VIII. Submission to Congress and the General Accounting Office

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 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 the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

Dated: August 31, 1998.

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. Section 180.489 is revised to read as follows:

§180.489 Sulfosate (Sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1)); tolerances for residues.

(a) *General* . Tolerances are established for residues of the herbicide sulfosate (sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1)) in or on the following raw and processed agricultural commodities:

Commodity	Parts per million
Almond, hulls (of which no more than 0.30 ppm is trimethylsulfonium (TMS)).	1.00
Aspirated grain fractions (of which no more than 60 ppm is TMS).	210.00
Bananas (imported only)a.	0.05
Cattle, fat	0.10
Cattle, mbyp	1.00
Cattle, meat	0.20
Citrus fruit group	0.05
Corn, field, forage	0.10
Corn, field and pop, grain (of which no more than 0.10 ppm is TMS).	0.20
Corn, field and pop, stover (of which no more than 0.20 ppm is TMS).	0.30
Eggs	0.02
Goats, fat	0.10
Goats, mbyp	1.00
Goats, meat	0.20
Grape	0.10
Hogs, fat	0.10
Hogs, mbyp	1.00
Hogs, meat	0.20
Horses, fat	0.10
Horses, mbyp	1.00
Horses, meat	0.20
Milk	0.20
Poultry, fat	0.05
Poultry, liver	0.05
Poultry, mbyp (except liver).	0.10
Poultry, meat	0.05
Prune (of which no more than 0.05 ppm is TMS).	0.20
Raisin (of which no more than 0.05 ppm is TMS).	0.20
Sheep, fat	0.10
Sheep, mbyp	1.0
Sheep, meat	0.20
Soybean, forage (of which no more than 1 ppm is TMS).	2.0
Soybean, hay (of which no more than 2 ppm is TMS).	5.0
Soybean, hulls (of which no more than 2 ppm is TMS).	7.0
Soybean, seed (of which no more than 1 ppm is TMS).	3.0
Stone fruit group	0.05
Tree nut group	0.05

aThere are no U.S. registrations as of the date of publication of the tolerance in the FEDERAL REGISTER.

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

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

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

PART 185 — [AMENDED]

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

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

§185.5375 [Removed]

2. By removing § 185.5375 Sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1).

[FR Doc. 98–24468 Filed 9–10–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300708; FRL 6026–5]

RIN 2070–AB78

Esfenvalerate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of esfenvalerate, ((*S*)-cyano-(3-phenoxyphenyl)methyl (*S*)-4-chloro-alpha-(1-methylethyl) benzeneacetate in or on the raw agricultural commodities mustard greens at 5.0 parts per million (ppm), kiwifruit at 0.5 ppm, globe artichoke at 1.0 ppm, and kohlrabi at 2.0 ppm. Esfenvalerate is the *S,S*-isomer of fenvalerate which consists of a racemic mixture of four isomers (*S,S;R,S;S,R*; and *RR*). Technical grade esfenvalerate, Asana, the only fenvalerate formulation sold in the United States for agricultural use at this time, is enriched in the insecticidally active *S,S*-isomer (84%). Tolerance expressions for esfenvalerate are based on the sum of all isomers. The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300708, 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–300708, 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300708]. 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: Sidney Jackson, 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: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–7610; e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 1998 (63 FR 18411), (FRL 5781–9) EPA, issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of a pesticide petition for tolerances by DuPont Agricultural Products, Wilmington, Delaware. This notice included a summary of the petition prepared by DuPont Agricultural Products, Wilmington, Delaware, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.533 be amended by establishing tolerances for residues of the insecticide esfenvalerate, ((*S*)-cyano-(3-phenoxyphenyl)methyl (*S*)-4-chloro-alpha-(1-methylethyl) benzeneacetate, in or on the raw agricultural commodities mustard greens at 5.0 parts per million (ppm), kiwifruit at 0.5 ppm, globe artichoke at 1.0 ppm, and kohlrabi at 2.0 ppm.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

A. Toxicity

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

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

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

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk

assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

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

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

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of esfenvalerate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of esfenvalerate (*S,S; R,S; S,R;* and *R,R* isomers) in or on the raw agricultural commodities mustard greens at 5 ppm, kiwifruit at 0.5 ppm, globe artichoke at 1.0 ppm, and kohlrabi at 2.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

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

1. *Acute toxicity*. A battery of acute toxicity studies places technical esfenvalerate in Toxicity category II for acute oral lethal dose LD_{50} at 87.2 milligrams/kilogram (mg/kg), Category III for acute dermal $LD_{50} > 2000$ mg/kg and primary eye irritation, and Category IV for primary skin irritation. Esfenvalerate is a non-sensitizer. Acute inhalation on technical grade active ingredient is waived due to negligible vapor pressure. The Acute Delayed Neurotoxicity (Guideline 81–8) remains a data gap.

2. *Genotoxicity*—i. In a reverse gene mutation assay in bacteria, *S. typhimurium* and *Escherichia coli* were exposed to fenvalerate in DMSO at concentrations of 15, 50, 150, 500, 1,500, or 5,000 micrograms (µg)/plate in the presence and absence of mammalian metabolic activation (S9-mix). There was no evidence of induced mutant colonies over background.

ii. In a mammalian cell gene mutation assay at the HGPRT locus, Chinese hamster V79 cells cultured *in vitro* were exposed to fenvalerate in DMSO at concentrations of 12.6, 42, 126, 420 µg/ml in the presence of mammalian metabolic activation (S9-mix) and at concentrations of 4.2, 12.6, 42, 126 µg/milliliter (ml) in the absence of S9-mix.

There was no evidence of induced mutant colonies over background. In Chinese hamster lung fibroblasts (V79 cells) forward gene mutation assay the test was negative up to cytotoxic and/or precipitating levels 126 µg/ml in the absence of metabolic activation -S9; 420 µg/ml in the presence of metabolic activation +S9).

iii. In a mammalian cell cytogenetics chromosomal aberration assay CHO-K1 cell cultures were exposed to fenvalerate in DMSO at concentrations of 4.2 µg/ml, 8.4 µg/ml, 21 µg/ml, 42 µg/ml respectively without exogenous metabolic activation (S9-mix) and at concentrations of 21 µg/ml, 42 µg/ml, 84 µg/ml, 210 µg/ml respectively with S9-mix. There was no evidence of a significant induction of chromosomal aberrations or polyploid cells over background.

iv. A mouse micronucleus assay was negative in male ICR mice up to the highest dose tested (HDT) (150 mg/kg) administered by intraperitoneal injection. Since there appears to be no sex specific difference in the toxicity of esfenvalerate, the use of males only is justifiable. No overt toxicity was observed, but suggestive evidence of bone marrow cytotoxicity was seen 48 hours post-administration at the highest dose level tested.

v. Other genetic toxicology studies submitted on racemic fenvalerate indicate that the mixture containing equal parts of the four stereoisomers is not mutagenic in bacteria. The racemic mixture was also negative in a mouse host mediated assay and in a mouse dominant lethal assay.

3. *Reproductive and developmental toxicity*—i. Esfenvalerate was administered to female rats at doses of 0,2.5, 5.0, 10.0 or 20.0 mg/kg/day from gestation days 6 through 15 (pilot study doses were 1.0, 2.0, 3.0, 4.0, 5.0 and 20 mg/kg/day). The Lowest Observed Effect Level (LOEL) is 2.5 mg/kg/day based on behavioral/Central Nervous System (CNS) clinical signs. The NOEL for maternal toxicity is 2.0 mg/kg/day (from the pilot study). There was no evidence of developmental toxicity at any dose. The NOEL is 20 mg/kg/day, the highest dose tested.

ii. Esfenvalerate was administered to rabbits at doses of 0, 3.0, 10.0 or 20.0 mg/kg/day from gestation days 7 through 19 (pilot study doses were 0, 2.0, 3.0, 4.0, 4.5, 5.0 or 20.0 mg/kg/day). The LOEL is 3.0 mg/kg/day based on behavioral/CNS clinical signs. The NOEL is 2.0 mg/kg/day (from the pilot study). There was no evidence of developmental toxicity at any dose. The LOEL is greater than 20.0 mg/kg/day. The NOEL is equal to or greater than 20.0 mg/kg/day, the HDT.

iii. In a 2-generation reproduction toxicity study in rats esfenvalerate was administered to rats at dose levels of 0, 3.75, 5.0,17.5 and 35.0/17.5 mg/kg/day. The LOEL for parental toxicity is 3.75 mg/kg/day based on decreases in mean body weights of F_1 females and an increased incidence of skin lesions. The NOEL could not be determined. The LOEL for reproductive toxicity is 5.0 mg/kg/day based on decreases in F_1 pup weights on day 21 of lactation; decreases in litter size and F_2 pup weights and an increased incidence of subcutaneous hemorrhage. The NOEL is 3.75 mg/kg/day.

4. *Subchronic toxicity*. i. In a 90–day feeding study, rats were administered 0, 4.7, 6.2, 7.8 or 18.7 mg/kg/day of esfenvalerate. The LOEL is 18.7 mg/kg/day based on neurological dysfunction. The NOEL is 7.8 mg/kg/day.

ii. In another 90–day feeding study, rats were administered 0, 5, 15, 30 or 50 mg/kg/day of esfenvalerate. The LOEL is 15 mg/kg/day based on neurological dysfunction. The NOEL is 5 mg/kg/day.

iii. Esfenvalerate was administered to mice at dose levels of 0, 10.5, 30.5 or 106 mg/kg/day (male) and 0, 12.6, 36.8 or 113 mg/kg/day (female). The LOEL for esfenvalerate is 106 mg/kg/day. The NOEL is 30.5 mg/kg/day.

5. *Chronic toxicity*—i. In a 21–day probe for a 1 year feeding study 2 male and 2 female beagles were administered 0, 2.80, 6.40 or 9.38 mg/kg/day in males and 0, 2.25, 7.37 or 8.50 mg/kg/day of esfenvalerate. The LOEL was determined to be 6.40 mg/kg/day based on nervous system involvement and decreases in body weight and food consumption. The NOEL is 2.25 mg/kg/day.

ii. In a 1–year feeding study, 6 male and 6 female beagles/group were administered 0, 0.68, 1.36 or 5.29 mg/kg/day esfenvalerate. The LOEL was determined to be 6.40 mg/kg/day based on nervous system involvement and decreases in body weight and food consumption. The NOEL was determined to be 5.29 mg/kg/day. These studies are acceptable and satisfies the requirement for a guideline series 83–1b chronic feeding study in dogs.

6. *Chronic/carcinogenicity toxicity*—i. In a chronic/carcinogenicity feeding study, rats were administered 0.050, 0.25, 1.25 or 12.5 mg/kg/day of fenvalerate in the diet for 2 years. The LOEL was greater than or equal to 12.5 mg/kg/day. There was no increase in tumors at 12.5 mg/kg/day. The NOEL was determined to be 12.5 mg/kg/day the highest dose tested (HDT) in the 2 year study. The study is supplementary and does not satisfy the requirement for a guideline series 83–5 combined chronic/carcinogenicity study in rats.

ii. In a lifetime feeding study, rats were administered 0 or 50.0 mg/kg/day of fenvalerate in the diet. Spindle cell sarcomas were produced in male rats only. The LOEL was 50.0 mg/kg/day based on loss of weight and neurological effects. The NOEL was 12.5 mg/kg/day as determined in the 2–year rat chronic/carcinogenicity feeding study above.

The conclusion that fenvalerate is associated with the production of spindle cell sarcomas was later retracted by EPA. The study is supplementary and does not satisfy the requirement for a guideline series 83–5 combined chronic/ carcinogenicity study in rats. When taken together with chronic/carcinogenicity feeding study, the guideline requirement for a 83–2a, cancer study in the rat is satisfied.

iii. In a 2–year feeding study mice were administered 0, 1.5, 7.5, 38.0 or 187.5 mg/kg/day fenvalerate in the diet. The LOEL was 7.5 mg/kg/day based on granulomatous changes (related to fenvalerate only, not esfenvalerate). The NOEL was 1.5 mg/kg/day. This study satisfies the requirement for combined chronic feeding carcinogenicity study in mice.

iv. In an 18-month feeding study, mice were fed 0, 15.0, 45.0, 150.0 or 450.0 mg/kg/day of fenvalerate in the diet. The LOEL is 45.0 mg/kg/day based on granulomatous changes in the liver and spleen. The NOEL is 15.0 mg/kg/day. No carcinogenicity was observed.

v. In a life span feeding study, mice were administered 0, 1.5, 4.5, 15.0 or 45.0 mg/kg/day of fenvalerate in the diet. The LOEL was determined to be 15 mg/kg/day based on the granulomatous lesions observed and on the change in hematological parameters. Fenvalerate was determined not to be carcinogenic in the specific test strain of the mouse. The NOEL was determined to be 3.48 mg/kg/day.

The following studies are considered data gaps in the toxicology data base: general metabolism, 21 day dermal, dermal penetration, and acute and subchronic 90–day neurotoxicity. Developmental neurotoxicity data requirements are reserved as an upper tier study which would only be required if effects in the acute and subchronic studies indicate concerns for increased sensitivity of the infant or neonate. Although these data are lacking EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change its risk assessment. These studies will be required under a special Data Call-In

letter pursuant to section 3 (c)(2)(B) of FIFRA.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA has established an NOEL of 2.0 mg/kg/day through the dietary route in rat and rabbit developmental studies. This NOEL is based on behavioral and central nervous system clinical signs. A MOE of 100 is required.

2. *Short - and intermediate - term toxicity*. To assess risk from (nonfood) short and intermediate term dermal exposure, EPA has established a NOEL of 2.0 mg/kg/day from the rat and rabbit developmental studies. No dermal penetration/absorption study is available and the NOEL incorporates a 25% dermal absorption based on the weight-of-evidence available for structurally related pyrethroids.

This NOEL is based on behavioral and central nervous system clinical signs. For exposure via inhalation the Agency used an oral NOEL of 2.0 mg/kg/day and assumed 100% absorption (based on the 2 mg/kg/day used for the dermal risk assessment since no appropriate inhalation toxicity studies are available).

3. *Chronic toxicity*. EPA has established the RfD for esfenvalerate ester at 0.02 mg/kg/day. This RfD is based on a NOEL of 2.0 mg/kg/day through the dietary exposure route in developmental study in rat. The NOEL is based on behavioral changes and clinical signs of neurotoxicity. This RFD is based on an uncertainty factor of 100.

4. *Carcinogenicity*. Esfenvalerate is classified as a Group E. There is no evidence of carcinogenicity in either rats or mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.533) for the residues of fenvalerate in or on a variety of raw agricultural commodities. EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. Field trial data and FDA monitoring data were used to generate anticipated residues or residue distribution for Monte Carlo analyses. Chronic dietary risk assessments used anticipated residues and percent crop treated refinements.

Risk assessments were conducted by EPA to assess dietary exposures and risks from esfenvalerate as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The NOEL used for the acute dietary exposure was 2.0 mg/kg/day. Potential acute exposures from food commodities were estimated using a Tier 3 acute dietary risk assessment (Monte Carlo Analysis). The MOEs (99.9th percentile) for the U.S. population based on an acute dietary exposure of 0.011717 mg/kg/day are 171. For children 1–6 years old (most highly exposed population) the MOEs based on an acute dietary exposure of 0.019445 mg/kg/day are 103. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger.

ii. *Chronic exposure and risk*. Potential chronic exposures were estimated using NOVIGEN's DEEM (Dietary Exposure Evaluation Model). The RfD used for the chronic dietary analysis is 0.02 mg/kg/day. Using tolerance values and anticipated residues discussed above the risk assessment resulted in use of 1.9% of the RfD for the general U.S. population and 4.6% of the RfD for children 1–6 years.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues;(2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for esfenvalerate were derived from federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by these data and the upper end of this range was used for the exposure assessment. By using this upper end of estimate of percent crop treated, the agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of these regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

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

i. *Acute exposure and risk*. Acute drinking water exposure is estimated for the U.S. population to be 0.000039 mg/kg/day with an MOE of 51,743. For non-nursing infants less than 1 year old the exposure is 0.000074 with a MOE of 27,042.

ii. *Chronic exposure and risk*. Chronic drinking water exposure is estimated for the U.S. population to be 0.000001 mg/kg/day and for the non-nursing infants 0.000005 mg/kg/day. Less than 0.1% of the RfD is occupied by both population groups.

3. *From non-dietary exposure*. Esfenvalerate is currently registered for use on the following residential non-food sites: spray treatments in and around commercial and residential areas, treatments for control of ectoparasites on pets, home care products including foggers, pressurized sprays, crack and crevice treatments, lawn and garden sprays, and pet and pet

bedding sprays. For the non-agricultural products, the very low amounts of active ingredient they contain, combined with the low vapor pressure (1.5×10^{-9} mm Mercury at 25 °C) and low dermal penetration, would result in minimal inhalation and dermal exposure. Individual non-dietary risk exposure analyses were conducted using a flea infestation scenario that included pet spray, carpet and room treatment, and lawn care, respectively.

4. *Short- and intermediate-term exposure and risk.* Short- and intermediate-term exposure and risk. The total aggregate non-dietary exposure including lawn, carpet, and pet uses (mg/kg/day) are: 0.000023 for adults; 0.00129 for children aged 1–6 years; and 0.00138 for infants less than 1 year old. It should be noted that carpet uses are considered short and intermediate term exposures because available data indicate that esfenvalerate dissipates over time and is thus unavailable to contribute as chronic exposure and risk.

For the adults, children aged 1–6 years, and infants less than 1 year old subgroups discussed above, the MOE is > 87,000, 1,500, and 1,400, respectively. Based on potential non-dietary exposure for esfenvalerate from existing product uses as discussed above, it can be concluded that non-dietary risk is well below levels of concern to the Agency.

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether esfenvalerate 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, esfenvalerate 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 esfenvalerate has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and drinking water. The potential acute exposure from food and drinking water to the overall U.S. population provides an acute dietary exposure of 0.011756 mg/kg/day with an MOE of 170. This acute dietary exposure estimate is considered conservative, using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to esfenvalerate will utilize 1.9% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 – 6 years. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. The potential short- and intermediate-term aggregate risk for the U.S. population is an exposure of 0.0082 mg/kg/day with an MOE of 244.

4. *Conclusion.* EPA concludes that there is reasonable certainty that no harm will result from acute, chronic or short- and intermediate-term aggregate exposure to esfenvalerate residues.

5. *Aggregate cancer risk for U.S. population.* Esfenvalerate is classified as a Group E carcinogen - no evidence of carcinogenicity in rats or mice. Therefore, a carcinogenicity risk analysis is not required. Based on available adequate data, EPA believes that approved use of this pesticide does not pose a significant cancer risk.

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 esfenvalerate, 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 post-natal 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 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.

ii. *Developmental toxicity studies.* In both prenatal developmental toxicity studies in rats and rabbits, there is no evidence of developmental toxicity at a dose up to 20 mg/kg/day. Maternal clinical neurotoxicity (based on behavioral and central nervous system clinical signs) was observed at a dose as low as 2.5 or 3.0 mg/kg/day for rats and rabbits, respectively. The maternal NOEL was 2.0 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproduction study in rats, offspring toxicity was observed only at dietary levels which were also found to be toxic to parental animals. The LOEL was 5.1 mg/kg/day based on decrease in mean body weights of females and increased incidence of dermal lesions. The NOEL for parental systemic toxicity was not determined. Effects on the offspring, including decreased pup weights in both generations during early and/or late lactation, decreased litter size, and increased incidence of subcutaneous hemorrhage, were observed at dietary levels of 6.70 mg/kg/day and above, with a NOEL of 5.1 mg/kg/day.

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

v. *Conclusion.* From available adequate data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. No developmental neurotoxicity studies are being required at this time. A developmental neurotoxicity data requirement is an upper tier study and required only if effects observed in the acute and 90–day neurotoxicity studies indicate concerns for frank neuropathy or alterations seen in the fetal nervous system in the developmental and reproductive toxicology studies. The FQPA conditional requirement of an additional tenfold margin of safety for pesticide residues be applied for infants and children to take into account potential pre-and post-natal toxicity was not imposed in this case. The Agency believes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional ten-fold (10x) uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The potential acute exposure from food and drinking water to the most sensitive population subgroup, children 1–6 years old is 0.019477 mg/kg/day with an MOE of 103. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to esfenvalerate from food and drinking water will utilize 4.6% of the RfD for children 1–6 years old, the most sensitive population subgroup based on a dietary exposure of 0.000912 mg/kg/day. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to esfenvalerate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* EPA has concluded that potential short- or intermediate -term aggregate exposure of esfenvalerate from chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure to children (1–6 years old) is 0.0113 mg/kg/day with an MOE of 177. For infants (less than 1 year old) the exposure is 0.0098 mg/kg/day with an MOE of 204. The Agency is not generally concerned for exposures where the MOE value is greater than 100.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to esfenvalerate residues.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately defined. EPA has concluded that the qualitative nature of the residue is the same for both fenvalerate and esfenvalerate. The residue to be regulated is fenvalerate: the *S,S; R,S; S,R;* and *R,R* isomers.

B. Analytical Enforcement Methodology

There is a practical analytical method utilizing electron-capture gas chromatography with nitrogen phosphorous detection available for enforcement with a limit of detection that allows monitoring food with residues at or above tolerance levels. The limit of detection for the updated method is the same as that of the current PAM II method, which is 0.01 ppm .

C. Magnitude of Residues

Tolerances are based on the sum of all isomers of fenvalerate. Fenvalerate is a racemic mixture of four isomers about 25% each. This product was registered as Pydrin®. However since 1992, an *S,S*-isomer enriched formulation, Asana® (esfenvalerate), has been the only fenvalerate formulation sold in the United States for agricultural use. Since the *S,S*-isomer is the insecticidally active isomer, the use rate for Asana® is four times lower than that for Pydrin®. A petition is pending (PP 4F4329), to convert tolerances (still to be expressed as the sum of all isomers) based on the use rates for Asana®. Bridging residue studies have shown Asana® residues to be 3–4 times lower than Pydrin residues. Available residue data support the tolerance levels being established by this Notice.

D. International Residue Limits

There are no Codex maximum residue levels (MRL's) for esfenvalerate on crops that are the subject of this notice. MRLs have been established for the related compound, fenvalerate, on a number of crops that also have U. S. tolerances. Use rate and isomer pesticidal activity are among factors that effect residue levels. The Agency will fully evaluate MRL values for all permanent tolerances when pesticides are reregistered.

IV. Conclusion

Therefore, the tolerances are established for residues of esfenvalerate, ((*S*)-cyano-(3-phenoxyphenyl)methyl (*S*)-4-chloro-alpha-(1-methylethyl) benzeneacetate and the *S,S; R,S; S,R;* and *R,R* isomers in or on the raw agricultural commodities mustard greens at 5.0 parts per million (ppm), kiwifruit at 0.5 ppm, globe artichoke at 1.0 ppm, and kohlrabi at 2.0 ppm.

V. Objections and Hearing Requests

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

Any person may, by November 10, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number OPP–300708 (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (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 the Office of Management and Budget (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 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.

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the 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 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: August 31, 1998.

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 § 180.533, by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.533 Esfenvalerate; tolerances for residues

(a)* * *

Commodity	Parts per million
Artichoke, globe	1.0
* * * *	*
Kiwifruit	0.5
Kohlrabi	2.0
* * * *	*
Mustard greens	5.0
* * * *	*

* * * * *

[FR Doc. 98–24770 Filed 9–10–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 73 and 74

[MM Docket No. 97–234, GC Docket No. 92–52, and GEN Docket No. 90–264; FCC 98–194]

Implementation of Competitive Bidding for Commercial Broadcast and Instructional Television Fixed Service Licenses

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This *First Report and Order* (*First R&O*) implements the Federal Communications Commission's amended auction authority. Specifically, the *First R&O* adopts rules and procedures for auctioning pending and future mutually exclusive applications for construction permits in the various commercial broadcast services; determines that competing Instructional Television Fixed Service (ITFS) applications are subject to auction; and adopts procedures for resolving pending broadcast comparative renewal cases, in which the Commission is not authorized to use auctions. To further the goals of the designated entity provisions of the Commission's auction authority, the *First R&O* adopts a tiered ''new entrant'' bidding credit for entities with controlling interests in either no, or less than four, other media entities. The *First R&O* notes that the Commission intends to continue its review of the barriers to entry or growth that may exist for small, minority- and women-owned businesses in broadcasting, and to make adjustments to its designated entity provisions, as appropriate, in light of these studies.

EFFECTIVE DATE: November 10, 1998.

FOR FURTHER INFORMATION CONTACT: Jerianne Timmerman, Video Services Division, Mass Media Bureau at (202) 418–1600; Lisa Scanlan, Audio Services Division, Mass Media Bureau at (202) 418–2720; Lee Martin, Office of General Counsel at (202) 418–1720.

SUPPLEMENTARY INFORMATION:

Summary

This *First R&O* implements: (1) amended Section 309(j) of the Communications Act (Act), which requires that the Commission use auctions to select from among virtually all mutually exclusive applications for initial licenses and construction permits, including broadcast construction permits, and (2) new Section 309(l) of the Act, which