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 13, 2002.

James Jones,

Acting Director, 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 374.

2. Section 180.579 is added to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) *General.* Tolerances are established for residues of fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-, (S)-) from the application of the fungicide fenamidone on the following raw agricultural commodities:

Commodity	Parts per million
Lettuce, head	15 ppm
Lettuce, leaf	20 ppm

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

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

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

[FR Doc. 02–24652 Filed 9–26–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0193; FRL–7199–8]

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on soybean, seed; soybean, forage; soybean, hay; corn, field, forage; corn, field, stover and corn, pop, stover; grain, cereal, group; corn, field, refined oil; corn, field, milled byproduct; grain, aspirated fractions; wheat milled byproducts, except flour; rice, hulls; rice, bran; barley, bran, oat, bran and rye, bran; milk; milk, fat; cattle, fat, goat, fat, hog, fat, horse, fat and sheep, fat; mustard greens; lettuce, leaf; lettuce, head; brassica, head and stem, subgroup; pea, southern, succulent; and pea, dry. Bayer Corporation and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0193, must be received on or before November 26, 2002.

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 ID number OPP–2002–0193 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: stanton.susan@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/. 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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0193. 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 November 20, 1998 (63 FR 64484–64489) (FRL–6030–9); March 1, 2000 (65 FR 11052–11057) (FRL–6489–9); and April 4, 2001 (66 FR 17887–17891) (FRL–6772–5), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 8F5023, 5F4475, and 0F6084) by Bayer Corporation, and (PP 0E6184 and PP 0E6075) by the IR–4. These notices included summaries of the petitions prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filings.

These petitions requested that 40 CFR 180.436 be amended by establishing tolerances for residues of the insecticide cyfluthrin, cyano (4-fluoro-3-phenoxyphenyl) methyl-3-(2,2-didichloroethenyl)-2,2-dimethyl-cyclopropane-carboxylate, as follows:

1. PP 8F5023 proposed establishment of tolerances for soybean, bean at 0.03 ppm; soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; field corn forage at 3.0 ppm; and field corn, fodder at 6.0 ppm.

2. PP 5F4475 proposed establishment of tolerances for cereal grains group; corn, starch; corn, refined oil (wet milling); corn, flour; corn, refined oil (dry milling); wheat, bran; corn, milled byproducts; rice, hulls; and wheat, milled by-products at 2.0, 3.0, 12, 4.0, 15, 3.0, 4.0, 9.0, and 3.0 ppm, respectively.

3. PP 0F6084 proposed establishment of tolerances for mustard greens, greens; lettuce, head; lettuce, leaf; and head and stem brassica subgroup (5A) at 7.0, 2.0, 3.0, and 2.0 ppm, respectively.

4. PP 0E6184 proposed establishment of a tolerance for southern pea at 0.23 ppm.

5. PP 0E6075 proposed establishment of a tolerance for dry peas (pigeon peas, chickpeas/garbanzo beans, lentils) at 0.05 ppm.

In the **Federal Register** of May 24, 2002 (67 FR 36596–36598) (FRL–7178–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the amended filing of PP 0F6084 by Bayer Corporation. The amended petition requested that the proposed tolerance for the head and stem brassica subgroup (5A) be increased from 2.0 ppm to 2.5 ppm. There were no changes in the proposed tolerances for mustard greens, greens; lettuce, head; or lettuce, leaf. There were no comments received in response to the amended notice of filing.

Based on EPA's review, the petitions described in Unit II. were revised by the petitioners (Bayer Corporation and IR-4) to propose tolerances for residues of cyfluthrin in or on soybean, seed at 0.03 ppm; soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; corn, field, forage at 3.0 ppm; corn, field, stover and corn, pop, stover at 6.0 ppm; grain, cereal, group at 4.0 ppm; corn, field, refined oil at 30 ppm; corn, field, milled byproduct at 7.0 ppm; grain, aspirated fractions at 600 ppm; wheat milled byproducts, except flour at 5.0 ppm; rice, hulls at 18 ppm; rice, bran at 6.0 ppm; barley, bran, oat, bran and rye, bran at 5.0 ppm; milk at 1.0 ppm; milk, fat at 30 ppm; cattle, fat, goat, fat, hog, fat, horse, fat and sheep, fat at 10 ppm; mustard greens at 7.0 ppm; lettuce, leaf at 3.0 ppm; lettuce, head at 2.0 ppm; brassica, head and stem, subgroup at 2.5 ppm; pea, southern, succulent at 0.25 ppm; and pea, dry at 0.15 ppm.

Although EPA requested a number of changes to the initial petitions, the nature of the changes (i.e., clarification and correction of commodity terms and changes in tolerance levels) are not considered significant. Therefore, EPA is issuing this as a final action.

EPA is also revising or deleting existing tolerances for cyfluthrin that are superseded or no longer needed, correcting administrative errors in existing tolerances, and updating tolerance terminology as follows:

1. Tolerances for residues of cyfluthrin in or on corn, forage and fodder, field and pop at 0.01 ppm; corn, grain, field and pop at 0.01 ppm; aspirated grain fractions at 300 ppm; milkfat (reflecting 0.5 ppm in whole milk) at 15.0 ppm; sorghum, grain at 4.0 ppm; and fat of cattle, goats, hogs,

horses, and sheep at 5.0 ppm are being revised or replaced as appropriate to reflect the new commodity terms and tolerance levels specified in Unit II.

2. Time-limited tolerances established for residues of cyfluthrin in or on barley, oat and wheat grain at 2.0 ppm and fat of cattle, goat, hog, horse, and sheep at 6.0 ppm in connection with section 18 emergency exemptions granted by EPA are no longer needed and are being deleted.

3. Administrative errors in existing tolerances for radishes, sweet corn forage and sweet corn fodder are being corrected as follows: The existing tolerance for residues of cyfluthrin in or on radishes at 1.0 ppm is being revised to specify the commoditiy as ''radish, roots.'' The existing tolerances for corn, sweet, fodder at 15 ppm and corn, sweet, forage at 30 ppm were inadvertantly reversed. They are being corrected and the commodity terminology is being updated to read ''corn, sweet, stover'' at 30 ppm and ''corn, sweet, forage'' at 15 ppm.

4. Commodity terms for existing tolerances are being updated to conform to the current Food and Feed Commodity Vocabulary. The Vocabulary data base is available on the EPA internet site at the following address: http://www.epa.gov/pesticides/foodfeed/

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. For further discussion of the regulatory requirements of section 408 of the FFDCA 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) 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of cyfluthrin on soybean, seed at 0.03 ppm; soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; corn, field, forage at 3.0 ppm; corn, field, stover and corn, pop, stover at 6.0 ppm; grain, cereal, group at 4.0 ppm; corn, field, refined oil at 30 ppm; corn, field, milled byproduct at 7.0 ppm; grain, aspirated fractions at 600 ppm; wheat milled byproducts, except flour at 5.0 ppm; rice, hulls at 18 ppm; rice, bran at 6.0 ppm; barley, bran, oat, bran and rye, bran at 5.0 ppm; milk at 1.0 ppm; milk, fat at 30 ppm; cattle, fat, goat, fat, hog, fat, horse, fat and sheep, fat at 10 ppm; mustard greens at 7.0 ppm; lettuce, leaf at 3.0 ppm; lettuce, head at 2.0 ppm; brassica, head and stem, subgroup at 2.5 ppm; pea, southern, succulent at 0.25 ppm; and pea, dry at 0.15 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cyfluthrin and its enriched isomer, beta-cyfluthrin are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

Beta-cyfluthrin is an enriched isomer of cyfluthrin. Bridging data on beta-cyfluthrin were submitted so that the toxicity of beta-cyfluthrin could be compared with that of cyfluthrin and the data bases could be combined to form one complete data base for both chemicals.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
870.3100	90–Day oral toxicity—rats Beta-cyfluthrin (99.7% active ingredient (a.i.))	NOAEL = 9.5/10.9 male/female (M/F) LOAEL = 37.0/43.0 (M/F) based on gait abnormalities, necrosis in head and neck region, mortality (2), decreased body weight gain.
870.3100	90–Day oral toxicity—rats Cyfluthrin (84.2% a.i.)	NOAEL ≥ 22.3/28.0 for males and females LOAEL not established
870.3150	90–Day oral toxicity—dogs Beta-cyfluthrin (99% a.i.)	LOAEL = 13.9/15.4 (M/F) based on gait abnormalities (both sexes), vomiting (both sexes) and suggestive decrease in body weight gain
870.3200	21/28–Day dermal toxicity—rats Cyfluthrin (95.5%)	Dermal NOAEL = 113 Systemic NOAEL = 376 Dermal LOAEL = 376 based on gross and histological skin lesions. Systemic LOAEL = 1077 based on decreased food consumption, red nasal discharge and urine staining.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
Non-guideline	28–Day oral toxicity Cyfluthrin	NOAEL = 15.0 (males & females) based on minimal decrease in blood glucose. LOAEL = 50 based on, gait abnormalities, salivation, nervousness, decrease in body weight, food consumption, changes in hematological, clinical chem. & urinalysis parameters, increases in selected organ wts., cytoplasmic swelling of glandular epithelium of submaxillary gland, minimal degrees of fiber degeneration in sciatic nerve (# not reported) which disappeared after recovery period.
870.3465	90–Day inhalation toxicity study—rats Cyfluthrin (94.9% a.i.)	NOAEL = 0.00009 mg/liter (L) (0.02 mg/kg/day; both sexes) LOAEL = 0.00071 mg/L (0.16 mg/kg/day) based on decreased body weights and body weight gains in males and clinical signs in females
Non-guideline	4–Week inhalation toxicity study—rats Cyfluthrin (93.8% a.i.)	NOAEL = 0.00044 mg/L (0.12 mg/kg/day; males & females) LOAEL = 0.006 mg/L (1.6 mg/kg/day; males & females) based on decreases in body weight and body weight gain in males, hypothermia, reduction in leukocyte counts (F) and low serum protein.
Non-guideline	4–Week subacute inhalation study—rat Beta-cyfluthrin (97.9% a.i.)	NOAEL = 0.00026 mg/L (0.07 mg/kg/day) LOAEL = 0.0027 mg/L (0.73 mg/kg/day) based on decreased body weights, 9 urine pH in males
Non-guideline	5–Day range-finding inhalation study—rat Beta-cyfluthrin (98% a.i.)	NOAEL = 0.00025 mg/L (0.07 mg/kg/day) LOAEL = 0.0038 mg/L (1.03 mg/kg/day) based on unpreened hair coat, piloerection, hepatoid foci in lungs.
Non-guideline	28–Day dog feeding study Beta-cyfluthrin	NOAEL = 2.0 (both sexes) LOAEL = 8.0 based on impaired movement and conjunctival irritation.
870.3700	Prenatal developmental toxicity study—rats Beta-cyfluthrin (96.5–97.3%)	Maternal NOAEL = 3 Developmental NOAEL = 10 Maternal LOAEL = 10 based on reduced body weight gain and reduced food consumption with post-treatment recovery. Developmental LOAEL = 40 based on reduced fetal body weights and increased skeletal variations.
870.3700	Prenatal developmental toxicity study—rats Cyfluthrin (93.4%)	Maternal NOAEL > 10 mg/kg/day Maternal LOAEL not established Developmental NOAEL > 10 mg/kg/day developmental LOAEL not established
870.3700	Prenatal developmental toxicity—rabbits Cyfluthrin (96% a.i.)	Maternal NOAEL = 20.0 Developmental NOAEL = 180.0 Maternal LOAEL = 60.0 based on decreased body weight gain and food consumption during the dosing period Developmental LOAEL > 180 mg/kg/day
870.3700	Prenatal developmental toxicity via inhalation–rat Cyfluthrin (96.2%)	Maternal NOAEL <0.00046 mg/L (< 0.125 mg/kg/day) Developmental NOAEL = 0.00046 mg/L (0.125 mg/kg/day) Maternal LOAEL = 0.00046 mg/L (0.125 mg/kg/day) based on decreased body weight gain and relative food efficiency Developmental LOAEL = 0.00255 mg/L (0.692 mg/kg/day) based on reduced fetal and placental weights and reduced ossification in phalanx, metacarpals, vertebrae
870.3700	Prenatal developmental toxicity via inhalation—rat Cyfluthrin (92.9% and 93%) 2 studies combined	Combined maternal NOAEL = 0.0011 mg/L (0.299 mg/kg/day Developmental NOAEL = 0.00059 mg/L (0.160 mg/kg/day) Combined maternal LOAEL= 0.0047 mg/L (1.277 mg/kg/day) based on reduced motility, dyspnea, piloerection, ungroomed coats, eye irritation Developmental LOAEL = 0.0011 mg/L (0.299 mg/kg/day) based on increased incidence of runts and skeletal anomalies in sternum.
Non-guideline	7–Day postnatal inhalation study (both pups & dams) in mice with spontaneous motor activity measurements Cyfluthrin (96.8%)	Maternal NOAEL = 0.058 mg/L (24.0 mg/kg/day; highest dose tested (HDT) Offspring NOAEL = 0.006 mg/L (2.48 mg/kg/day) Maternal LOAEL > 0.058 mg/L (> 24.0 mg/kg/day) Offspring LOAEL = 0.015 mg/L (6.21 mg/kg/day) based on clinical signs of toxicity and spontaneous motor activity observed in females 4 months after exposure.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
870.3800	Reproduction and fertility effects study—rat (dietary) Cyfluthrin (95.4% a.i.)	Parental NOAEL = Parental: 3/4 (M/F) Offspring NOAEL = 7 (M/F) Parental LOAEL = 9/10 (M/F) based on reductions in body weights and food consumption. Offspring LOAEL = 19 based on coarse tremors in pups during lactation and decreases in mean litter weight .
Non-guideline	''Supplemental'' 2–generation reproduction study—rat (1997) Cyfluthrin (95.5% a.i.)	Systemic parental NOAEL = 3.8/4.2 Systemic offspring NOAEL = 3.8/4.2 (Male/Female) Systemic parental LOAEL > 3.8/4.2 Systemic offspring LOAEL > 3.8/4.2 (Male/Female)
Non-guideline	Pilot 1–generation reproduction study—rat Cyfluthrin (95.7–96.2% a.i.)	Parental systemic NOAEL = 22.9 Offspring systemic NOAEL = 7.8 Parental systemic LOAEL = 59.6 based on hind leg splay, ataxia, reduction in body weight gain. Pup systemic LOAEL = 22.9 based on tremors during lactation and pup weight decreases.
Non-guideline	Multigeneration reproduction study—rats Cyfluthrin	Parental NOAEL = 12.3/15.1 Offspring NOAEL = 5.4 Parental LOAEL = 37.2/48.5 based on decreased body weight gain. Offspring LOAEL = 15.1 based on decreased viability during lactation period and decreased body weight gains
870.4100	Chronic toxicity—feeding study—dog Cyfluthrin (94.9–95.1% a.i.)	NOAEL = 2.43/3.61 (M/F) LOAEL = 10.64/10.74 (M/F) based on clinical signs, gait abnormalities, and abnormal postural reactions in males and females.
870.4100	Chronic toxicity—feeding study—dog Cyfluthrin 50%	NOAEL = 4.0 (males & females) LOAEL = 16.0 (males & females) based on gait abnormalities, vomiting, liquid feces, decreased body weights (males).
870.4100	Chronic toxicity—6–month dog feeding study Cyfluthrin	NOAEL = 5.0 (males & females) LOAEL = 15.0 (males & females). Gait abnormalities, arching backs, vomiting, diarrhea.
870.4200	Carcinogenicity feeding study—mice Cyfluthrin (93.9% a.i.)	NOAEL = 31.9 (males) and 140.6 (females) LOAEL = 114.8 (males) based on ear skin lesions and reduced body weight gains. 309.7 (females) based on clinical signs; macroscopic and microscopic pathology findings; and reduced body weights, body weight gains, and food consumption. Under the conditions of this study, there was no evidence of carcinogenic potential.
870.4200	Carcinogenicity feeding study—mice Cyfluthrin (49.7–51.0% a.i.)	No evidence of carcinogenic potentialstudy not acceptable for chronic toxicity
870.4300	Combined chronic toxicity/carcinogenicity feeding study—rat Cyfluthrin (94.7% a.i.)	NOAEL = 2.6 (males), 3.3 (females) LOAEL = 11.6 (males), 14.4 (females) based on overall declines in body weight gain by 12 and 10% in males and females, respectively. No carcinogenic effects.
870.4300	Combined chronic toxicity/carcinogenicity feeding study—rat Cyfluthrin (49.7–51.0%)	NOAEL = 6.19 (males), 8.15 (females) LOAEL = 19.20 (M), 25.47 (F) based on decreased body weights and body weight gains. No carcinogenic effects.
870.5100	Gene mutation—bacterial reverse mutation assay with cyfluthrin	No increases in reverse mutations with and without activation
870.5100	Gene mutation—yeast reverse mutation assay with cyfluthrin	No increase in number of revertants with S138 cultures increase in number of revertants with S211 culture but not dose-related; no increase in number of revertants when assay repeated
870.5100 870.5500	Gene mutation—bacterial reverse mutation assay with cyfluthrin Bacterial DNA damage with cyfluthrin	In rec-assay, no inhibition at doses of 100–10,000 μg/disk in reverse mutation assay, no increase in number of revertant colonies, with and without activation

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
870.5300	*In vitro* mammalian cell gene mutation with cyfluthrin	Cyfluthrin did not induce forward mutations under conditions of assay
870.5575	*Saccharomyces cerevisiae* mitotic gene conversion with cyfluthrin	Not mutagenic under conditions of assay
870.5550	Unscheduled DNA Synthesis (UDS) in rat hepatocytes with cyfluthrin	No increase in UDS
870.5915	Sister Chromatid Exchange (SCE) in Chinese Hamster Ovary (CHO) cells with cyfluthrin	No increase in SCE frequency in treated cells
870.5550	DNA damage and repair in *E. coli* with cyfluthrin	No induction of inhibition, both with and without activation
870.5100	Gene mutation—bacterial reverse mutation assay with beta-cyfluthrin	No increases in reverse mutations in *S. typhimurium* strains TA 1535, TA 1537, TA 98, or TA 100 with and without activation
87.5300	*In vitro* mammalian cell gene mutation test with beta-cyfluthrin	No mutagenic response in CHO cells hypoxanthine guanine phophoribosyl transferase (HGPRT) assay with and without activation
870.5395	Mammlian erythrocyte micronucleus test with beta-cyfluthrin	No increased frequency of micronucleated polychromatic erythrocytes in mice bone marrow cells
870.5375	*In vitro* mammalian chromosome aberration test with beta-cyfluthrin	Not clastogenic in human lymphocytes
870.5550	UDS in mammalian cells in culture with beta-cyfluthrin	No evidence of UDS in rat hepatocytes
870.6100	Neurotoxic esterase (NTE)—hen Cyfluthrin	All hens died within 3 days; NTE activity was not inhibited
870.6100	Neurotoxicity oral studies—hen Cyfluthrin	In the single-dose study, at 5,000 mg/kg, five of the ten hens died. Moderate fiber alterations (axon fragmentation, occasional swelling and eosinophilia of the axon fragments and vacuolation of the myelin sheaths) in the sciatic nerve were observed in two hens. Six hens at 2,500 mg/kg showed signs of excitation during the first 3 days following treatment. In the two-dose study, hens showed initial signs of intoxication during the first 3 days but were normal until the second dose was administered when four hens died. Symptoms following the second treatment subsided; however, a second set of symptoms developed in 4/30 hens. These symptoms resembled delayed type neurotoxicity. Nerve fiber degeneration was present in the majority of the hens. The myelin sheath was distended and the myelin sheath was described as being optically void or granularly disintegrated. The axons were described as swollen or fragmented and in some areas activated or proliferated Schwann's cells were noted. The nerves also contained macrophages in which cytoplasm contained granular material. In the 5–day study, 4/10 hens died. All hens showed initial toxic responses which eventually disappeared. Behavioral disorders accompanied by drowsiness and a cramped gait were observed in 3 of the 6 survivors. Mottled kidneys and brittle livers were noted at necropsy. Treatment-related fiber degeneration (distension or granular disintigration of the medullary sheath, swollen or fragmented axis cylinders and proliferated Schwann's cell in the sciatic nerve were reported. One hen had similar lesions in the spinal marrow.
870.6100	Neurotoxicity oral studies—hen Cyfluthrin	In the single-dose study, the hens showed an initial weight loss but recovered. No other treatment-related effects were observed. In the two-dose study, one hen showed some signs of neurotoxicity on day 30. There were no microscopic lesions in the nervous system.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
870.6100	Neurotoxicity dermal studies—hen Cyfluthrin	In the first study there were 2 deaths on the 3rd and 10th day. All other hens had symptoms (apathy and disturbed behavior) but recovered. Local irritation and weight loss were also noted. Two hens had minimal segment-like nerve fiber degeneration (sciatic nerve), but this type is often found in hens. In the second study, the hens were apathetic. These symptoms disappeared after the first week in all hens except 2, in which they persisted until the 38th and 51st day after the start of the treatment, respectively. Local irritation and body weight loss were also observed. No other neurologic effects were observed, including microscopic.
870.6100	Acute delayed neurotoxicity—hen Cyfluthrin	Nine of 10 hens died at 0.596 mg/L and none died in any of the lower concentrations. These had some nonspecific symptoms (behavior disturbances, sedation, eye irritancy), which disappeared after 2 days. Some initial weight loss was also noted. In the 3–week study, one hen died. Nonspecific symptoms were again observed. Nothing remarkable was noted at necropsy.
870.6100	Acute delayed neurotoxicity and NTE—hen Cyfluthrin	4,300, 1,500: Mortality, aggression, somnolence, cyanosis of crest. Sl. axonal degenration of sciatic nerve in one hen given a single dose; sl. axonal degeneration of spinal cord in one hen given two doses. No treatment-related changes in NTE activity.
870.6200	Acute oral neurotoxicity [gavage]—rat Beta cyfluthrin (≥96.9% a.i.)	NOAEL = 2 LOAEL = 10 based on clinical signs, changes in functional observational battery (FOB) parameters and decreases in motor activity.
870.6200	Subchronic oral neurotoxicity [feeding]—rat Beta-cyfluthrin (≥96.5% a.i.)	NOAEL = 7.99 (males) 9.40 (females) LOAEL = 26.81 (males) 30.83 (females) based on clinical signs, changes in FOB measurements and possibly decreased body weights, body weight gains, and food consumption
870.7485	Metabolism and pharmacokinetics Cyfluthrin (98%)	Following oral administration, the test material was rapidly and nearly completely absorbed. Greater than 95% of the administered radioactivity was excreted within 48 hours. Radioactivity was excreted in the urine and feces with virtually none being excreted in expired air. By 48 hours after dosing, >98% of the total retrieved radioactivity was recovered in the urine and feces. The ratio of radioactivity in urine/feces was higher in males than in females. About 50% of the total urinary radioactivity was recovered during the first 6–8 hours after dosing and about 90% within the first 24 hours. At 48 hours, only the fat tissue (renal fat) contained levels of radioactivity that clearly exceeded the overall mean body level, being 6–11X higher. Levels of radioactivity in brain were quite low, being 15–20X lower than the overall mean body level. Different dose levels (0.5 or 10 mg/kg) or pretreatment (14X) did not appreciably affect the above findings. Some sex differences, however, were observed as indicated by higher urine/feces ratios in males and slightly higher organ/tissue levels of redioactivity in females (except for fat tissue). Following intravenous administration, a 2 phase plasma elimination pattern was observed with plasma half-lives of about 2.1 and 20 hours. Greater than 90% of the administered radioactivity was excreted within 48 hours. By 48 hours after dosing, about 93–94% of the total retrieved radioactivity was recovered in the urine and feces. Residual levels of radioactivity in the body and in individual organs/tissues were higher than after oral administraiton. In other respects, the results following intravenous dosing were quite similar to those described for oral dosing. Studies in male rats with bile fistulas indicated an enterhepatic circulation of test material.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results (NOAEL/LOAEL in milligram/kilogram/day (mg/kg/day))
870.7485	Metabolism and pharmacokinetics Cyfluthrin (98%)	Excretion of radioactivity was rapid. Following oral administration, >95% of the administered radioactivity was excreted within 48 hours, and following intravenous injection, >90% within 48 hours. Most of the radioactivity was excreted in urine, the urine/fecal ratio being about 2–3X in males and about 1.6–1.8X in females following oral administration and about 2.5X in males and about 2.6X in females following intravenous injection. Parent cyfluthrin is cleaved at the ester bond and then oxidized to yield 3-phenoxy-4-fluorobenzoic acid. This intermediate is then either hydroxylated and subsequently conjugated and excreted or first bound to glycine and then hydroxylated, conjugated, and excreted. Identified metabolites and parent cyfluthrin (in urine, feces, and body) accounted for 65–73% of the recovered radioactivity after a single oral or intravenous dose of 0.5 mg/kg and about 82–83% of the recovered radioactivity after a single-oral dose of 10 mg/kg or after 14 daily-oral doses.

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 intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) 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 SF.

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 Cyfluthrin used for human risk assessment is shown in Table 2 of this unit. The toxicology data bases for cyfluthrin and its enriched isomer, beta-cyfluthrin, were considered together in selecting endpoints for risk assessment.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYFLUTHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute Dietary general population including infants and children	NOAEL = 2.0 mg/kg/day UF = 100 Acute RfD = 0.02 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.02 mg/kg/day	Acute mammalian neurotoxicity (beta-cyfluthrin) LOAEL = 10 mg/kg/day based on clinical signs, changes in FOB parameters and decreases in motor activity.
Chronic Dietary all populations	NOAEL = 2.4 mg/kg/day UF = 100 Chronic RfD = 0.024 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.024 mg/kg/day	53–Week chronic toxicity—feeding—dog (cyfluthrin) LOAEL = 10.64 mg/kg/day based on clinical signs, gait abnormalities, and abnormal postural reactions.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYFLUTHRIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Incidental Oral Short- and Intermediate-Term (Residential)	NOAEL = 2.36/2.5 mg/kg/day	LOC for MOE = 100 (Residential)	90–Day dog feeding study (beta-cyfluthrin) LOAEL = 13.9/15.4 mg/kg/day for males/females, based on gait abnormalities, increased incidence of vomiting, and suggestive decreased body weight gain.
Short-Term Dermal (1 to 30 days); and Intermediate-Term Dermal (1 to 6 months) (Residential)	Oral study NOAEL = 2.36/2.5 mg/kg/day (dermal absorption rate = 5%)	LOC for MOE = 100 (Residential)	90–Day dog feeding study (beta-cyfluthrin) LOAEL = 13.9/15.4 mg/kg/day for males/females, based on gait abnormalities, increased incidence of vomiting, and suggestive decreased body weight gain.
Long-Term Dermal (several months to lifetime) (Residential)	Oral study NOAEL = 2.4 mg/kg/day (dermal absorption rate = 5%when appropriate)	LOC for MOE = 100 (Residential)	53–Week chronic toxicity—feeding—dog (cyfluthrin) LOAEL = 10.64 mg/kg/day based on clinical signs, gait abnormalities, and abnormal postural reactions.
Short-Term Inhalation (1 to 30 days) (Residential)	Inhalation study NOAEL = 0.07 mg/kg/day	LOC for MOE = 100 (Residential)	28–Day inhalation study—rat (beta-cyfluthrin) LOAEL = 0.73 mg/kg/day based on decreases in body weight in both sexes and decreased urinary pH in males.
Intermediate-Term Inhalation (1 to 6 months); and Long-Term Inhalation (several months to lifetime) (Residential)	Inhalation study NOAEL = 0.02 mg/kg/day	LOC for MOE = 100 (Residential)	13–Week inhalation study—rat (cyfluthrin) LOAEL = 0.16 mg/kg/day based on decreases in body weight and body weight gain in males and clinical signs in females
Cancer (oral, dermal, inhalation)	N/A		Cyfluthrin is classified as ''not likely to be carcinogenic in humans''

* The reference to the FQPA Safety Factor (SF) refers to any additional SF 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 180.180.436) for the residues of cyfluthrin, in or on a variety of raw agricultural commodities. Tolerances have been established on plant commodities ranging from 0.01 ppm for corn grain and potatoes to 300 ppm for aspirated grain fractions and on animal commodities ranging from 0.01 ppm for poultry commodities to 15 ppm for milk fat, and a tolerance of 0.05 ppm has been established in food or feed commodities exposed to the insecticide during treatment of food-handling or feed-handling establishments where food and food products, or feed and feed products, are held, processed, prepared, or served. Risk assessments were conducted by EPA to assess dietary exposures from cyfluthrin in food as follows:

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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (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: A refined acute probabilistic assessment was conducted using anticipated residues from field trials and percent of crop treated (%CT) and market share information. For existing uses, the acute assessments are moderately refined based on field trial residues and estimated %CT information. For new uses, tolerance level residues and 100 %CT were assumed for dried peas and soybeans, but field trial residues and market share information were used to estimate cyfluthrin residues in brassica, lettuce, mustard greens, and certain stored grains.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (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: For existing uses, the chronic assessments are moderately refined based on field trial residues and estimated %CT information. For

proposed uses, tolerance level residues and 100 %CT were assumed with the exception of stored grains for which there are existing time-limited tolerances; for these grains, %CT estimates and market share information were used.

iii. *Cancer*. Cyfluthrin has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, a dietary exposure assessment was not conducted.

iv. *Anticipated residue and %CT information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of %CT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on %CT.

The Agency used %CT information as follows.

For existing uses, the Agency used estimates of %CT for the acute and chronic exposure assessments which were determined using Doanes Market Survey Data (1996–2000). The following chronic and acute %CT estimates were used for existing registrations: Carrot (3.9 chronic; 8.0 acute); citrus—orange (5.4 chronic; 11.0 acute); citrus—lemon (3.3 chronic; 7.0 acute); citrus—grapefruit (1.2 chronic; 2.5 acute); corn, field and pop, grain (3.0 chronic; 6.0 acute); corn, sweet (2.1 chronic; 3.5 acute); cottonseed (9.3 chronic; 19 acute); peppers (20.0 chronic; 40.0 acute); potatoes (8.0 chronic; 16.0 acute); radishes (1.0 chronic; 2.0 acute); sugarcane (2.5 chronic; 5.0 acute); sunflowers (0.8 chronic; 2.0 acute); tomatoes (4.0 chronic; 9.0 acute); food handling establishments (13.7 chronic; N/A acute).

The Agency believes that the three conditions listed in Unit III.C.1.iv. have been met. With respect to Condition 1, %CT estimates are derived from market survey data, which are reliable and have a valid basis. EPA uses an average %CT for chronic dietary exposure estimates. An average of the %CT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average %CT over a lifetime. For acute assessments, the Agency incorporates %CT information by creating a residue distribution file which includes the measured residue values from field trials, and zero residue values added to account for the percent of crop not treated. This approach is used only for non-blended or partially blended commodities as defined under EPA SOP99.6. For blended commodities, a single-point estimate is created from the residue value multiplied by the upper bound %CT. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation.

For the new uses, the Agency used %CT estimates for the acute exposure assessment based on market share projections as follows: Stored grain—wheat, oats, barley (9.0 %); stored grain, sorghum (3.7 %); mustard greens (9.0 %); lettuce, leaf (19.0 %); lettuce, head (19.0 %); broccoli (14.0 %); brussels sprouts (9.0 %); cabbage (9.0 %); and cauliflower (16.0 %).

The following methods were used to estimate market share for the new uses: For cole crops and leafy vegetables, the year 2000 base acres treated with all pyrethroids/pyrethrins were used along with the assumption of up to 25% market share within 3 years of market entry. For stored cereal grains, the market share estimate for cyfluthrin was based on usage data for chlorpyrifos-methyl.

The Agency believes that the three conditions previously discussed have been met regarding %CT estimates for the new cyfluthrin registrations. With respect to Condition 1, EPA finds that the %CT information described in Unit II.C.1.iv. for cyfluthrin on cole crops, leafy vegetables, and stored cereal grains is reliable and has a valid basis. For cole crops, leafy vegetables, dry peas, and soybeans, the %CT estimates are based on usage data for all pyrethroids/pyrethrins and the generous assumption that cyfluthrin will gain 25% of the total market within 3 years. For stored grains, the estimate is derived from usage data for chlorpyrifos-methyl, historically the most widely used insecticide for control of insect pests in stored grains. These estimates should not underestimate actual usage of cyfluthrin on the new crops/sites. To further support the reliability of these %CT estimates, as a condition of registration, the registrant will be required to agree to report annually on the market share attained for the new uses for which cyfluthrin is registered. As a condition of registration, they will also be required to agree to mitigate dietary risk as deemed appropriate by the Agency should the market share data raise a concern for increased dietary risk. The Agency will then compare that market share information with the %CT estimates used to evaluate potential dietary risk. In those instances where percent market share is approaching or exceeding the predicted %CT estimate used in the Agency's risk assessment, EPA will conduct a new dietary risk assessment to evaluate the new dietary risk. If the market share data raise a concern for increased pesticide risk, the Agency will act to mitigate that dietary risk and could employ several approaches, including but not limited to production caps, geographical limitations, removal of uses, or other means deemed appropriate by the Agency. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those

estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyfluthrin may be applied in a particular area.

2. *Dietary exposure from drinking water*. Cyfluthrin has low mobility and moderate persistence and will remain sorbed to the soil for weeks following a treatment. The low mobility indicates that groundwater contamination with the insecticide is highly unlikely. However, under runoff conditions cyfluthrin is likely to reach surface water resources bound to soil particles. Once in the water system, cyfluthrin tends to partition to sediments.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cyfluthrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of cyfluthrin.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. 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 estimated environmental concentrations (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 cyfluthrin they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of cyfluthrin for acute exposures are estimated to be 1.2 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 1.2 ppb for surface water and 0.006 ppb for ground water. The EECs for cyfluthrin are based on the simulated aerial application of the insecticide on Mississippi cotton at a total annual use rate of 0.50 lbs ai/acre (0.050 lbs a.i./acre) applied 10 times per year.

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).

Cyfluthrin is currently registered for use on the following residential non-dietary sites: Ornamental gardens, lawns, turf, and general insect control in, around and on buildings, structures, and immediate surroundings. There are also uses for spot treatments and crack and crevice treatments for insects in, on, and around homes, buildings, and other structures and for subsoil treatment around structures for control of termites (termiticide use). The risk assessment was conducted using the following residential exposure assumptions: Residential MOEs were assessed for indoor (carpet treatment) and outdoor (lawn) uses of cyfluthrin, including application and post-application exposure. The assessments were based on the conservative assumption that lawn and carpet treatments would occur on the same day. The residential exposure assessment for adults included estimates of exposure via the inhalation and dermal routes; the assessment for infants and children included estimates of exposure via the inhalation, dermal, and oral (hand-to-mouth) routes. Residential applicator exposure from the indoor total release fogger use was not assessed, because homeowner exposure from outdoor lawn treatments is considered to represent the worst-case exposure scenario.

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

EPA does not have, at this time, available data to determine whether cyfluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyfluthrin 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 cyfluthrin 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. *In general*. 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 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of rats or rabbits to *in utero* exposure in developmental oral studies; however, there was some indication of increased susceptibility in developmental inhalation studies. The data also demonstrated increased

susceptibility of rats and mice to postnatal exposure to cyfluthrin.

3. *Conclusion*. The scientific quality of the toxicity data base for cyfluthrin and beta-cyfluthrin is relatively high, and the toxicity profiles of both cyfluthrin and beta-cyfluthrin can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects. A developmental neurotoxicity (DNT) study is required based on evidence of neurotoxicity seen throughout the toxicology data bases with cyfluthrin and beta-cyfluthrin. Nevertheless, the toxicology data bases together are considered adequate for selecting toxicity endpoints for risk assessment. Cyfluthrin toxicity data have been used as bridging data for beta-cyfluthrin.

The degree of concern for the effects observed in the inhalation developmental studies was considered low, noting that a clear NOAEL was established for the fetal effects in every case. No residual uncertainties were identified. The NOAEL used for short-term inhalation exposure scenarios is protective of the effects seen in the developmental studies via the inhalation route. The degree of concern for the effects observed in the reproductive studies was considered low, noting that a clear NOAEL was established for the offspring effects in every case. No residual uncertainties were identified. The NOAEL used to establish the cRfD for all populations is protective of the effects seen in the young in the reproduction studies.

Preliminary results from the required DNT study on beta-cyfluthrin corroborate these findings. The data indicate a similar NOAEL for parents and pups, based on decreases in body weight. Furthermore, the preliminary NOAEL is comparable to the NOAELS used as the basis for the aRfDs and cRfDs. This information supports the dose analysis conducted by EPA as well as the removal of the special FQPA SF required for the protection of infants and children. Therefore, the FQPA SF (as discussed in the February 2002, OPP 10X guidance document) was reduced to 1X.

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 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 at the 99.9th percentile of exposure from food to cyfluthrin will occupy 50% of the aPAD for the U.S. population, 51% of the aPAD for females 13 years and older, 82% of the aPAD for infants less than 1 year old and 77% of the aPAD for children 1 to 6 years old. In addition, there is potential for acute dietary exposure to cyfluthrin 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 Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYFLUTHRIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. Population	0.02	50	1.2	0.006	350
All infants (<1 year old)	0.02	82	1.2	0.006	40
Children (1–6 years old)	0.02	77	1.2	0.006	50
Females (13–50 years old)	0.02	51	1.2	0.006	300

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyfluthrin from food will utilize 9% of the cPAD for the U.S. population, 6% of the cPAD for all infants less than 1 year old and 17% of the cPAD for children 1 to 6 years old. The registered residential termiticide uses of cyfluthrin do constitute a chronic inhalation exposure scenario; however, the vapor pressure of cyfluthrin is so low (3.3×10^{-8} torr) that such exposures are anticipated to be negligible. In addition, there is potential

for chronic dietary exposure to cyfluthrin 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 Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYFLUTHRIN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. Population	0.024	9	1.2	0.006	770
All infants (< 1 year old)	0.024	6	1.2	0.006	230
Children (1–6 years old)	0.024	17	1.2	0.006	200

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). Cyfluthrin is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for cyfluthrin.

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 360 for adults, 330 for children 1 to 6 years old and 470 for infants less than 1 year old. These aggregated MOEs include average exposure from cyfluthrin residues in food as well as inhalation and dermal exposure of adults; and inhalation, dermal and oral (hand-to-mouth) exposure of infants and children from the residential uses of cyfluthrin on lawns and indoors on carpet.. 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 cyfluthrin 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 Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CYFLUTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Adult male	360	100	1.2	0.006	610
Adult female	360	100	1.2	0.006	520
Child	330	100	1.2	0.006	170
Infants	470	100	1.2	0.006	190

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).

Cyfluthrin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for cyfluthrin.

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 210 for adults, 230 for children 1 to 6 years old and 260 for infants less than 1 year old. These aggregated MOEs include average exposure from cyfluthrin residues in food as well as inhalation and dermal exposure of adults; and inhalation, dermal and oral (hand-to-mouth) exposure of infants and children from the residential uses of cyfluthrin on lawns and indoors on carpet. 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 cyfluthrin 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 Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CYFLUTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Adult male	210	100	1.2	0.006	440
Adult female	210	100	1.2	0.006	370
Child	230	100	1.2	0.006	140
Infants	260	100	1.2	0.006	150

5. *Aggregate cancer risk for U.S. population*. Cyfluthrin has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, cyfluthrin is not expected to pose a cancer risk to humans.

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 cyfluthrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A GC method with electron capture detection (GC/ECD) is available for the enforcement of tolerances for cyfluthrin residues in/on plant commodities. This method has an LOQ of 0.05 ppm for cyfluthrin and was previously described in Mobay Report 85823 (''A Gas Chromatographic Method for Baythroid® 2 Residues in Crops,'' MRID 40301501). This method has undergone a successful petition method validation and is available in PAM, Vol II. A GC/ECD method is also available for enforcing tolerances for cyfluthrin residues in animal commodities and is published in PAM II.

B. International Residue Limits

There are no established Codex Maximum Residue Limits (MRLs) for residues of cyfluthrin in/on the commodities for which tolerances are being established, with the exception of maize (field corn grain) at 0.05 ppm. Codex MRLs are currently expressed in terms of cyfluthrin per se. Due to the post harvest use on stored grains, the U.S. tolerance for corn grain is much higher than the Codex maize MRL.

V. Conclusion

Therefore, tolerances are established for residues of cyfluthrin, cyano (4-fluoro-3-phenoxyphenyl) methyl-3-(2,2-didichloroethenyl)-2,2-dimethyl-cyclopropane-carboxylate in or on soybean, seed at 0.03 ppm; soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; corn, field, forage at 3.0 ppm; corn, field, stover and corn, pop, stover at 6.0 ppm; grain, cereal, group at 4.0 ppm; corn, field, refined oil at 30 ppm; corn, field, milled byproduct at 7.0 ppm; grain, aspirated fractions at 600 ppm; wheat milled byproducts, except flour at 5.0 ppm; rice, hulls at 18 ppm; rice, bran at 6.0 ppm; barley, bran, oat, bran and rye, bran at 5.0 ppm; milk at 1.0 ppm; milk, fat at 30 ppm; cattle, fat, goat, fat, hog, fat, horse, fat and sheep, fat at 10 ppm; mustard greens at 7.0 ppm; lettuce, leaf at 3.0 ppm; lettuce, head at 2.0 ppm; brassica, head and stem, subgroup at 2.5 ppm; pea, southern, succulent at 0.25 ppm; and pea, dry at 0.15 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2002–0193 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 26, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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 ID number OPP–2002–0193, 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 20460–0001. 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 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). 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 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 section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. 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 18, 2002.

Debra Edwards,

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 180.436 is amended by removing from the table in paragraph (b) the entries barley, grain; cattle, fat; goat, fat; hog, fat; horse, fat; oat, grain; sheep, fat; and wheat, grain and by revising paragraph (a)(1) to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethyl-cyclopropane-carboxylate; CAS No. 68359–37–5) in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa	5.0
Alfalfa, hay	10.0
Barley, bran	5.0
Brassica, head and stem, subgroup	2.5
Carrot	0.20
Cattle, fat	10.0
Cattle, meat	0.40
Cattle, meat by-products	0.40
Citrus, dried pulp	0.3
Citrus, oil	0.3
Corn, field, forage	3.0
Corn, field, milled byproducts	7.0
Corn, field, refined oil	30.0
Corn, field, stover	6.0
Corn, pop, stover	6.0
Corn, sweet, forage	15.00
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	30.00
Cotton, hulls	2.0
Cotton, refined oil	2.0
Cotton, seed	1.0
Egg	0.01
Fruit, citrus, group	0.2
Goat, fat	10.0
Goat, meat	0.40
Goat, meat byproducts	0.40
Grain, aspirated fractions	600
Grain, cereal, group	4.0
Hog, fat	10.0
Hog, meat	0.40
Hog, meat byproducts	0.40
Hop, dried cones	20.0
Hop, fresh	4.0
Horse, fat	10.0
Horse, meat	0.40
Horse, meat by-products	0.40
Lettuce, head	2.0
Lettuce, leaf	3.0
Milk	1.0
Milk, fat	30.0
Mustard greens	7.0
Oat, bran	5.0
Pea, dry	0.15
Pea, southern, succulent	0.25
Pepper	0.50
Potato	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat by-products	0.01
Radish, roots	1.0
Rice, bran	6.0
Rice, hulls	18.0
Rye, bran	5.0
Sheep, fat	10.0
Sheep, meat	0.40
Sheep, meat by-products	0.40
Sorghum, grain, forage	2.0
Sorghum, grain, stover	5.0
Soybean, forage	8.0
Soybean, hay	4.0
Soybean, seed	0.03
Sugarcane, cane	0.05
Sugarcane, molasses	0.20
Sunflower, forage	5.0
Sunflower, seed	0.02
Tomato	0.20
Tomato, paste	0.5
Tomato, pomace	5.0
Wheat milled by-products, except flour	5.0

* * * * *

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPT–2002–0030; FRL–7186–9]

RIN 2070–AB27

Revocation of Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking significant new use rules (SNURs) for eight substances promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) based on new data. Based on the new data the Agency no longer finds that activities not described in the corresponding TSCA section 5(e) consent orders for these chemical substances may result in significant changes in human or environmental exposure.

DATES: This final rule is effective on November 26, 2002.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

For technical information contact: James Alwood, Chemical Control Division, Office of Pollution Prevention and Toxics (7405M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–8974; e-mail address: alwood.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this revocation. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Chemical manufacturers	325	Manufacturers, importers, processors, and users of chemicals