Subpart HH—New York

■ 2. Section 52.1683 is amended by removing and reserving paragraphs (h)(3) and (i)(4), removing paragraphs (i)(6)(v) and (i)(6)(vi) and adding paragraph (j) to read as follows:

§ 52.1683 Control strategy: Ozone.

* * * * *

(j)(1) The 1990 and 2007 conformity emission budgets for the New York portion of the New York-Northern New Jersey-Long Island nonattainment area contained in New York's January 29, 2003 SIP revision, amended by New York's June 29, 2003 submittal and January 18, 2005 comment letter.

(2) The revised commitment to perform a mid-course review and submit the results by December 31, 2004 included in the January 29, 2003 SIP revision is approved.

[FR Doc. 05–18094 Filed 9–12–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0205; FRL–7725–7]

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on almond hulls, cucurbit vegetable crop group 9, fruiting vegetable group 8; grass forage; grass hay; grape; grape, raisin; leafy Brassica greens, subgroup 5B; leafy vegetable group, except Brassica, group 4; pistachio; pome fruit group 11; stone fruit group 12; tuberous and corm vegetable subgroup 1C; peanut; peanut, hay; pea and bean, dried shelled, except soybean, subgroup 6C; tree nuts, Crop Group 14; turnip greens; wheat forage; wheat hay; and wheat straw. Bayer CropScience and the Interregional Research Project Number 4 (IR–4) requested the tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 13, 2005. Objections and requests for hearings must be received on or before November 14, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0205.All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Olga Odiott, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; e-mail address: *odiott.olga@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of January 28, 2004 (69 FR 4143) (FRL–7339–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 1F6290, 2F6445, and 2F6479) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709; and (PP 1E6318, 3E6776, and 3E6583) by the Interregional Research Project Number 4 (IR-4), Technology Centre and Rutgers State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–390. The petitions requested that 40 CFR 180.436 be amended by establishing tolerances for residues of the insecticide cyfluthrin, cyano (4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate, in or on almond hulls at 1.0 parts per million (ppm); pistachio at 0.01 ppm; and tree nuts, crop group 14 at 0.01 ppm (PP 1F6290); cucurbit vegetable crop group at 0.10 ppm; fruiting vegetable group at 0.5 ppm; leafy Brassica greens subgroup at 7.0 ppm; leafy vegetable group at 6.0 ppm; pome fruit group at 0.10 ppm; pome fruit wet pomace at 0.30 ppm; stone fruit group at 0.30 ppm; wheat forage, wheat hay and wheat straw at 5.0 ppm; and wheat shorts at 3.5 ppm (PP 2F6445); grape at 0.8 ppm; grape, raisin at 3.5 ppm; peanut at 0.01 ppm; and peanut, hay at 6.0 ppm (PP 2F6479); tuberous and corm vegetable subgroup at 0.01 ppm (PP 1E6318); turnip greens at 7 ppm (PP 3E6583); and grass forage at 6 ppm; grass hay at 8 ppm; and pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm (PP 3E6776). That notice included a summary of the petition prepared by Bayer Crop Science, the registrant. The registrant has submitted a request to voluntarily

cancel uses of cyfluthrin on stored grains effective December 31, 2004.

Based on EPA's review, the petitions were revised by the petitioners as follows: i. by increasing proposed tolerances for grapes to 1.0 ppm and the proposed tolerances for wheat hay and straw to 6.0 ppm; ii. by increasing the proposed pome fruit crop group tolerance to 0.5 ppm to harmonize with the Codex apple MRL and deleting the proposed tolerance on pome fruit wet pomace since expected residues are below the pome fruit tolerance of 0.5 ppm; iii. by decreasing proposed tolerances for almond hulls to 0.5 ppm; iv. by removing tolerances for peanut oil since residues will be lower than residues in peanuts; v. by removing tolerances in prume since maximum expected residues are below the proposed tolerance for the stone fruit crop group; and vi. by withdrawing the proposed tolerance for wheat shorts since it is already covered under wheat milled by products.

Although EPA requested a number of changes to the initial petitions, the nature of the changes (changes in tolerance levels) are not considered significant. Therefore, EPA is issuing this as a final action. EPA is also removing the existing tolerance for potato, since a tolerance is being established on the entire tuberous and corm vegetable subgroup; removing time-limited tolerances established for grape and grape, raisin at 1.0 and 1.5 ppm, respectively, in connection with Section 18 emergency exemptions since they are no longer needed; and establishing tolerances with regional registrations for grass forage and hay.

One comment was received in response to the notice of filing. The comment is described and discussed in Unit V. Comments.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances in the **Federal Register** November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for the cyfluthrin tolerances described in Unit II. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered 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 and its enriched isomer, beta-cyfluthrin] as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 27, 2002 (67 FR 60976) (FRL–7199–8).

Cyfluthrin is a type II pyrethroid (i.e., it has a cyano group at the carbon position of the alcohol moiety and it is more effective when the ambient temperature is raised). Beta-cyfluthrin is an enriched isomer of cyfluthrin. Bridging data on beta-cyfluthrin were submitted so that the toxicity of beta-cyfluthrin could be compared with that of cyfluthrin and the databases could be combined to form one complete database for both chemicals. The scientific quality of the data is relatively high, and the toxicity profiles of both cyfluthrin and beta-cyfluthrin can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects. A beta-cyfluthrin developmental neurotoxicity study has been submitted and a preliminary review indicates that effects are seen only at doses higher than those chosen for risk assessment purposes.

B. Toxicological Endpoints

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

Three other types of safety or uncertainty factors may be used: ''Traditional UFs'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional UF,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and

10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for cyfluthrin used for human risk assessment is shown in following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYFLUTHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 2.0 mg/kg/day UF = 100 Acute RfD = 0.02 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD = 0.02 mg/kg/day	Acute mammalian neurotoxicity (beta-cyfluthrin) LOAEL = 10 mg/kg/day based on clinical signs, changes in FOB parameters and decreases in motor activity.
Chronic dietary (all populations)	NOAEL = 2.4 mg/kg/day UF = 100 Chronic RfD = 0.024 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD = 0.024 mg/kg/day	53–week chronic toxicity feeding - dog (cyfluthrin) LOAEL = 10.64 mg/kg/day based on clinical signs, gait abnormalities, and abnormal postural reactions.
Incidental oral short term, and intermediate-term (1 to 30 days and 1 to 6 months)(residential)	NOAEL = 2.36/2.5 mg/kg/day	Special FQPA SF = 1 LOC for MOE = 100	90–day dog feeding study (beta-cyfluthrin) LOAEL = 13.9/15.4 mg/kg/day for males/females, respectively based on gait abnormalities, increased incidence of vomiting, and suggestive decreased body weight gain.
Short-term and intermediate-term dermal (1 to 30 days and 1 to 6 months) (residential)	oral study NOAEL = 2.36/2.5 mg/kg/day (dermal absortion rate = 5%	LOC for MOE = 100	90–day dog feeding study (beta- cyfluthrin) LOAEL = 13.9/15.4 mg/kg/day for males/females, respectively, based on gait abnormalities, increased incidence of vomiting, and suggestive decreased body weight gain.
Long-term dermal (several months to lifetime) (residential)	Oral study NOAEL = 2.4 mg/kg/day (dermal absorption rate = 5% when appropriate)	LOC for MOE = 100	53–week chronic toxicity feeding - dog (cyfluthrin) LOAEL = 10.64 mg/kg/day based on clinical signs, gait abnormalities, and abnormal postural reactions.
Short-term inhalation (1 to 30 days) (residential)	inhalation study NOAEL = 0.00026 mg/L (0.07 mg/kg/day) (inhalation absorption rate = 100%)	LOC for MOE= 100	28–day inhalation study - rat (beta-cyfluthrin) LOAEL = 0.0027 mg/L (0.73 mg/kg/day) based on decreases in body weight in both sexes and decreased urinary pH in males.
Intermediate and long-term inhalation (1 to 6 months and <6 months) (residential)	inhalation study NOAEL = 0.00009 mg/L (0.02 mg/kg/day) (inhalation absorption rate = 100%)	LOC for MOE = 100	13–week inhalation study - rat (cyfluthrin) LOAEL = 0.00071 mg/L (0.16 mg/kg/day) based on decreases in body weight and body weight gain in males and clinical signs in females.
Cancer (oral, dermal, inhalation)	Classification: ''Not Likely to be Carcinogenic to Humans''		

C. Exposure Assessment

The residue included in the risk assessment and tolerance expression for plants and animals is cyfluthrin *per se*. Parent cyfluthrin is also the residue of concern in the drinking water assessment.

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.436) for the residues of cyfluthrin, in or on a variety of raw agricultural commodities. Tolerances have been established on plant commodities ranging from 0.01 ppm for corn grain and potatoes to 300 ppm for aspirated grain fractions and on animal commodities ranging from 0.01 ppm for poultry commodities to 15 ppm for milk fat. In addition, a tolerance of 0.05 ppm is established for cyfluthrin in animal feeds and processed foods as a

result of its use in food, and feed-handling establishments.

Although the uses on stored grain have been voluntarily cancelled by the registrant established tolerances reflecting these uses are to remain in 40 CFR § 180.436(a)(1) to allow for clearance of the remaining product and treated stored grain from the channels of trade. Although the Agency did not specifically include potential cyfluthrin residues in stored grains in the dietary exposure assessments, the Agency concludes that these assessments do not underestimate dietary exposure and risk because:

- About 90% of the stored grain usage was for treatment of stored wheat grain, so potential exposure from cyfluthrin use on stored grains would come from wheat;
- Residue monitoring data in wheat flour indicate very low or non-detectable residues from cyfluthrin use on stored grain;
- The current dietary exposure estimates from the remaining existing and the newly proposed uses includes a new foliar use on wheat. The wheat field trial data used to estimate dietary exposure reflect maximum rates and minimum pre-harvest intervals (PHI's), and these residues were significantly higher than monitoring data residues for wheat. Monitoring data residues in wheat flour from cyfluthrin use on stored grain were so low that they would not increase dietary exposure estimates if they had been included in the assessment;
- Exposure from residues in wheat (based on the high end foliar use residues) was not significant for any of the population subgroups, including infants and children; and
- Residues in stored grains were not a major component of secondary residue estimates in livestock commodities, and concomitant dietary exposure from consumption of animal commodities such as meat and milk.

Risk assessments were conducted by EPA to assess dietary exposures from cyfluthrin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™/FCID), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996, and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Percent crop treated (PCT) values for crops with established tolerances, for crops with proposed tolerances, anticipated residues in animal commodities, and processing factors (including washing and peeling factors). Crop field trial data were used for proposed commodities and Pesticide Data Program (PDP) monitoring data were used for registered commodities.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM™ software with the FCID, which incorporates food consumption data as reported by respondents in the USDA 1994–1996, and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Average PCT values for crops with established tolerances, projected PCT estimates for crops with proposed tolerances, anticipated residues in animal commodities, and processing factors (including washing and peeling factors). Crop field trial data were used for proposed commodities, and PDP monitoring data were used for registered commodities.

iii. Anticipated residue and PCT information. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) 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. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5–years from the date of issuance of this tolerance.

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

The Agency used PCT information as follows. Average and maximum values for PCT data were used in the chronic and acute analyses, respectively, for the following commodities with established tolerances: Alfalfa (1 chronic, 2.5 acute), broccoli (3 chronic, 5 acute) cabbage (8 chronic, 12 acute), cantaloupes (2 chronic, 5 acute), carrots (1 chronic, 5 acute), cauliflower (1 chronic, 2.5 acute), corn (5 chronic, 10 acute), cotton (10 chronic, 15 acute), garlic (1 chronic, 2.5 acute), grapefruit (1 chronic, 2.5 acute), green beans (1 chronic, 2.5 acute), lemons (5 chronic, 10 acute), lettuce (5 chronic, 10 acute), mustard greens (1 chronic, 2.5 acute), onions (1 chronic, 2.5 acute), oranges (15 chronic, 20 acute), peas (1 chronic, 2.5 acute), peppers (10 chronic, 15 acute), potatoes (25 chronic, 35 acute), pumpkins (1 chronic, 5 acute), sorghum (1 chronic, 2.5 acute), soybeans (1 chronic, 2.5 acute), squash (1 chronic, 2.5 acute), sugarcane (5 chronic, 8 acute), sunflowers (3 chronic, 5 acute), sweet corn (5 chronic, 8 acute), tangerines (5 chronic, 8 acute), tomatoes (5 chronic, 8 acute), and watermelons (5 chronic, 8 acute).

Projected PCT estimates were used for commodities with proposed tolerances as follows: Apples 73%, grapes 23%, peaches 39%, pears 59%, plums 28%, spinach 15%, winter wheat 4%, and collards greens 15%.

The Agency believes that the three conditions listed in Unit III.C.1.iii have been met. With respect to Condition 1, PCT estimates are derived from available federal, state, and private market survey data. For existing crop sites on pesticide registrations (''existing use''), EPA uses an average PCT for chronic dietary exposure estimates. The average PCT figure is derived by combining available federal, state, and private market survey data on the existing use, averaging by year, averaging across all years, and rounding

up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases < 1% is used as the average and < 2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary exposure estimates. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. However, in cases where the rounded average PCT and the maximum PCT were initially identical at 5%, the maximum was further adjusted upward to 8%. In most cases, EPA uses available data from United States Department of Agriculture /National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation

The Agency projects PCT for a new pesticide use by assuming that the PCT for the pesticide's initial five years will not exceed the average PCT of the dominant pesticide (the one with the largest PCT) within its chemical type over three latest available years. For apples, grapes, peaches, pears, plums, and winter wheat the chemical type within which cyfluthrin was compared consisted of all other insecticides. For spinach and collards the corresponding chemical type consisted of all other synthetic pyrethroids with which cyfluthrin was price competitive (which excluded permethrin for spinach). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is non-proprietary and directly available without computation. The assumption was made that cyfluthrin would entirely replace the current market leader among all insecticides for each crop. This assumption is a conservative one because it is not likely that cyfluthrin will entirely replace the market leader for each commodity. For spinach and collard greens, the Agency looked at all the competing pyrethroids only (as opposed to all insecticides) and assumed that cyfluthrin would compete with pyrethroids that are priced competitively with cyfluthrin. The assumption was made that cyfluthrin would entirely replace the current market leader among all competitive pyrethroids for spinach and collards. The value of 15% used for spinach and collard greens is very consistent with the PCT values determined for the registered commodities. These are considered to be conservative estimates of the percent crop treated that cyfluthrin will obtain.

This method of projecting PCT for a new pesticide, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant pesticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant pesticide could be exceeded are whether the new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide within its similar type, whether it is more cost-effective than the dominant pesticide, and whether it is likely to be readily accepted by growers and experts. These factors have been considered for cyfluthrin, and they indicate that it is unlikely that actual PCT for cyfluthrin will exceed the PCT for the dominant pesticide in the next five years.

As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyfluthrin may be applied in a particular area.

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

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cyfluthrin they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of cyfluthrin for acute exposures are estimated to be 3.4 ppb for surface water and 0.0016 ppb for ground water. The EECs for chronic exposures are estimated to be 0.082 ppb for surface water and 0.0016 ppb for ground water.

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

Cyfluthrin is currently registered for use on a variety of indoor (e.g. total release fogger and crack and crevice spray) and outdoor (e.g. spray fogger) applications. Residential exposure for adults was assessed via the inhalation and dermal routes, while exposure for infants and children was assessed via inhalation, dermal, and oral (hand-to-mouth) routes. Outdoor handler inhalation and dermal exposure were assessed. Residential applicator for indoor total release fogger was not assessed quantitatively, because indoor inhalation exposure to a homeowner would likely be less than inhalation exposure to a homeowner that would result from outdoor lawn treatments.

Residential post-application inhalation exposure following treatments to lawns was estimated using time weight averages from an imidacloprid study (Eberhart and Ellisor, 1994). In the study, air concentration measurements were taken in the vicinity of the volunteer subjects performing the Jazzercize routines. These data served as appropriate surrogate data for cyfluthrin since the vapor pressure of cyfluthrin (3.3×10^{-8} torr) is similar to that of imidacloprid (6.9×10^{-9} torr).

Residential MOEs were assessed for indoor and outdoor uses for application and post-application exposure. This is considered a conservative assessment assuming the lawn and carpet uses happen on the same day. All residential cyfluthrin MOEs calculated were well above the target MOEs (100 for inhalation, oral, and dermal exposures) and therefore, do not exceed the Agency's level of concern.

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

Cyfluthrin is a member of the pyrethroid class of pesticides. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data show that there are multiple types of sodium channels and it is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect. Nor do we have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility of rats or rabbits to *in utero* exposure in developmental oral studies; however, there was some indication of increased susceptibility in developmental inhalation studies. A clear NOAEL was established for the fetal effects in every case. No residual uncertainties were identified.

The data also demonstrated increased susceptibility of rats and mice to postnatal exposure to cyfluthrin. A clear NOAEL was established for the offspring effects in every case. No residual uncertainties were identified.

3. *Conclusion.* EPA determined that the FQPA SF to protect infants and children should be removed. The recommendation is based on the following:

- The toxicology databases for cyfluthrin and beta-cyfluthrin together are considered adequate for selecting toxicity endpoints for risk assessment. The toxicity profiles of both cyfluthrin and beta-cyfluthrin can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.
- There is no evidence of increased susceptibility of rats or rabbits to *in utero* exposure in developmental oral studies, and the degree of concern for the effects observed in the inhalation developmental studies is considered low since a clear NOAEL was established for the fetal effects in every case.
- The NOAEL used for short-term inhalation exposure scenarios is protective of the effects seen in the developmental studies via the inhalation route.
- The degree of concern for the effects observed in the reproductive studies was considered low since a clear NOAEL was established for the offspring effects in every case.
- The NOAEL used to establish the cRfD for all populations is protective of the effects seen in the young in the reproduction studies.
- A beta-cyfluthrin developmental neurotoxicity study has been submitted and a preliminary review indicates that effects are seen only at doses higher than those chosen for risk assessment purposes.

E. Aggregate Risks and Determination of Safety

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

food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cyfluthrin will occupy 42% of the aPAD for the U.S. population, 34% of the aPAD for females 13–years and older, 85% of the aPAD for all infants < 1 year old, and 81% of the aPAD for children 3-5 years old, the children population at greatest exposure. In addition, there is potential for acute dietary exposure to cyfluthrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYFLUTHRIN

Population Subgroup	aPAD (mg/kg/ day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.02	42	3.4	0.0 016	400
All infants (<1 year old)	0.02	85	3.4	0.0016	30
Children (1–2 years old)	0.02	81	3.4	0.0 016	40
Females (13–49 years old)	0.02	34	3.4	0.0 016	400

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyfluthrin from food will utilize 1.5% of the cPAD for the U.S. population, 2.4% of the cPAD for all infants <1 year old, the infant subpopulations at greatest exposure, and 5.7% of the cPAD for children 1–2 years old, the children subpopulation at greatest exposure. The registered residential termiticide uses do constitute a chronic inhalation exposure scenario, however, the vapor pressure of cyfluthrin is so low (3.3×10^{-8} torr) that such exposures are anticipated to be negligible. In addition, there is potential for chronic dietary exposure to cyfluthrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO CYFLUTHRIN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.024	1.5	0.082	0.0016	840
All infants (<1 year old)	0.024	2.4	0.082	0.0016	230
Children (1–2 years old)	0.024	5.7	0.082	0.0016	230
Females (13–49 years old)	0.024	1.0	0.082	0.0016	720

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

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

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs =/>500. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of cyfluthrin in ground water and surface water. After calculating DWLOCs and comparing them to-the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CYFLUTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Adult male	500	100	0.082	0.0016	630
Adult female	500	100	0.082	0.0016	540
Child	500	100	0.082	0.0016	180
Infant	550	100	0.082	0.0016	200

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs =/ > 250. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of cyfluthrin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in following Table 5:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Adult male	250	100	0.082	0.0016	490
Adult female	250	100	0.082	0.0016	420
Child	300	100	0.082	0.0016	160
Infant	290	100	0.082	0.0016	160

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC/electron capture detection (ECD) methods) is available in PAM Vol. II to enforce the tolerances. GC/ECD enforcement method 85823, and Bayer's GC/MS method 108139–1, with modifications, were used to analyze samples in the current crop field trials and processing studies. Each method was adequately validated using fortified control samples analyzed in conjunction with the field trial or processing study samples.

B. International Residue Limits

A tolerance of 0.5 ppm is recommended for the pome fruit crop group to harmonize with the Codex apple MRL.

V. Comments

In response to the notice of filing one communication was received from a private citizen objecting to the establishment of the proposed tolerances. The comment contained general and unsubstantiated objections to the use of pesticides on food , the use of animal testing to determine the safety of pesticides, and EPA's risk assessment and safety finding methodologies. The Agency understands the commentor's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

The Agency disagrees with the commenter's objections to animal testing. Since humans and animals have complex organ systems and mechanisms for the distribution of chemicals in the body, as well as processes for eliminating toxic substances from their systems, EPA relies on laboratory animals such as rats and mice to mimic the complexity of human and higher-order animal physiological responses when exposed to a pesticide. EPA is committed, however, to reducing the use of animals whenever possible. EPA-required studies include animals only when the requirements of sound toxicological science make the use of an animal absolutely necessary. The Agency's goal is to be able to predict the potential of pesticides to cause harmful effects to humans and wildlife by using fewer laboratory animals as models and have been accepting data from alternative (to animals) test methods for several years. As progress is made on finding or developing non-animal test models that reliably predict the potential for harm to humans or the environment, EPA expects that it will need fewer animal studies to make safety determinations.

VI. Conclusion

Therefore, tolerances are established for residues of cyfluthrin as requested in the revised petitions.

VII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0205 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 14, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0205, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601*et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not

alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.''''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 22, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.436 is amended by removing the commodity potato from the table in paragraph (a); by alphabetically adding new commodities to the table in paragraph (a); and by adding paragraph (c) to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	0.5
Brassica, leafy greens, subgroup 5B	7.0
Fruit, pome, group 11	0.5
Fruit, stone, group 12	0.3
Grape	1.0
Grape, raisin	3.5
Nut, tree, group 14	0.01
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Peanut	0.01
Peanut, hay	6.0
Pistachio	0.01
Turnips, greens	7.0
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8	0.5
Vegetable, leafy greens, except Brassica, group 4	6.0
Vegetable, tuberous and corm, subgroup 1C	0.01
Wheat, forage	5.0
Wheat, hay	6.0
Wheat, straw	6.0

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of cyfluthrin in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage	6.0
Grass, hay	8.0

* * * * *

[FR Doc. 05–17823 Filed 9–12–05; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

45 CFR Part 61

RIN 0906–AA46

Health Care Fraud and Abuse Data Collection Program: Reporting of Final Adverse Actions; Correction

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Correction amendment.

SUMMARY: This document corrects the final regulations establishing the Healthcare Integrity and Protection Data Bank (HIPDB), the national health care fraud and abuse data collection program for the reporting and disclosing of certain adverse actions taken against health care providers, suppliers and practitioners and for maintaining a data base of final adverse actions taken against health care providers, suppliers and practitioners. In the implementing HIPDB regulations published in the **Federal Register** on October 26, 1999 (64 FR 57740), an inadvertent error appeared in the regulations text concerning the definition of the term