermethrin. Therefore, studies on both are included.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for zeta-cypermethrin and its inactive R-isomers used for human risk assessment is shown in the following Table 3:

TABLE 3.—SUMMARY OF THE TOXICOLOGICAL DOSE AND ENDPOINTS FOR ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 1 aPAD = acute RfD FQPA SF = 0.10 mg/kg/day	Acute neurotoxicity study in the rat (zeta-cypermethrin). LOAEL = 50 mg/kg/day based on clinical signs of toxicity and FOB findings.

TABLE 3.—SUMMARY OF THE TOXICOLOGICAL DOSE AND ENDPOINTS FOR ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations)	NOAEL = 6 mg/kg/day UF = 100 Chronic RfD = 0.06 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.06 mg/kg/day	Chronic feeding study in the dog (cypermethrin). LOAEL = 20.4/18.1 mg/kg/day based on clinical signs of neurotoxicity and mortality in males, and decreased body weights and body weight gains in females.
Short-term incidental oral (1 to 7 days) (residential)	NOAEL = 10 mg/kg/day	LOC for MOE = 100 (residential)	Acute neurotoxicity study in the rat (zeta-cypermethrin). LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity and changes in the FOB
Intermediate-term incidental oral (1 week to several months) (residential)	NOAEL = 5.0 mg/kg/day	LOC for MOE = 100 (residential)	Subchronic neurotoxicity study in the rat (zeta-cypermethrin). LOAEL = 26.3 mg/kg/day based on decreased motor activity, increased landing foot splay, and decreased body weights, body weight gains, and food consumption
Short- and intermediate-term dermal (1 to 7 days and 1 week to several months) (residential)	No hazard identified to support quantitation of risk.	Not applicable	No systemic effects in 21-day dermal study up to 1,000 mg/kg/day and no observed developmental effects in developmental studies.
Long-term dermal (several months to lifetime) (residential)	Oral study NOAEL= 6 mg/kg/day (dermal absorption rate = 2.5%)	LOC for MOE = 100 (residential)	Chronic feeding study in the dog (cypermethrin). LOAEL = 20.4/18.1 mg/kg/day based on clinical signs of neurotoxicity and mortality in males, and decreased body weights and body weight gains in females.
Inhalation (all durations) (residential)	Inhalation study NOAEL = 0.01 mg/L (2.7 mg/kg/day)	LOC for MOE = 100 (residential) for short- and intermediate-term exposure. Long-term exposure: LOC for MOE 300 for the lack of alternative study. Route-to-route estimation would result in less protective endpoint.	21-Day inhalation study in the rat (cypermethrin). LOAEL = 0.05 mg/L/day based on body weight decrease
Cancer (oral, dermal, inhalation)	N/A	Category C (possible human carcinogen). No quantization required	Mouse oncogenicity study with cypermethrin.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure 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: Cabbage at 2.0 ppm, animal fat (cattle, goat, hog, horse, and sheep) at 0.05 ppm, animal meat byproducts at 0.05 ppm, animal meat at 0.05 ppm, cottonseed at 0.5 ppm, head lettuce at 10.0 ppm, milk at 0.05 ppm, bulb onions at 0.10 ppm, and pecans at 0.05 ppm. Tolerances for cypermethrin (parent compound) are the same as those for zeta-cypermethrin with the exception that there are cypermethrin tolerances for green onions at 6.0 ppm, heads and stem Brassica at 2.0 ppm and leafy Brassica at 14.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from zeta-cypermethrin and its inactive R-isomers in food as follows:

Zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin. Both cypermethrin and zeta-cypermethrin are mixtures of eight isomers, with the active components consisting of the S-enantiomers (''S''configuration at the cyano bearing carbon). The two differ in that cypermethrin has a 50:50 R/S ratio whereas zeta-cypermethrin is enriched in the S-enantiomers with a ratio of 90:10 of S/R. The enriched isomer formulation provides for similar insect control but at lower use rates. Since use of both cypermethrin and zeta-

cypermethrin result in human exposure to the same eight isomers, dietary and non-dietary (residential) aggregate risk assessment was conducted by adding the uses of the two chemicals.

i. *Acute exposure*. 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 Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance-level residues and 100% crop treated have been used in these analyses for all commodities having either established or proposed tolerances of cypermethrin or zeta-cypermethrin. In cases where a commodity has an established tolerance for cypermethrin and a proposed tolerance for zeta-cypermethrin, the larger of the two values was used in the assessment. DEEM™ default processing factors were used for all commodities in this assessment.

TABLE 4.—SUMMARY OF ACUTE DIETARY EXPOSURE AND RISK FOR ZETA-CYPERMETHRIN

Population Subgroup	Acute Dietary	
	Dietary Exposure (mg/kg/day)	%aPAD
U.S. population	0.020013	20
Infants (<1 year old)	0.021554	22
Children (1-6 years)	0.030121	30
Females (13-50 years)	0.019736	20

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance-level residues and 100% crop treated have been used in these analyses for all commodities having either established or proposed tolerances of cypermethrin or zeta-cypermethrin. For chronic risk assessments, residue estimates for foods (e.g., apples) or food-forms (e.g., apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg bwt/day and as a percent of the cPAD.

TABLE 5.—SUMMARY OF CHRONIC DIETARY EXPOSURE AND RISK FOR ZETA-CYPERMETHRIN

Population Subgroup	Chronic Dietary	
	Dietary Exposures (mg/kg/day)	%cPAD
U.S. population	0.006477	11
Infants (<1 year old)	0.005748	10
Children (1-6 years)	0.011906	20
Females (13-50 years)	0.005749	10

As shown by the summarized acute and chronic results in Tables 4 and 5, all risk estimates fall below EPA's level of concern (≥100% PAD). All exposures are Tier 1 estimates that are extremely conservative and likely overestimate actual dietary exposure. Refinements to the analyses in the form of percent crop treated considerations and/or anticipated residues would likely reduce the exposure and risk estimates for zeta-cypermethrin.

iii. *Cancer*. Cypermethrin has been classified as a Category C, possible human carcinogen, based on an increased incidence of lung adenomas and adenomas plus carcinomas combined in female mice (Cancer Peer Review Committee, 1988). The evidence was not considered strong enough to warrant a quantitative estimation of human risk. Cypermethrin has not been classified under the more current, Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996). Because zeta-cypermethrin is an enriched isomer of cypermethrin, it is also classified as a Category C carcinogen and a RfD approach was recommended for human risk assessment purposes.

2. *Dietary exposure from drinking water*. Based on the available data, cypermethrin/zeta-cypermethrin is a moderately persistent chemical that primarily degrades by photolysis in water and biodegradation. Depending on the environmental circumstances, it may persist for periods of months post-treatment. Cypermethrin is tightly bound to soil particles and is not likely to move to ground waters. However, the degradate DCVA is mobile and likely to reach ground waters. Additional information about the mobility of this degradate has been requested. Cypermethrin can contaminate surface waters through spray drift. Under some conditions it may also have a potential for runoff into surface waters (primarily through erosion), for several months post-application. Since zeta-cypermethrin is preferentially associated to the soils, the fraction of the chemical in the water column should be small. In addition, it is expected that treatment of drinking waters would remove substantial portions of cypermethrin/zeta-cypermethrin present in water.

Although the Agency has not addressed residues of DCVA in water, we have concluded that DCVA does not need to be included in the dietary risk for food.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use EECs from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cypermethrin and zeta-cypermethrin and its inactive R-isomers, they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models, the EECs of cypermethrin and zeta-cypermethrin and its inactive R-isomers for acute exposures are estimated to be 8.9 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.46 ppb ppb for surface water and 0.006 ppb for ground water. These values generally represent upper-bound estimates of the concentrations that might be found in surface water and ground water due to the use of cypermethrin on Brassica vegetables, which has the highest application rate among both cypermethrin and zeta-cypermethrin on all crops over which the chemicals are applied.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Zeta-cypermethrin and its inactive R-isomers is not registered for use on any sites that would result in residential exposure. However, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). The analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same. Therefore, dietary and non-dietary residential aggregate risk assessment is conducted by adding the uses of the two chemicals.

4. *Cumulative exposure to substances with a 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.''

EPA does not have, at this time, available data to determine whether zeta-cypermethrin and its inactive R-isomers has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, Zeta-cypermethrin and its inactive R-isomers does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that zeta-cypermethrin and its inactive R-isomers has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. The data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to either zeta-cypermethrin or cypermethrin. In the prenatal developmental toxicity studies in rats, there was no evidence of developmental toxicity at the highest dose tested (35 mg/kg/day). Maternal toxicity (decreased body weight gain (both chemicals), and food consumption, ataxia, urine and feces-stained for (zeta-cypermethrin)) was observed at the LOAEL of 25 mg/kg/day. The maternal NOAELs were established at 12.5 mg/kg/day for zeta-cypermethrin and 17.5 mg/kg/day for cypermethrin. In the definitive rabbit developmental toxicity study conducted with cypermethrin, the maternal LOAEL was 450 mg/kg/day based on decreased body weight gain. No developmental toxicity was observed at dose levels up to 700 mg/kg/day. In the two-generation reproduction study in rats conducted with zeta-cypermethrin, offspring toxicity (decreased pup weight gain during lactation) was observed at the same treatment level which resulted in parental systemic toxicity (NOAEL: 27 mg/kg/day; LOAEL: 45 mg/kg/day). In the definitive multigeneration reproduction study conducted with cypermethrin, the parental NOAEL/LOAEL is lower than the pup NOAEL/LOAEL, both based on decreases in body weight gain (2.5/7.5 mg/kg/day for the parents versus 7.5/37.5 mg/kg/day for the pups).

iii. *Conclusion*. There is a complete toxicity data base for zeta-cypermethrin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposure based on the considerations above. The safety factor can be removed for zeta-cypermethrin and its inactive R-isomers

because: (1) There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; (2) the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study - and a safety factor (e.g., neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore does not warrant an FQPA safety factor; and (3) the dietary (food and drinking water) and non-dietary exposure assessments will not underestimate the potential exposures for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to zeta-cypermethrin and its inactive R-isomers will occupy 20% of the aPAD for the U.S. population, 20% of the aPAD for females 13 years and older, 22% of the aPAD for infants (<1 year old), and 30% of the aPAD for children (1-6 years). In addition, there is potential for acute dietary exposure to zeta-cypermethrin and its inactive R-isomers in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

Population Subgroup	aPAD,mg/kg/day	%aPAD (Food)	Ground Water EEC[1], ppb	Surface Water EEC[1], ppb	Acute DWLOC[2], ppb
U.S. population	0.10	20%	0.006	8.9	2,800
All infants (<1 year old)	0.10	22%	0.006	8.9	780
Children (1-6 years old)	0.10	30%	0.006	8.9	700
Females (13-50 years old)	0.10	20%	0.006	8.9	2,400

[1]EECs resulting from the maximum proposed application rate (Cypermethrin on Brassica vegetables)
[2]The acute DWLOC was calculated as follows:
DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/µg

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to zeta- cypermethrin and its inactive R-isomers from food will utilize 11% of the cPAD for the U.S. population, 10% of the cPAD for all infants (< 1 year old), and 20% of the cPAD for children (1-6 years old).

There are no residential uses for zeta-cypermethrin and its inactive R-isomers that result in chronic residential exposure to zeta-cypermethrin and its inactive R-isomers. However, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). The analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same. Therefore, dietary and non-dietary residential aggregate risk assessment is conducted by adding the uses of the two chemicals. Based on the use pattern, chronic residential exposure to residues of zeta-cypermethrin and its inactive R-isomers is not expected. In addition, there is potential for chronic dietary exposure to zeta-cypermethrin and its inactive R-isomers in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 7:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE

Population Subgroup	cPAD, (mg/kg/day)	%cPAD (Food)	Ground Water EEC[1], (ppb)	Surface Water EEC[1], (ppb)	Chronic DWLOC[2], (ppb)
U.S. population	0.06	11%	0.006	0.46	1,900
All infants (<1 year old)	0.06	10%	0.006	0.46	540
Children (1-6 years old)	0.06	20%	0.006	0.46	480
Females (13-50 years old)	0.06	10%	0.006	0.46	1,600

[1] EECs resulting from the maximum proposed application rate (cypermethrin on Brassica vegetables)
[2] Chronic DWLOCs were calculated as follows: DWLOC (μg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/μg

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Zeta-cypermethrin and its inactive R-isomers is currently not registered for use that could result in short-term residential exposure; however, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). Cypermethrin registered residential uses constitute short- and intermediate-term exposure scenarios; endpoints have been selected for short- and intermediate-term incidental oral and inhalation exposures, and the acceptable MOEs for short- and intermediate-term exposures are 100. Since the toxicological effects through the inhalation exposure route are similar to those toxicological effects through the oral routes, short-term aggregate risk assessment was conducted adding inhalation, oral non-dietary exposure, and average food and water exposure.

Since all the acceptable MOEs are at the same level, the aggregate risks for population subgroups can be estimated by calculating aggregate Margin of Exposure values ($MOE_{aggregate}$). $MOE_{aggregate} = 1/(1/MOE_I + 1/MOE_D + 1/MOE_O + 1/MOE_{food} + 1/MOE_{water})$

where I = inhalation, D = dermal (no dermal endpoints was selected for zeta-cypermethrin), O = non-dietary oral, MOE_{food} = average food from the chronic DEEM run.

As residue values in water from monitoring data are not available, therefore, as with the acute dietary aggregate risk estimate, for the short- and intermediate-term aggregate risk assessments, the DWLOCs have to be back calculated.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,500 for adult males, 1,700 for adult females, 830 for a child, and 1,700 for infants. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of zeta-cypermethrin and its inactive R-isomers in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 8:

TABLE 8.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

Population Subgroup	Target Aggregate MOE	Aggregate MOE (food and residential)[1]	Ground Water EEC[2] (μg/L)	Surface Water EEC[2] (μg/L)	DWLOC[3] (μg/L)
Adult male	100	1,500	0.006	0.46	3,300
Adult female	100	1,700	0.006	0.46	2,800
Child	100	670	0.006	0.46	850
Infants	100	1,100	0.006	0.46	910

[1] Aggregate MOE (food and residential) = 1 ÷ [(1 ÷ MOE food) + (1 ÷ MOE oral) + (1 ÷ MOE dermal) + (1 ÷ MOE inhalation)]
[2] The crop producing the highest level was used.
[3] DWLOC (μg/L) = allowable water exposure (mg/kg/day) x body weight (kg) water consumption (L) x 10^{-3} mg/μg body weights for male, female, and children are 70, 60, and 10 kg. Water consumption for male, female, and children are 2, 2, and 1 L/day

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Zeta-cypermethrin and its inactive R-isomers is currently not registered for use that could result in intermediate-term residential exposure; however, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). Cypermethrin registered residential uses constitute short- and intermediate-term exposure scenarios; endpoints have been selected for short- and intermediate-term incidental oral and inhalation exposures, and the acceptable MOEs for short- and intermediate-term exposures are 100. Since the toxicological effects through the inhalation exposure route are similar to those toxicological effects through the oral routes, short-term aggregate risk assessment was conducted adding inhalation, oral non-dietary exposure, and average food and water exposure.

Since all the acceptable MOEs are at the same level, the aggregate risks for population subgroups can be estimated by calculating aggregate Margin of Exposure values ($MOE_{aggregate}$). $MOE_{aggregate} = 1/(1/MOE_I + 1/MOE_D + 1/MOE_O + 1/MOE_{food} + 1/MOE_{water})$

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 760 for adult males, 860 for adult females, 350 for a child and 600 for infants. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of zeta-cypermethrin and its inactive R-isomers in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 9:

TABLE 9.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

Population Subgroup	Target Aggregate MOE	Aggregate MOE (food and residential)[1]	Ground Water EEC[2] (µg/L)	Surface Water EEC[2] (µg/L)	DWLOC[3] (µg/L)
Adult male	100	760	0.006	0.46	1,500
Adult female	100	860	0.006	0.46	1,300
Child	100	350	0.006	0.46	360
Infants	100	600	0.006	0.46	420

[1] Aggregate MOE (food and residential) = 1 ÷ [(1÷MOE food) + (1 ÷ MOE oral) + (1 ÷ MOE dermal) + (1 ÷ MOE inhalation)]
[2] The crop producing the highest level was used.
[3] DWLOC (µg/L) = allowable water exposure (mg/kg/day) x body weight (kg) water consumption (L) x 10^{-3} mg/µg body weights for male, female, and children are 70, 60, and 10 kg. Water consumption for male, female, and children are 2, 2, and 1 L/day

5. *Aggregate cancer risk for U.S. population*. Cypermethrin/zeta-cypermethrin has been classified as a Category C carcinogen, based on an increased incidence of lung adenomas and adenomas plus carcinomas combined in female mice. However, the evidence was not considered strong enough to warrant a quantitative estimation of human risk. An RfD approach was recommended for human risk assessment purposes. Dietary risk concerns due to long-term consumption of zeta-cypermethrin are adequately addressed in the chronic exposure analysis. For the U.S. population only 11% of RfD is occupied by chronic food and water exposure.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to zeta-cypermethrin and its inactive R-isomers residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of cypermethrin residues in plants and animal products in PAM II (Method I). This method involves initial acetone-hexane extraction, followed by partitioning with water. The organic layer is evaporated, then redissolved in cyclohexane-methylene chloride and passed through a gel permeation column. The eluate is evaporated, redissolved in hexane and passed through a Florisil column. Cypermethrin residues are analyzed by gas chromatography (GC) with an electron capture detector (ECD). Since zeta-cypermethrin is an isomer enriched form of cypermethrin, and the PAM II method is not stereospecific, this method is considered adequate for enforcement of the proposed tolerances of zeta-cypermethrin.

B. International Residue Limits

1. Current status indicates that a Codex maximum residue level (MRL) of 0.05 ppm for residues of cypermethrin has been established for sweet corn (corn-on-the-cob). Based on zeta-cypermethrin residues observed in sweet corn ears in the U.S. field trials, the sweet corn tolerance for zeta-cypermethrin is lowered to 0.05 ppm to achieve harmonization with Codex. No Codex MRLs have been established for sweet corn forage/fodder. Canadian or Mexican MRLs have not been established for residues of cypermethrin in/on sweet corn ears or forage/fodder.

2. Current status indicates that Codex, Canadian, or Mexican MRLs have been established for residues of zeta-cypermethrin (or cypermethrin) in/on alfalfa forage (5 ppm), maize (0.05 ppm), maize fodder (5 ppm), bulb onion (0.1 ppm), root and tuber vegetables (0.05 ppm), sweet corn on the cob (0.05 ppm), and vegetable oils (0.5 ppm). The recommended tolerances will be the same as the international tolerances for maize (as applied to field, seed, and pop corn), bulb onions, and root and tuber vegetables (applied to sugar beets). The U.S. field corn fodder tolerance will be lower than the maize fodder tolerance; however, it is unlikely that maize fodder will be shipped to the U.S. In addition, if it were imported, from a practical enforcement perspective, the higher tolerance needed for sweet corn stover (15 ppm; PP 4F3012) would likely apply. Since there is no processed food tolerance for corn oil, the field corn grain tolerance of 0.05 ppm would apply. The international tolerance for vegetable oils is much higher (0.5 ppm) and cannot be harmonized with the U.S. tolerance as the later would have to be set much higher than necessary.

3. Current status indicates that no Codex, Canadian, or Mexican MRLs have been established for residues of zeta-cypermethrin in/on rice.

4. Current status indicates that a Codex MRL of 2 ppm for residues of cypermethrin (racemic) has been established for head lettuce and 1 ppm for Brassica vegetables. This is inconsistent with the proposed U.S. tolerance of 10.0 ppm for zeta-cypermethrin for Crop Group 4 (leafy vegetables except Brassica), 2.0 ppm for Crop Group 5A (head and stem Brassica), and 14.0 ppm for Crop Group 5B (leafy Brassica). Harmonization of U.S. tolerances with Codex tolerances is not possible because at the proposed maximal use rates, residues greater than

the Codex MRLs were found in the U.S. field trials. No Mexican MRLs have been established for residues of cypermethrin or zeta-cypermethrin in any relevant crop, but Canada has established cypermethrin MRLs of 1.0 ppm for celery and 0.5 ppm for broccoli, cabbage, cauliflower, and Brussels sprouts.

V. Conclusion

Therefore, the tolerances are established for residues of zeta-cypermethrin and its inactive R-isomers in or on alfalfa, hay at 15 ppm, alfalfa, forage at 5.0 ppm, alfalfa, seed at 0.5 ppm; beets, sugar, roots at 0.05 ppm, beets, sugar, tops at 0.20 ppm; corn, field, grain at 0.05 ppm, corn, pop, grain at 0.05 ppm, corn, field, forage at 0.20 ppm, corn, field, stover at 3.0 ppm, corn, pop, stover at 3.0 ppm, corn, sweet, (K + CWHR) at 0.05 ppm, corn, sweet, forage at 15 ppm, corn, sweet, stover at 15 ppm; onions, green at 3.0 ppm; leafy vegetables except Brassica at 10 ppm, head and stem Brassica at 2.0 ppm, leafy Brassica at 14 ppm; sugarcane at 0.6 ppm; rice, grain at 1.5 ppm, rice, straw at 2.0 ppm, rice, hulls at 6.0 ppm; fat of cattle, goat, horse, sheep, hogs at 1.0 ppm; meat of cattle, goat, horse, sheep, hogs at 0.1 ppm; milk, fat at 2.5 ppm (reflecting 0.10 ppm in whole milk); poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, poultry, meat by-products at 0.05 ppm; and eggs at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301171 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 16, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301171, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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). Because this rule has

been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any tribal implications as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. Policies that have tribal implications is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 6, 2001.

Peter Caulkins,

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. 321(q), 346(a) and 371.

2. Section 180.418 is amended by revising 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 Z-cypermethrin (S-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate and its inactive R-isomers in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, hay	15.00
Alfalfa, forage	5.00
Alfalfa, seed	0.50
Beets, sugar, roots	0.05
Beets, sugar, tops	0.20
Brassica, head and stem	2.00
Brassica, leafy	14.00
Cabbage	2.00
Cattle, fat	1.00
Cattle, mbyp	0.05
Cattle, meat	1.00
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, field, forage	0.20
Corn, field, stover	3.00
Corn, pop, stover	3.00
Corn, sweet, (K + CWHR)	0.05
Corn, sweet, forage	15.00
Corn, sweet, stover	15.00
Cottonseed	0.5
Eggs	0.05
Goat, mbyp	0.05
Goat, meat	1.00
Hogs, fat	1.00
Hogs, mbyp	0.05
Hogs, meat	1.00
Horse, fat	1.00
Horse, mbyp	0.05
Horse, meat	1.00
Leafy vegetables except, Brassica	10.00
Lettuce, head	10.00
Milk	0.05
Milk, fat (reflecting 0.10 in whole milk)	2.50
Onions, bulb	0.10
Onions, green	3.00
Pecans	0.05
Poultry, fat	0.05

Commodity	Parts per million
Poultry, mbyp	0.05
Poultry, meat	0.05
Rice, grain	1.50
Rice, hulls	6.00
Rice, straw	2.00
Sheep, fat	1.00
Sheep, mbyp	0.05
Sheep, meat	1.00
Sugarcane	0.60

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301170; FRL–6801–4]

RIN 2070–AB78

Mefenoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of mefenoxam in or on globe artichoke, starfruit, kiwifruit, papaya, black sapote, star apple, canistel, mamey sapote, mango, sapodilla, sugar apple, atemoya, custard apple, lingonberry, fresh herbs, and dried herbs. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The risk assessment performed for mefenoxam is an aggregate risk assessment which includes the proposed new uses of mefenoxam and all current metalaxyl tolerances/uses. Consequently, EPA has reassessed a total of 122 existing tolerances for metalaxyl. By law, EPA is required by August 2002 to reassess 66% of the tolerances in existence on August 2, 1996, or about 6,400 tolerances. The 122 tolerances reassessed in this final rule count toward the August, 2002 review deadline.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301170, must be received by EPA on or before November 16, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301170 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301170. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 30, 2000 (65 FR 52746) (FRL–6739–4), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) 9F05044, 9E06005, and 9E06057 for tolerances by IR-4, Technology Centre of New Jersey, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. These notices included summaries of the petitions prepared by Novartis Crop Protection, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide mefenoxam, (*R*)- and (*S*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester, its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester,