and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 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 the rule in the **Federal Register**. This 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: June 23, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.442, by amending paragraph (a) by revising the introductory text and the tolerance level for ''corn forage'' and by alphabetically adding the following entries to the table:

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the following food commodities:

Commodity	Parts per million
Artichoke, globe	1.0
Brassica, head and stem, subgroup, excluding cabbage.	0.6
Cabbage	4.0
* * * *	* * *
Corn, forage	3.0
* * * *	* * *
Corn, sweet, kernel plus cob with husk removed.	0.05
Eggplant	0.05
* * * *	* * *
Pea and bean, succulent shelled, subgroup.	0.05
* * * *	* * *
Rapeseed	0.05
* * * *	* * *
Vegetable, cucurbit, crop group.	0.4
Vegetable, legume, edible podded, subgroup.	0.6

* * * * *

[FR Doc. 99–16575 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300887; FRL–6088–9]

RIN 2070–AB78

Cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate]; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate] in or on potatoes at 0.01 parts per million (ppm). It also removes time limitations for tolerances for residues of cyfluthrin on sweet corn, field corn, and pop corn (including forage and fodder). Bayer Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 30, 1999. Objections and requests for hearings must be received by EPA on or before August 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300887], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300887], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of

Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300887]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mark Dow, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 222, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5533, dow.mark@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 5, 1995 (60 FR 34874) (FRL-4963-2), EPA issued a time-limited tolerance for cyfluthrin use in or on corn (field, pop, and sweet) in combination with another insecticide, the organophosphate tebupirimifos (originally known as phostebupirim) (O-[2-(1-dimethylethyl)-5-pyrimidinyl]O-ethyl-O-ethyl-O-(1-methylethyl)phosphorothioate) with an expiration date of 5 July 1999. These time-limited tolerances were established due to a lack of mammalian neurotoxicity data and the need for confirmatory soil metabolism and product chemistry data for tebupirimiphos. Bayer Corporation requested the Agency to remove the time limitations for cyfluthrin on corn in a notice of filing published in the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL–5748–2), and in a March 8, 1999 letter based on the fact that the time limitation was due to data deficiencies for tebupirimifos and not for cyfluthrin. Since (1) cyfluthrin is registered for use on corn; (2) the data base is complete for tolerance assessment purposes and ; (3) these tolerances were considered by EPA for risk assessment purposes, EPA has no objection to the removal of the time-limitations and the establishment of permanent tolerances for the residues of cyfluthrin on corn. In the **Federal Register** of August 14, 1998 (63 FR 43705) (FRL–6019–8), EPA issued a notice 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 a pesticide petition (PP) 4F4330 for tolerance by Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120. This notice included a summary of the petition prepared by Bayer Corporation, the registrant.

The petition requested that 40 CFR 180.436 be amended by establishing a tolerance for residues of the insecticide cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate], in or on potatoes at 0.01 ppm. Cyfluthrin controls cabbage looper, potato leafhopper, Colorado potato beetle, European corn borer, flea beetles, potato tuberworm, potato psyllid, tarnished plant bug and aphids on potatoes.

There were no comments received in response to the Notices of Filing.

I. Background and Statutory Findings

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).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate] and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of cyfluthrin on potatoes at 0.01 ppm and removal of time limitations for tolerances for residues of cyfluthrin on corn (field, pop, and sweet). EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cyfluthrin are discussed in this unit.

1. *Acute toxicity*. The required toxicity battery studies for acute oral (LD_{50} ≧16.2 miligrams/kilograms (mg/kg)), dermal (LD_{50} >5,000 mg/kg), inhalation (LC_{50} ≧0.468 mg/liter (L)), primary eye irritation (category III), primary dermal irritation (category IV), and dermal sensitization have been conducted and were found adequate. Cyfluthrin is not a dermal sensitizer.

2. *Mutagenicity*. There are seven acceptable studies upon which the Agency based its evaluation: three reverse mutation assays (*Salmonella typhimurium*, *E. coli* and *Saccharomyces cerevisiae*); one reverse mutation, mitotic recombination and conversion assay in *Saccharomyces cerevisiae*); one Chinese Hampster Ovary/ Hypoxanthine guanine phophoribosyl transferase (CHO/HGPRT) assay; one sister chromatid exchange assay in CHO cells; and one Unscheduled DNA synthesis (UDS) assay in primary rat hepatocytes. All these studies were negative. There is no mutagenicity concern.

3. *Reproductive and developmental toxicity* — i. *Oral developmental study in rats*. Cyfluthrin was administered via gavage to pregnant female rats during

days 6–15 of gestation at dose levels of 0, 1, 3, or 10 mg/kg/day. A maternal Lowest Observable Adverse Effect Level (LOAEL) was not observed (i.e., the maternal No Observable Adverse Effect Level (NOAEL) is ≧10 mg/kg/day). A developmental LOAEL was not observed. The developmental NOAEL is ≧10mg/kg/day. This developmental study in rats was classified core guideline.

ii. *Oral developmental study in rabbits*. Cyfluthrin was administered via gavage to pregnant female rabbits during days 6–18 of gestation at dose levels of 0, 20, 60, or 180 mg/kg/day. The maternal LOAEL is 60 mg/kg/day based on decreased body weight gain and food consumption during the dosing period. The maternal NOAEL is 20 mg/kg/day. The developmental LOAEL is 60 mg/kg/day based on increased numbers of resorptions and percent incidence of postimplantation loss. The developmental NOAEL is 20 mg/kg/day. This study was classified core guideline.

iii. *Rat developmental studies via inhalation*. In the first study, pregnant female rats at day 0 gestation were exposed head-only to cyfluthrin concentrations of 0, 1.1, 4.7 or 23.7mg/m^3/day (milligrams per cubic meter per day) for 6 hours/day on gestation days 6–15. In the second study, the dams were exposed to analytical concentrations of 0, 0.09, 0.25, 0.59 or 4.2 mg/m^3 of the test material. The dams were sacrificed on day 20 and their pups removed by caesarian section. The maternal NOAEL was 1.1 mg/m^3 and the maternal LOAEL was 4.7 mg/m^3 (reduced motility, dyspnea, piloerection, ungroomed coats and eye irritation). The developmental NOAEL was 0.59 mg/m^3 and the developmental LOAEL was 1.1 mg/m^3 based on increases in the incidence of runts and skeletal anomalies in the sternum (1.1 mg/m^3 and above); and increases in post-implantation losses and decreases in pup weights (4.7 mg/m^3 and above) and increased incidences of late embryonic deaths, in skeletal anomalies in the extremities, pelvis and skull and microphthalmia (23.7mg/m^3). The study was graded core minimum.

In a third study, a developmental toxicity study via inhalation, cyfluthrin was administered to female rats at 0.46, 2.55, 11.9 or 12.8 mg/m^3 exposure levels for gestational days 6–15 in a nose only inhalation chamber. The rats were exposed to the test material 6 hr/day, 7 days/week. The maternal NOAEL/LOAEL were <0.46/<0.46 mg/m^3 based on decreased body weight gain and reduced relative food efficiency. The developmental NOAEL/LOAEL were 0.46/2.55 mg/m^3 based on reduced fetal and placental weight, reduced ossification in the phalanx, metacarpals and vertebrae. This study was classified as core guideline.

iv. *3-Generation reproduction study*. Cyfluthrin was administered in the diet to male and female rats dose levels of 0, 50, 150, or 450 ppm (actual animal intake; 0, 2.5, 7.5, or 22.5 mg/kg/day). The LOAEL for parental toxicity was 450 ppm (22.5 mg/kg/day) based on decreased body weight gains. The NOAEL for parental toxicity is 150 ppm (7.5 mg/kg/day). The LOAEL for reproductive toxicity was 150 ppm (7.5 mg/kg/day) based on decreased viability and lactational indices and decreased pup body weight gains. The reproductive NOAEL was 50 ppm (2.5 mg/kg/day). The multigeneration reproductive study in the rat was classified core minimum.

4. *Subchronic toxicity* — i. *28–Day oral toxicity study in rats*. Cyfluthrin was administered to SPF-Wistar rats via gavage at 0, 5, 20, or 80 (40) mg/kg/day. The high dose was 80 mg/kg/day during the first and third weeks and 40 mg/kg/day during the second and fourth weeks. The LOAEL was 80 (40) mg/kg/day in both sexes based on clinical signs of nerve toxicity, decreases in body weight gain, and changes in liver and adrenal weights. The NOAEL was 20 mg/kg/day. This study was classified as core minimum.

ii. *28-Day oral toxicity study in rats*. Rats were dosed with cyfluthrin in the diet at 0, 100, 300, or 1,000 ppm (equivalent to 0, 5, 15, or 50 mg/kg/day). The LOAEL was 15 mg/kg/day in both sexes based on decreased blood glucose. The NOAEL was 5 mg/kg/day. This study was classified core supplementary.

iii. *3–Month feeding study in rats*. SPF Wistar rats were dosed with cyfluthrin in the diet at 0, 30, 100, or 300 ppm (equivalent to 0, 1.5, 5, or 15 mg/kg/day) for 3 months. No treatment related effects were observed at any of the levels tested, thus the NOAEL for this 3–month rat feeding study was 15 mg/kg/day for both sexes. This study was classified core minimum.

iv. *6–Month dog feeding study*. Cyfluthrin was administered in the diet to dogs at 0, 65, 200 or 600 ppm (equivalent to 0, 1.62, 5 or 15 mg/kg/day) for 26 weeks. The LOAEL for this study was 15 mg/kg/day for both sexes, based on neurological effects (hindlimb abnormalities) and gastrointestinal disturbances. The NOAEL was 5 mg/kg/day for males and females. The study was classified as core minimum.

v. *21–Day dermal study in rats*. In a 21–day repeated dose dermal toxicity study, male and female rats were treated with cyfluthrin by dermal occlusion at target doses of 0, 100, 340, or 1,000 mg/kg/day for 6 hours/day (average actual dose levels were 0, 113, 376, or 1,077 mg/kg/day). No mortality was observed, and there were no treatment-related effects on body weight, ophthalmology, organ weights, clinical biochemistry, or hematology. The LOAEL for dermal effects was 376 mg/kg/day for male and female Sprague-Dawley rats based on gross and histological skin lesions. The NOAEL for dermal effects for technical Baythroid was 113 mg/kg/day. The LOAEL for systemic effects was 1,077 mg/kg/day based on decreased food consumption, red nasal discharge and urine staining. The NOAEL for systemic effects was 376 mg/kg/day. This study was classified as acceptable.

vi. *3–Week inhalation toxicity studies in rats* —a. Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin at concentrations of 0, 2.3, 11.5, or 69.6 mg/kg/day for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOAEL was 2.3 mg/m^3, based on the treatment-related effects on body weight and temperature observed during the 3–week exposure period. A NOAEL was not established; therefore this study was repeated using lower doses.

b. Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin at concentrations of 0, 0.4, 1.4, or 10.5 mg/m^3 for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOAEL was 10.5 mg/m^3, based on the treatment-related behavioral effects as well as effects on body and organ (spleen) weights. The NOAEL is 1.4 mg/m^3. These studies were classified as core minimum.

vii. *4–Week inhalation toxicity study in rats*. Rats were dynamically exposed by inhalation (nose only) to cyfluthrin at concentrations of 0, 0.44, 6.04, or 46.6 mg/m^3 for 6 hours/day, 5 consecutive days/week for 4 weeks (20 exposures). The LOAEL is 6.04 mg/m^3 based on the decrease in body and thymus weights, hypothermia, reduction in leukocytes counts (females), and low serum protein. The NOAEL is 0.44 mg/m^3. This subacute inhalation toxicity study in rats was classified as supplementary.

viii. *13–Week inhalation toxicity study in rats*. Rats were dynamically exposed by head-only inhalation to cyfluthrin at concentrations of 0, 0.09, 0.71, or 4.51 mg/m^3 for 6 hours/day, 5 consecutive days/week for 13 weeks. All animals survived the 13–week study, and no treatment-related changes were observed in organ weight, gross pathology and histopathology. The LOAEL was 0.71 mg/m^3, based on the

treatment-related behavioral effects in females as well as the increased urinary protein in males. The NOAEL was 0.09 mg/m^3. This study was classified as core minimum.

5. *Chronic toxicity* — i. *1–Year dog study*. Cyfluthrin was fed to beagle dogs at 0, 40, 160, or 640 ppm (equivalent to 0, 1, 4, or 16 mg/kg/day) for 52 weeks. The NOAEL was 4 mg/kg bw/day. The LOAEL was 16 mg/kg bw/day for both sexes, based on slight ataxia in two dogs on single occasions, decreased body weight in males, and on observations of increased vomiting and diarrhea at the high dose. The NOAEL is 4 mg/kg bw/day. This study was classified as core minimum.

ii. *Chronic/carcinogenicity-rat*. Cyfluthrin was administered for 24 months in the diet to rats at dose levels of 0, 50, 150, or 450 ppm (equivalent to 2.02, 6.19, or 19.20 mg/kg bw/day in males and 2.71, 8.15, or 25.47 mg/kg/day in females based on food consumption and body weights). The chronic LOAEL was 150 ppm (equivalent to 6.19 mg/kg/day in males and 8.15 mg/kg/day in females) based on decreased body weights in the high-dose animals and the mid-dose males. The chronic NOAEL was 50 ppm (equivalent to 2.02 mg/kg/day in males and 2.71 mg/kg/day in females). Under the conditions of this study, there was no evidence of carcinogenic potential. The study was classified core minimum for both chronic toxicity and oncogenicity.

iii. *Chronic/carcinogenicity- mouse*. In a chronic/carcinogenicity study, cyfluthrin was administered in the diet for 23 months to mice at dose levels of 0, 50, 200, or 800 ppm (equivalent to 11.6, 45.8, or 194.5 mg/kg/day in males and 15.3, 63.0, or 259.9 in females based on food consumption and body weights). There were no treatment related changes noted in the clinical observation, food consumption, hematology, gross observation, organ weight, and microscopic data. The chronic LOAEL is 50 ppm (equivalent to 11.6 mg/kg/day in males and 15.3 mg/kg/day in females) based on increased alkaline phosphatase activity in the dosed males. A chronic NOAEL was not established in male and female mice. Under the conditions of this study, there was no evidence of carcinogenic potential. This study was classified core minimum for carcinogenicity and supplementary for chronic toxicity.

6. *Animal metabolism*. Metabolism studies in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Neurotoxicity*. Other studies evaluated included a subacute oral neurotoxicity study in rats (LOAEL of 50 mg/kg/day; no NOAEL observed); a second subacute oral neurotoxicity study (NOAEL of 40 mg/kg/day); a subchronic neurotoxicity study in rats (NOAEL <60 mg/kg/day), and a subacute inhalation study in mice NOAEL for pups, 0.006 mg/L; parental NOAEL 0.058 mg/L Highest Dose Tested (HDT). These studies were all graded acceptable/guideline. Additional neurotoxicity data may be required under a special Data-Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has a sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

The Agency has determined that an additional uncertainty factor (UF) is needed for risk assessments for cyfluthrin because there was evidence of increased sensitivity of pups in the 3–generation reproduction study based on decreased pup weight gains at a dose in which there were no effects in the parents. The FQPA factor of 10 was reduced to 3x because of the lack of severity of effects (reduced body weight gain in pups) and the availability of acceptable reproduction (rat) and developmental (rats and rabbits) toxicity studies.

1. *Acute toxicity — Acute dietary*. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day from the rabbit developmental study. This endpoint is due to increases in resorption and percent incidence of postimplantation loss at the Lowest Effect Level (LEL) of 60 mg/kg/day. The population adjusted dose for acute dietary (aPAD) is determined by dividing NOAEL by Ufs of 300 (10x for interspecies differences, 10x for intraspecies variability and 3x FQPA safety factor): aPAD = 20/ (10x 10x 3) = 0.07 mg/kg bwt/day. This aPAD applies to all population subgroups.

2. *Short and intermediate term toxicity*. For the short and intermediate term dermal endpoints, a NOAEL of 20 mg/kg/day was determined from the rabbit developmental study due to an increase in resorption and percent incidence of postimplantation loss at the LEL of 60 mg/kg/day. The dermal absorption rate is 25%. This rate is based on the weight of the evidence available for structurally related synthetic pyrethroids. For short term inhalation a NOAEL of 0.00044 mg/L is based on decreases in body and thymus weights, hypothermia, and clinical pathology at 0.00604 mg/L in a 28–day inhalation study.

For the Intermediate Term Inhalation Endpoint a NOAEL of 0.00009 mg/L is based on behavioral effects in rats at 0.00071 mg/L in a 90–day inhalation study. The 3x FQPA UF was included for inhalation because an inhalation study is available in the mouse which indicates increased sensitivity of the pups in comparison to the dams.

3. *Chronic toxicity — Chronic dietary*. A NOAEL of 2.5 mg/kg/day was determined from the rat chronic toxicity/ carcinogenicity study and is based on decreased body weight gains in males and inflammatory foci in the kidneys of females at the LEL of 6.2 mg/kg/day. The chronic population adjusted dose (cPAD) is determined by dividing the NOAEL by Ufs: cPAD = 2.5/ (10x10x3) = 0.008 mg/kg bwt/day. This cPAD applies to all population subgroups.

Long-term Dermal Endpoint For the chronic dermal endpoint, the same study used for determining the chronic dietary endpoint was used here.

4. *Carcinogenicity*. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity in humans), since carcinogenicity studies in rats and mice were negative.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.436) for the residues of cyfluthrin, in or on a variety of raw agricultural commodities. For purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum preharvest intervals were used. To assess secondary exposure from edible animal commodities, animal dietary burdens were calculated using mean field trial residues, adjusted for percent crop treated (PCT) and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures from cyfluthrin as follows:

i. *Acute dietary exposure and risk*. aPAD = 0.07 mg/kg bwt/day.

aPAD = NOAEL/UFs = 20/(10 x 10 x 3) = 0.07 mg/kg bwt/day.

An acute dietary (food) risk assessment was conducted. In the assessment, a Monte Carlo analysis (Tier 3) was used. The anticipated residue values used were determined from field trial data reflecting maximum application rates and minimum preharvest intervals. Field trial residue distributions were used in the Monte Carlo simulation for those foods

identified by EPA as single-serving commodities. For those considered to be blended or processed, mean field trial residues were calculated, substituting the full limit of detection (LOD) for those samples for which residues were reported below the LOD. For the analysis, current registered uses plus potatoes were used.

In the Monte Carlo analysis for potatoes, the tolerance used is 0.01 ppm and 100% crop treated was assumed. Data files used include (a) The highest field trial data for dried hops (16.6 ppm) and radishes (0.38 ppm) were used instead of the tolerances (dried hops: 20 ppm, radishes: 1.0 ppm); (b) Processing factors for corn were used since the processing study was available (concentration factor for corn oil: 7.6); (c) New available residue levels on potato and its commodities, all at 0.01 ppm (LOD), were used; (d) Secondary residues in milk, milk sugar, milk based water, and animal fat were adjusted (decreased) due to the slight change of dietary burden as a result of the above changes.

Analysis evaluates individual food consumption as reported in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99.9th percentile) and percentage of the aPAD utilized are shown in Table 1. The most highly exposed population subgroup (Non-Nursing infants, <1 year) utilizes 9.7% of the aPAD.

An acceptable acute dietary exposure (food plus water) of 100% or less of the aPAD is needed to protect the safety of all population subgroups. EPA generally has no concern for aPAD of less than 100%.

Table 1. Acute Dietary (Food Only) Exposure Analysis by Dietary Exposure Evaluation Model (DEEM) for Cyfluthrin

Population Subgroup	Exposure @ 99.9th Percentile (mg/kg bwt/day)	Percent aPAD[1]
U.S. Population (48 Contiguous States)	0.0045	6.4%
All infants (< 1 yr)	0.0062	8.9%
Nursing infants (< 1 yr)	0.0037	5.3%
Non-nursing infants (< 1 yr)	0.0068	9.7%
Children (1–6 yrs)	0.0059	8.4%
Children (7–12 yr)	0.0042	6.0%

[1]Percentage Acute PAD (% aPAD) = Exposure X 100% / aPAD

The subgroups listed above are: (1) the U.S. population (48 Contiguos States) and (2) those for infants and children.

ii. *Chronic dietary exposure and risk.* cPAD = 0.008 mg/kg bwt/day.

cPAD = NOAEL/ UFs = 2.5/ (10 x10 x3) = 0.008 mg/kg bwt/day.

In the DEEM analysis for chronic dietary (food only) risk assessment the anticipated residue values used were determined from field trial data conducted at maximum application rates and minimum preharvest intervals. Mean anticipated residue values were calculated substituting half of the LOD for those samples for which residues were reported below the LOD.

For the chronic dietary analysis, all registered food uses plus potatoes were included. In the analysis, the residue levels used for potatoes and potato commodities are all 0.005 ppm, and 100% crop treated was assumed. Other ''assumptions'' are: (1) Mean field trial data for radishes (0.09 ppm) and hops (13.7 ppm) have been used instead of tolerances; (2) Residue for alfalfa sprout was adjusted for the percent crop treated (from 0.01 ppm to 0.14 ppm); (3) Processing factors for citrus, corn, cottonseed, sugarcane, sunflower, and tomatoes were used since these processing studies were available; (4) Residue levels used for potatoes and potato commodities were changed from 0.05 ppm to 0.005 ppm(half of LOD); (5) Secondary residues in meat, milk, poultry, and eggs were adjusted since the slight change of dietary burden as a result of the above changes (meat and poultry: slight decrease in residue levels, milk and milk-based water: slight increase in residue levels).

The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. Summaries of the Anticipated Residue Concentration (ARC) and their representations as percentages of cPAD for the general population and subgroups of interest are in Table 2. The most highly exposed population subgroup (Non-Nursing infants < 1yr) will utilize 1.9% of the cPAD.

An acceptable chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups. EPA generally has no concern for cPAD of less than 100%.

Table 2. Chronic Exposure Analysis by the DEEM System for Cyfluthrin

Population Subgroup	Exposure (mg/kg/day)	Percent cPAD[1]
U.S. Population (48 Contiguous States)	0.000067	0.8%
Non-Nursing Infants (<1 year old)	0.00015	1.9%
Children (1–6 years old)	0.00014	1.8%

[1]Percentage cPAD = Exposure X 100% / cPAD

The subgroups listed above are: (1) the U.S. population (48 Contiguous States); (2) highest exposed population subgroup that includes infants and children.

Section 408(b)(2)(E) 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), 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 the tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings: (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; (2) that the exposure estimate does not underestimate exposure for any significant subpopulation group and; (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 PCT as required by the section 408 (b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency believes that the three conditions, discussed in section 408(b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. With respect to (1), percent crop treated estimates are derived from federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates is supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimate. As to (2) and (3), regional consumption information and consumption information for significant sub populations 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 sub population group and allows the Agency to be reasonably certain that no regional pupulation 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 may be applied in a particular area. EPA finds that the PCT information is reliable and has a valid basis.

2. *From drinking water.* There is no established Maximum Concentration Level for residues of cyfluthrin in drinking water. Although data indicate little potential for soil mobility or leaching, cyfluthrin is moderately persistent. Estimates of potential concentrations of cyfluthrin in water were generated with the Pesticide Root Zone Model (PRZM 1) and Exposure Analysis Modeling System (EXAMS) computer models in 1993 for comparative ecological risk assessment for cyfluthrin. The estimated environmental concentrations (EECs) of cyfluthrin residues are 0.236 µg/L for acute surface water and 0.044 µg/L for chronic surface water. The primary use of these models is to provide a screen for sorting out pesticides for which EPA has a high degree of confidence tht the true levels of the pesticide in drinking water will be less that the human health drinking water levels of concern (DWLOCs). A DWLOC is a theoretical upper limit of a pesticide's concentration in drinking water in light of total aggregate exposure to that pesticide in food and through residential uses. A DWLOC will vary depending on the toxic endpoint, consumption and body weight. Different populations will have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, the DWLOC is used as a point of comparison against conservative model estimates of potential pesticide concentration in water. DWLOC values are not regulatory standards for drinking water.

For this acute risk assessment, the estimated maximum concentration for cyfluthrin in surface and ground waters (which is 0.236 µg/L) is used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the acute endpoint. These DWLOCs for various population categories are summarized in Table 3.

Table 3. Drinking Water Levels of Comparison for Acute Exposure to Cyfluthrin[1]

Population Category[2]	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure3 (mg/kg/day)	DWLOC 4,5,6 (µg/L)	DWEC,7 (µg/L)
U.S. Population (48 Contiguous States) Male.	0.07	0.0045	0.066	2300	0.24
U.S. Population (48 Contiguous states) Females.	0.07	0.0045	0.066	2000	0.24
Non-Nursing Infants (<1 year old)	0.07	0.0068	0.063	630	0.24

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = [aPAD or cPAD (mg/kg/day) - Food Exposure (mg/kg/day).
[4] DWLOC (µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/µg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7] DWEC: Drinking Water Estimate Concentration. (Acute value).

For purposes of chronic risk assessment, the estimated maximum concentration for cyfluthrin in surface and ground waters (which is 0.04 µg/L) should be used for comparison to the back-calculated human health DWLOCs for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in Table 4.

Table 4. Drinking Water Levels of Comparison for Chronic Exposure to Cyfluthrin[1]

Population Category[2]	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC [4,5,6](µg/L)	DWEC,[7](µg/L)
U.S. Population (48 Contiguous States) Male	0.008	0.000067	0.0079	270	0.044
U.S. Population (48 Contiguous States) Female	0.008	0.000067	0.0079	240	0.044
Non-Nursing infants < 1 yr	0.008	0.00015	0.0079	80	0.044

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = [aPAD or cPAD (mg/kg/day) - Food Exposure (mg/kg/day).
[4] DWLOC (µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10–3 mg/µg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7]DWEC: Drinking Water Estimate Concentration. (Acute value).

As indicated in the Tables above, the estimated maximum concentration of cyfluthrin in surface and ground water are less than the DWLOCs as a contribution to acute and chronic exposure. The estimated concentrations of cyfluthrin in surface and ground water are conservative estimates. Therefore the Agency concludes with reasonable certainty that residues of cyfluthrin in food and drinking water will not result in an unacceptable estimate of acute or chronic human health risk.

3. *From non-dietary exposure.* Cyfluthrin is currently registered for use on the following residential non-food sites: outdoor lawn/gardens, inside households, carpets and as a termiticide. Exposure to cyfluthrin may occur as a result of inhalation or contact from indoor and outdoor uses. Thus these uses constitute a short- and intermediate-term exposure scenario. A worst case scenario which aggregates all the above exposure routes was conducted for risk assessment purposes.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Cyfluthrin is a member of the Synthetic Pyrethroids. Other members of this class include bifenthrin, cypermethrin, lambda-cyhalothrin, zeta-cypermethrin, deltamethrin, esfenvalerate, permethrin, fenpropathrin, tefluthrin and tralomethrin. Four members of this class produce a common metabolite known as DCVA. These pyrethroids are cyfluthrin, cypermethrin, z- cypermethrin and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and therby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound the toxicity of DCVA has been assumed to be equivalent to the parent compound. However, due to the different toxicological profiles of cyfluthrin, cypermethrin, z-cypermethrin, and permethrin, EPA does not believe that it would be appropriate to cumulate DCVA for these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides.

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. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Using a Monte Carlo analysis, it is estimated the acute exposure to cyfluthrin from food for the population subgroup (U.S. Population-all season) will utilize 6.4% of the aPAD, and for the most highly exposed population subgroup that includes children (Non-Nursing infants, <1 year) will utilize 9.7% of the aPAD, as shown in Table 1. It was determined that an acute dietary exposure (food plus water) of 100% or less of the aPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to cyfluthrin in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the aPAD for adults, infants and children. The maximum concentration of cyfluthrin in surface and ground water for acute exposure is very small compared to the DWLOC as shown in Table 3. Under current Agency guidelines, non-dietary uses of cyfluthrin do not constitute an acute exposure scenario. The Agency concludes that there is a reasonable certainty that no harm will result to adults, infants and children from acute aggregate exposure to cyfluthrin residues.

2. *Chronic risk.* Using the exposure assumptions described above, it is estimated that the chronic exposure to cyfluthrin from food for the most highly exposed population subgroup (Non-Nursing infants < 1yr) will utilize 1.9% of the cPAD as shown in Table 2. It was determined that a chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to cyfluthrin in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the cPAD. The maximum concentration of cyfluthrin in surface and ground water for chronic exposure is very small compared to the DWLOC as shown in Table 4. Although the registered residential termiticide use of cyfluthrin constitutes a possible chronic exposure scenario (inhalation), it is not aggregated into dietary exposure due to the fact that the toxicological endpoints were from different studies

with different toxicological effects. The Agency also concludes that a single source chronic risk from exposure to a termiticide use is negligible due to the fact that the vapor pressure of cyfluthrin is very low (3.3×10^{-8} torr). The Agency concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to cyfluthrin residues.

3. *Short- and intermediate-term risk*. The short- and intermediate-term aggregate risks are estimated by combining exposure from food (chronic), water and residential uses.

Since residue values in water from monitoring data were not available, the DWLOCs have to be back calculated for the short- and intermediate-term aggregate risk assessments.

For cyfluthrin, the registered residential use sites include outdoor lawn/gardens, inside households and termiticide. These uses constitute a short, and intermediate term exposure scenario. Endpoints have been selected for short- and intermediate-term dermal and inhalation exposures. For adults, the routes of exposure from these registered residential uses include dermal and inhalation, and for infants and children, the routes of exposure include dermal, inhalation, and oral (nondietary).

According to Agency aggregate risk assessment guidelines, exposures with toxicological endpoints selected from different studies with different toxicological effects should not be aggregated. Since the toxicological effects through the inhalation exposure route is different from those toxicological effects through the dermal, chronic food, and oral non-dietary routes, short- and intermediate-term aggregate risk assessment should only include dermal, chronic food and water, and oral non-dietary exposure routes. However, a worst case scenario which aggregated all exposure routes (includes inhalation, dermal, chronic food and water, and oral non-dietary) has previously been calculated (see the Final Rule on Cyfluthrin Residue Tolerances (62 FR 62961), November 26, 1997 (FRL–5755–2), and the Margin of Exposure (MOE) is above 2,000 for all population subgroups. The current action does not change this previous assessment. EPA generally has no concern for MOEs greater than 300.

4. *Aggregate cancer risk for U.S. population*. The Agency has concluded that there is no evidence of carcinogenicity in studies of either the rat or mouse. Therefore a carcinogenicity risk assessment is not required.

5. *Determination of safety*. Based on the above risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and postnatal toxicity and the completeness of the database 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The Agency has determined that an additional UF is needed for risk assessments for cyfluthrin. This is due to evidence of increased sensitivity of pups in the 3–generation reproduction study. It was observed that there were decreased pup weight gains at a dose in which there were no effects in the parents. The additional UF is determined to be 3x due to the lack of severity of effects (reduced body weight gain in pups) and the availability of acceptable reproduction (rat) and developmental (rats and rabbits) toxicity studies.

ii. *Conclusion*. There is a complete toxicity database for cyfluthrin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Taking into account the completeness of the data base, EPA concludes the use of the additional safety factor would be safe for infants and children.

2. *Acute risk*. For nonnursing infants >1 year old, the aggregate acute exposure is 0.0068 mg/kg bw/day and a MOE ≤ 2000. For cyfluthrin, EPA has no concern for MOEs over 300.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to cyfluthrin from food will utilize 9.7% of the aPAD for the most highly exposed population subgroup (non-nursing infants less than 1–year). It is determined that an acceptable chronic dietary exposure (food plus water) of 100% or less of the cPAD is neede to protect the safety of all populations subgroups. The Agency generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short or intermediate term risk*. For children and non-nursing infants < 1 year, EPA estimates the aggregate short and intermediate term exposures are 0.007662 and 0.008255 mg/kg bw/day respectively with resulting MOE's of 2600 and 2400 respectively. For cyfluthrin, EPA has no concern for MOE's over 300.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of cyfluthrin in plants and animals is aequately understood. Studies have been conducted to delineate the metabolism of radio labeled cyfluthrin in various crops and animals all showing similar results. The residue of concern is cyfluthrin.

B. Analytical Enforcement Methodology

Adequate analytical methodology (gas/liquid chromatography with an electron capture detector) is available for enforcement purposes.

C. Magnitude of Residues

Field trial residue and feeding study data have been submitted and reviewed in support of the tolerance on potatoes.

D. International Residue Limits

There are no Codex, Canadian, or Mexican Limits established for cyfluthrin on potatoes. There are not Canadian or Mexican Limits established for corn. There is a Codex Maximum Residuce Limit for maize (0.05 mg/kg). The U.S. tolerances are 0.05 ppm for sweet corn and 0.01 ppm for field corn and pop corn. These differences could be caused by differences in methods to establish tolerances, calculation of animal dietary exposure, and as a result of different agricultural practices. The Agency will specifically address these differences when this pesticide is reregistered.

E. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further information.

IV. Conclusion

Therefore, the tolerance is established for residues of cyfluthrin in potatoes at 0.01 ppm and the tolerances for corn and corn byproducts are made permanent..

V. Objections and Hearing Requests

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

Any person may, by August 30, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300887] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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). 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 as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and*

Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 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 the rule in the **Federal Register**. This 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: June 24, 1999.

James Jones,

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), (346a), and 371.

2. Section 180.436, is amended to read as follows:

i. By alphabetically adding ''Potatoes'' to the table under paragraph (a)(1).

ii. By transferring the entries in the table in paragraph (a)(2) to the table in paragraph (a)(1) and removing the expiration dates; and removing the remainder of paragraph (a)(2).

iii. By redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(2) and (a)(3).

The additions and amendments to § 180.436 read as follows:

180.436 Cyfluthrin; tolerances for residues

(a)(1) * * *

Commodity	Parts per million
* * * * *	*
Corn, forage and fodder field and pop.	0.01
Corn, grain, field and pop	0.01
Corn, sweet, (K+CWHR)	0.05
Corn, sweet, fodder	15.00
Corn, sweet, forage	30.00
* * * * *	*
Potatoes	0.01
* * * * *	*

* * * * *

[FR Doc. 99–16637 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300874; FRL–6084–3]

RIN 2070–AB78

Paraquat; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of