40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Feed additives, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. Section 180.438 is amended by revising paragraph (a) to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3- phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, on plants and livestocks, as indicated in the following table.

Commodity	Parts per million
Broccoli	0.4
Cabbage	0.4
Cattle, fat	3.0
Cattle, meat	0.2
Cattle, mbyp	0.2
Corn, grain (field and pop)	0.05
Corn, fodder	1.0
Corn, forage	6.0
Corn, grain flour	0.15
Corn, sweet (K+kwhr)	0.05
Cottonseed	0.05
Dry bulb onion	0.1
Eggs	0.01
Garlic	0.1
Goats, fat	3.0
Goats, meat	0.2
Goats, mbyp	0.2
Hogs, fat	3.0
Hogs, meat	0.2
Hogs, mbyp	0.2
Horses, fat	3.0
Horses, meat	0.2
Horses, mbyp	0.2
Lettuce, head	2.0
Milk, fat (reflecting 0.2 ppm in whole milk).	5.0
Peanuts	0.05
Peanuts, hulls	0.05
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, mbyp	0.01
Rice, grain	1.0
Rice, hulls	5.0
Rice, straw	1.8
Sheep, fat	3.0
Sheep, meat	0.2
Sheep, mbyp	0.2
Soybeans	0.01
Sorghum, grain	0.2
Sorghum, grain dust	1.5
Sunflower, forage	0.2
Sunflower, hulls	0.50
Sunflower, oil	0.30
Sunflowers, seeds	0.2
Tomatoes	0.1
Tomato pomace (dry or wet)	6.0
Wheat, grain	0.05
Wheat, forage	2.0
Wheat, hay	2.0
Wheat, straw	2.0
Wheat, grain dust	2.0
Wheat, bran	0.2

(2) A food additive tolerance of 0.01 part per million is established for residues of the insecticide [1α(*S**),3α(*Z*)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate (lambdacyhalothrin) as follows:

(i) In or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed, or prepared.

(ii) Application shall be limited solely to spot and/or crack and crevice treatment with a spray solution maximum of a 0.06-percent active ingredient by weight. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food. Food-contact surfaces and equipment should be thoroughly cleaned with an effective cleaning compound and rinsed with potable water before using.

(iii) For spot treatment, a coarse low-pressure spray shall be used. Limit individual spot treatments to an area no larger than 20 percent of the surface area. Any individual spot treatment shall not exceed 2 square feet.

(iv) For crack and crevice treatment, equipment capable of delivering a pin-stream of spray directly into the cracks and crevices shall be used.

(v) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(3) A food additive tolerance is established for residues of the insecticide [1α (*S**),3α(*Z*)]-(±)-cyano-(3-phenoxylphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate as follows:

Commodity	Parts per million
Hops, dried	10.0

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PART 185—[AMENDED]

2. In part 185:

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

Authority: 21 U.S.C. 348.

§ 185.3765 [Removed]

b. Section 185.3765 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

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

§ 186.3765 [Removed]

b. Section 186.3765 is removed.

[FR Doc. 97–30959 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300582; FRL–5755–2]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on the raw agricultural commodities in or on the following raw agricultural commodities: alfalfa; alfalfa, hay; aspirated grain fractions; carrots; cattle, fat; cattle, meat; cattle, meat by-products (mbyp); citrus, crop group; citrus dried pulp; citrus oil; cottonseed; cottonseed,

hulls; cottonseed, oil; eggs; goats, fat; goats, meat; goats, mbyp; hogs, fat; hogs, meat; hogs, mbyp; horses, fat; horses, meat; horses, mbyp; milkfat; peppers; poultry, fat; poultry, meat; poultry, mbyp; radishes; sheep, fat; sheep, meat; sheep, mbyp; sorghum, fodder; sorghum, forage; sorghum, grain; sugarcane; sugarcane, molasses; sunflower, forage; sunflower, seed; tomato; tomato, concentrated products; and tomato, pomace (wet and dry). It also removes time limitations for tolerances for residues of cyfluthrin on the same commodities. Bayer Ag Corporation requested these tolerances 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 November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300582], 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–300582], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, 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 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–300582]. 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: George T. LaRocca, Product Manager 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 1988 (53 FR 1924), EPA established time-limited tolerances under Section 408 and 409 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348 for residues of cyfluthrin. These tolerances expire on November 15, 1997. On September 15, 1997, Bayer requested that the time limitation for tolerances established for residue of the insecticide cyfluthrin in the above mentioned commodities be removed based on environmental effects data that they had submitted as a condition of the registration and time-limited tolerances. Bayer also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of Thursday, September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (4F3046, 9F3731, 3F4204, 4F4313, 2F4137, and 4F4313 and food/feed additive petitions 4H5427, 9H5574, 3H5670, 4H5686, and 4H5687) for tolerances by the Bayer Ag Corporation, 8400 Hawthorn Rd., Kansas City, MO 64120. This notice included a summary of the petitions prepared by the Bayer Ag Corporation. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.436 be amended by establishing permanent tolerances for residues of the insecticide cyfluthrin, in or on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sweet corn, sunflowers and tomatoes at the following levels part per million (ppm): alfalfa, 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus, dried pulp at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, oil, at 2.0 ppm; cottonseed, hulls, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 ppm.

In the Notice of Filing, the established tolerance levels for cattle, fat; goat, fat; hog, fat; and horse, fat were incorrectly listed as 1.0 ppm. The correct tolerance level for these commodities is 5.0 ppm as stipulated in PP No. 2F4137 in the **Federal Register** of July 31, 1996 (61 FR 39883)(FRL–5387–2). A tolerance level of 5.0 ppm was considered by EPA for risk assessment purposes.

The basis for time-limited tolerances that expire November 15, 1997 was given in the **Federal Register** of October 20, 1993 (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limed due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerances with expiration dates if none of the conditions of registration have any bearing on human dietary risk. This current action meets that condition and thus expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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 ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if

each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of cyfluthrin on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sunflowers and tomatoes at the following levels (ppm): alfalfa, forage, at 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus dried pulp, at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, hulls, at 2.0 ppm; cottonseed, oil, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 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 cyfluthrin are discussed below.

1. *Acute toxicity*. The required toxicity battery studies for acute oral (LD_{50} ≥16.2 mg/kg), dermal (LD_{50} >5,000 mg/kg), inhalation (LC_{50} ≥0.468 mg/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 CHO/HGPRT assay; one sister chromatid exchange assay in CHO cells; and one 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 milligrams/kilograms/day (mg/kg/day). A maternal LOEL was not observed. (i.e. the maternal NOEL is >10 mg/kg/day). A developmental LOEL was not observed. The developmental NOEL is >10 mg/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 LOEL is 60 mg/kg/day based on decreased body weight gain and food consumption during the dosing period. The maternal NOEL is 20 mg/kg/day. The developmental LOEL is 60 mg/kg/day based on increased numbers of resorptions and percent incidence of postimplantation loss. The developmental NOEL is 20 mg/kg/day. This study was classified core guideline.

iii. *Rat developmental studies via inhalation.* In the first two studies, pregnant female rats at day 0 gestation were exposed head-only to cyfluthrin concentrations of 0, 1.1, 4.7 or 23.7 mg/m^3/day (milligrams/per cubic meter/day) for 6 hours/day on gestation days 6 through 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 NOEL was 1.1 mg/m^3 and the maternal LOEL was 4.7 mg/m^3 (reduced motility, dyspnea, piloerection, ungroomed coats and eye irritation. The developmental NOEL was 0.59 mg/m^3 and the developmental LOEL was 1.1 mg/m^3 (increases in the incidence of runts and skeletal anomalies in the sternum (1.1 mg/m^3 and above); 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 in microphthalmia (23.7 mg/m^3). The study was graded core minimum.

In a third study, In 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 through 15 in a nose only inhalation chamber. The rats were exposed to the test material 6 hours per day, 7 days per week. The maternal NOEL/LOEL were < 0.46/<0.46 mg/m^3 based on decreased body weight gain and reduced relative food efficiency. The developmental NOEL/LOEL 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 LOEL for parental toxicity was 450 ppm (22.5 mg/kg/day) based on decreased body weight gains. The NOEL for parental toxicity is 150 ppm (7.5 mg/kg/day). The LOEL 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 NOEL 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 LOEL 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 NOEL 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 LOEL was 15 mg/kg/day in both sexes based on decreased blood glucose. The NOEL 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 NOEL 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 LOEL for this study was 15 mg/kg/day for both sexes, based on neurological effects (hindlimb abnormalities) and gastrointestinal disturbances. The NOEL 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 LOEL for dermal effects was 376 mg/kg/day for male and female Sprague-Dawley rats based on gross and histological skin lesions. The NOEL for dermal effects was for technical Baythroid was 113 mg/kg/day. The LOEL for systemic effects was 1,077 mg/kg/day based on decreased food consumption, red nasal discharge and urine staining. The NOEL 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 in at concentrations of 0, 2.3, 11.5, or 69.6 mg/ for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOEL 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 NOEL 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 LOEL was 10.5 mg/m^3, based on the treatment-related behavioral effects as well as effects on body and organ (spleen) weights. The NOEL 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 LOEL 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 NOEL 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 LOEL 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 NOEL 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 NOEL was 4 mg/kg bw/day. The LOEL was 16 mg/kg/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 NOEL is 4 mg/kg/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/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 LOEL 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 NOEL 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 LOEL 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 NOEL 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 (LOEL of 50/mg/kg/day; no NOEL observed); a second subacute oral neurotoxicity study (NOEL of 40 mg/kg/day); a subchronic neurotoxicity study in rats (NOEL <60 mg/kg/day), and a subacute inhalation study in mice NOEL for pups, 0.006 mg/L; parental NOEL 0.058 mg/L 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

1. *Acute toxicity*. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits.

2. *Short - and intermediate - term toxicity.* For the short and intermediate

term dermal exposures, the Agency used a NOEL of 20 mg/kg/day from the rabbit developmental study. The dermal absorption rate was 25%. This factor is based on the weight of evidence available for structurally related pyrethroids. For the short term inhalation exposures, the Agency used a NOEL of 0.00044 mg/L based on decreases in body and thymus weights, hypothermia, and clinical pathology at 0.00604 mg/L in a 28-day inhalation study. The recommended MOE is 300 which includes FQPA considerations. For the intermediate term inhalation exposure, the Agency used a NOEL of 0.00009 mg/L based on behavioral effects in rats at 0.00071 mg/L in a 90-day inhalation study. The additional certainty factor 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*. EPA has established the RfD for cyfluthrin at 0.008 mg/kg/day. This RfD is based on a chronic/carcinogenicity feeding study in the rat with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 300.

4. *Carcinogenicity*. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.436) for the parent 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 and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures and risks from cyfluthrin 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 day or single exposure. For the acute dietary exposure analysis for cyfluthrin treated raw agricultural commodities and processed food items, residue field trial data incorporating percent crop treated refinement and anticipated residues were used in Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document). The acute exposure via food was estimated as 0.004917 mg/kg/day for adults in the U.S., and 0.010687 mg/kg/day for nonnursing infants < 1 year old (most highly exposed subgroup. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits. The resulting margin of exposure (MOE) is 4,068 for the general U.S. population, and 1,871 for nonnursing infants < 1 year old. For cyfluthrin, EPA generally has no concern for MOEs over 300.

ii. *Chronic exposure and risk*. The chronic dietary exposure assessment incorporated tolerance values and percent crop treated information. The RfD used was 0.008 mg/kg/day. Exposure was estimated at 0.000076 mg/kg/day for the U.S. population, and 0.000151 mg/kg/day for nonnursing infants < 1 year old. The percent RfD occupied is 1.0 % for the U.S. population, and 1.9% for infants < 1 year old. EPA generally has no concern for RfD of less than 100%

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticides 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 five 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 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 cypermethrin were derived from federal and market basket survey data. EPA considers these data reliable. A range of estimates supplied by this data and upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer based model for evaluating exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a 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 FIFRA.

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 were generated with the PRZM I and EXAMS computer models in 1993 for comparative ecological risk assessment for these chemicals.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates for cyfluthrin for the general U.S. population as estimated by the Agency was 0.000054 mg/kg/day. The acute drinking water exposure and risk estimate for non-nursing infants <1 year old was 0.000104 mg/kg/day. Using these values and an endpoint of 20 mg/kg/day, the margin of exposure (MOE) for the U.S. population is estimated at 368,982. For non-nursing infants <1 year old, the MOE is estimated at 192,308. For cyfluthrin, the Agency general has concern for risk estimates only below 300.

ii. *Chronic exposure and risk.* For the U.S. population, exposure is estimated at 0.000001 mg/kg/day, resulting in negligible risk. For nonnursing infants < 1 year old, exposure is estimated as 0.000005 mg/kg/day, which occupies 0.1% of the RfD.

3. *From non-dietary exposure.* Cyfluthrin is currently registered for use on non-food sites including golf courses, ornamental shrubs, indoor foggers, wood surfaces, lawns, and carpet. Nonoccupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses.

Short- and intermediate-term exposure and risk. Exposure is estimated at 0.00524 mg/kg/day for the

U.S. population, and 0.00810 mg/kg/day for nonnursing infants < 1 year old.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Cyfluthrin is a member of the synthetic pyrethroid class of pesticides. 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 doe 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 evaluation 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.

Four members of the insecticide class Pyrethroids produce a common metabolite known as DCVA. These insecticides 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 thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound the toxicity of 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.

Accordingly, 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 produces 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.

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

The Agency has determined that an aggregate systemic (oral) and dermal exposure risk assessment is appropriate for cyfluthrin because of concern for the developmental effects seen after oral exposure. An aggregate oral and inhalation exposure risk assessment is also appropriate due to similarity in systemic toxicity observed in rats via these routes.

1. *Acute risk.* Aggregate acute dietary exposure is estimated at 0.004971 mg/kg/day resulting in a MOE of 4,023 for the U.S. population.

2. *Chronic risk.* EPA has concluded that aggregate exposure to cyfluthrin from food and water is estimated at 0.000076 mg/kg/day and will utilize 1% of the RfD for the U.S. population.

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. For the general U.S. population, exposure is estimated at 0.0053 mg/kg/day, resulting in an MOE of 3,800.

E. Aggregate Cancer Risk for U.S. Population

Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse. Therefore there is no concern for cancer in humans.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

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

1. *Safety factor for infants and children— In general.* In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, EPA considered data from a developmental toxicity study in the rat (see unit II.A.3. of this preamble). In addition, data from a 7-day inhalation study conducted with mouse dams and their offspring were considered (see also unit II.A.3.). There were no data gaps for the assessment of the effects of cyfluthrin following in utero or early postnatal exposure. Suggested sensitivity of rats to in utero exposure to cyfluthrin was hypothetically linked to bradypnea in the dams and was judged not be a valid consideration in the calculation of risk. However, evidence of increased sensitivity of young rats following pre- and/or postnatal exposure to cyfluthrin was observed in the two-generation reproduction study and in the 7-day inhalation study in mice.

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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes a 3-fold safety factor for children is appropriate for cyfluthrin based on lack of severity of the effect.

Based on the submitted studies, EPA concludes that reliable data support the use of a 300-fold uncertainty factor for infants and children.

2. *Acute exposure.* For nonnursing infants <1year old, the aggregate acute exposure is 0.010791 mg/kg/day, with a resulting MOE of 1,853. For cyfluthrin, EPA has no concern for MOEs over 300.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cyfluthrin from food and water will utilize 2% of the RfD for infants and children (nonnursing infants <1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a

lifetime will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate nondietary exposure to cyfluthrin to infants <1 year is 0.008255 mg/kg/day. The MOE is estimated at 2,400.

Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin 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.

G. Endocrine Disrupter Effects

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

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of cyfluthrin in plants and animals is adequately 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 tolerances on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sunflowers and tomatoes. Tolerances to support these uses were proposed in pesticide petitions 4F3046, 9F3731, 3F4204, 4F4313, 2F4137, and 4F4313 and food/feed additive petitions 4H5427, 9H5574, 3H5670, 4H5686, and 4H5687.

D. International Residue Limits

Codex maximum residue levels (MRLs) are establish for residues of cyfluthrin in milk, whole (0.01 ppm) ; cottonseed (0.05 ppm); peppers, sweet (0.2 ppm); and tomatoes (0.5 ppm). Mexico has established a tolerance on cottonseed at 1 ppm. There are no Canadian tolerances for cyfluthrin. As indicated in unit II. of this preamble there are differences between the section 408 tolerances and the Codex MRL values for specific commodities. 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. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerances are established for residues of cyfluthrin in/on alfalfa, 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus dried pulp, at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, oil, at 2.0 ppm; cottonseed, hulls, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 ppm. tomatoes at ppm.

In addition to the tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated distinctions between raw and processed food, EPA is combining the tolerances that appear in §§ 185.1250 and 186.1250 with § 186.436 and is removing tolerances under §§ 185.1250 and 186.1250.

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 January 26, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection

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

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300582] (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 1132 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 Hwy., 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

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).

In addition, since these 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 General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

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.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.436 is amended as follows:

i. By designating the text following the heading in paragraph (a) as paragraph (a)(1) and by revising the table in newly designated paragraph (a)(1).

ii. Paragraph (b) is redesignated as paragraph (a)(2).

iii. New paragraphs (b), (c), and (d) are added and reserved with headings.

The revised table to § 180.436 reads as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Alfalfa	5.0
Alfalfa, hay	10.0
Aspirated grain fractions	300
Carrots	0.20
Cattle, fat	5.0
Cattle, mbyp	0.40
Cattle, meat	0.40
Citrus, crop group	0.2
Citrus, dried pulp	0.3
Citrus, oil	0.3
Cottonseed	1.0
Cottonseed hulls	2.0
Cottonseed oil	2.0
Eggs	0.01
Goats, fat	5.0
Goats, mbyp	0.40
Goats, meat	0.40
Hogs, fat	5.0
Hogs, mbyp	0.40
Hogs, meat	0.40
Hops, dried	20.0
Hops, fresh	4.0
Horses, fat	5.0
Horses, mbyp	0.40
Horses, meat	0.40
Milkfat (reflecting 0.5 ppm in whole milk)	15.0

Commodity	Parts per million
Peppers	0.50
Poultry, fat	0.01
Poultry, mbyp	0.01
Poultry, meat	0.01
Radishes	1.0
Sheep, fat	5.0
Sheep, mbyp	0.40
Sheep, meat	0.40
Sorghum, fodder	5.0
Sorghum, forage	2.0
Sorghum, grain	4.0
Sugarcane	0.05
Sugarcane, molasses	0.20
Sunflower, forage	5.0
Sunflower, seed	0.02
Tomato	0.20
Tomato, concentrated products	0.5
Tomato, pomace	5.0

(2) * * *

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

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

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

PART 185—[AMENDED]

2. In part 185:

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

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

§ 185.1250 [Removed]

b. In § 185.1250:

i. Paragraph (c) introductory text, (c)(1), (c)(2), and (c)(3) are transferred to § 180.436 and redesignated as paragraph (a)(3) introductory text, (a)(3)(i), (a)(3)(ii), and (a)(3)(iii), respectively.

ii. The remainder of § 185.1250 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.1250 [Removed]

b. In § 186.1250:

i. Paragraph (c) introductory text, (c)(1), (c)(2), and (c)(3) are transferred to § 180.436 and redesignated as paragraph (a)(4) introductory text, (a)(4)(i), (a)(4)(ii), and (a)(4)(iii), respectively.

ii. The remainder of § 186.1250 is removed.

[FR Doc. 97–31101 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300575; FRL–5754–6]

RIN 2070–AB78

Fenvalerate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenvalerate, including the S,S-enriched isomer esfenvalerate in or on cottonseed at 0.2 parts per million (ppm). It also removes time limitations for tolerances for residues of fenvalerate on the same commodities that expire on November 15, 1997. DuPont Agricultural Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170). This tolerance was established under petition number PP 7F2013.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300575], 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 withthe Hearing Clerk identified by the docket control number, [OPP–300575], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. 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–300575]. 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: John Hebert, 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) 308–3068, e-mail: hebert.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On October 20, 1993 EPA established time limited tolerances under Section 408 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of esfenvalerate on cottonseed. These tolerances expire on November 15, 1997. DuPont Agricultural Products, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide fenvalerate, including the S,S-enriched isomer esfenvalerate in or on cottonseed at 0.2 parts per million (ppm) be removed based on ecological and environmental effects data that they had submitted as a condition of the registration. DuPont Agricultural Products also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337)(FRL 5748–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by DuPont Agricultural Products, P.O. Box 80038, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by DuPont Agricultural Products. There were no comments received in response to the notice of filing.

The basis for time limited tolerances that expire November 15, 1997 was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and