

EPA-APPROVED REGULATIONS IN THE TEXAS SIP—Continued

State citation	Title/subject	State approval/submittal date	EPA approval date	Explanation
Division 2: Early Reductions				
Section 115.920	Applicability	04/26/02	02/27/08 [Insert FR page number where document begins].	
Section 115.923	Documentation	04/26/02	02/27/08 [Insert FR page number where document begins].	
Division 3: Compliance and Control Plan Requirements				
Section 115.930	Compliance Dates	04/26/02	02/27/08 [Insert FR page number where document begins].	
Section 115.932	Congtrol Plan Procedure	04/26/02	02/27/08 [Insert FR page number where document begins].	
Section 115.934	Control Plan Deviation	04/26/02	02/27/08 [Insert FR page number where document begins].	
Section 115.936	Reporting Procedure	11/10/93	05/22/97, 62 FR 27964.	
Section 115.940	Equivalency Determination	04/26/02	02/27/08 [Insert FR page number where document begins].	
Section 115.950	Use of Emissions Credits for Compliance.	12/06/00	09/06/06, 71 FR 52698.	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0857; FRL-8350-3]

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on grass, forage, fodder and hay group 17, forage at 12 ppm; grass, forage, fodder and hay, group 17, hay at 50 ppm; beet, sugar, roots at 0.10 ppm; and beet, sugar, dried pulp at 1.0 ppm. Interregional Research Project Number 4 (IR-4), and Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2008. Objections and requests for hearings must be received on or before April 28, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0857. To access the

electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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 those engaged in the following activities:

- 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 to provide 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0857 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 as required by 40 CFR part 178 on or before April 28, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0857, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for

deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petition for Tolerance

In the **Federal Registers** of October 27, 2006 (71 FR 63011) (FRL-8100-2), and May 9, 2007 (72 FR 26372) (FRL-8121-5) EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) 6E7058 by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ, 08540; and (PP) 6F7160 by Bayer CropScience, 2.T.W. Alexander Drive, PO Box 12014, Research Triangle Park, NC 27709. 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-dimethylcyclopropanecarboxylate, in or on grass, forage at 15 parts per million (ppm) (PP 6E7058); grass, hay at 40 ppm (PP 6E7058); beet, sugar, roots at 0.09 ppm (PP 6F7160); and beet, sugar, dried pulp at 11 ppm (PP 6F7160). The notices referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received from a private citizen on the notices of filing concerning the tolerances for grass, forage; grass, hay; beet, sugar, roots; and beet, sugar, dried pulp. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the commodity and/or tolerance expressions for the proposed petitions. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of cyfluthrin on grass, forage, fodder and hay, group 17, forage at 12 ppm; grass, forage, fodder and hay, group 17, hay at 50 ppm; beet, sugar, roots at 0.10 ppm; and beet, sugar, dried pulp at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Toxicologically, the primary target for cyfluthrin/beta-cyfluthrin is the neuromuscular system; other non-specific effects include decreased body weight gain, and decreased food consumption. The observed neuromuscular effects (tremors, gait abnormalities, abnormal postural reactions, splaying of limbs and decreases in activity) occurred mainly in oral studies in the dog and the rat. In general, the toxicity data base does not indicate that any major differences in toxicity exist between beta-cyfluthrin and cyfluthrin via the oral route. Data from the inhalation toxicity study showed evidence of clinical signs as well as hypothermia and decreased body weight gains. In a postnatal inhalation study in mice, there were clinical signs of neurotoxicity in the pups as well as increased spontaneous motor activity and paresthesia (tingling, burning or pricking - also seen in oral studies).

In oral developmental studies no increased susceptibility was observed in the rat or rabbit; however, increased susceptibility was observed in inhalation developmental studies. Increased susceptibility was also seen in oral reproduction studies and in a

developmental neurotoxicity study on beta-cyfluthrin. The data also demonstrate increased susceptibility of rats and mice to cyfluthrin postnatally.

The database does not indicate that either cyfluthrin or beta-cyfluthrin induces any endocrine disruption; and, there is no concern of mutagenicity. EPA has classified cyfluthrin/beta-cyfluthrin as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by cyfluthrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the Cyfluthrin: Human Health Risk Assessment for New Uses on Grasses, Alfalfa, and Sugar Beet Seed and Revised Tolerances on Cereal Grain Commodities on pages 54–64 at www.regulations.gov. The referenced document is available in docket EPA–HQ–OPP–2006–0857.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles

EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for cyfluthrin used for human risk assessment can be found at <http://www.regulations.gov> in the Cyfluthrin: Human Health Risk Assessment for New Uses of Grasses, Alfalfa, and Sugar Beet Seed and Revised Tolerances on Cereal Grain Commodities on pages 23 and 24 for docket ID number EPA–HQ–OPP–2006–0857.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyfluthrin, EPA considered exposure under the petitioned-for tolerances as well as all existing cyfluthrin tolerances in (40 CFR 180.436). EPA assessed dietary exposures from cyfluthrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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 estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA's analysis was based on tolerance level residues, crop field trial data, Pesticide Data Program (PDP) monitoring data, percent crop treated, anticipated residues in animal commodities, and processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996, and 1998 CSFII. As to residue levels in food, EPA's analysis was based on tolerance level residues, crop field trial data, PDP monitoring data, average percent crop treated, anticipated residues in animal commodities, and processing factors.

iii. *Cancer.* A cancer dietary exposure analysis was not performed because EPA has classified cyfluthrin as being "not likely to cause cancer in humans."

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of 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 residues that have been measured in food. If EPA relies on such information, EPA must pursuant to

FFDCA 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data 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:

a. 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.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

c. 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information for chronic dietary exposures as follows:

Almond 1%; cabbage 5%; cantaloupe 1%; field corn 5%; cotton 10%; cucumber 1%; pecan 1%; pepper 10%; potato 25%; pumpkin 1%; sorghum 1%; soybean 1%; squash 5%; sugarcane 1%; sunflower 1%; and watermelon 2.5%.

EPA uses an average PCT for the acute and chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% 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 risk analysis. 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 5%. 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 used projected PCT information for chronic dietary exposures as follows:

Apple 69%; collard 22%; grape 15%; kale 13%; mustard greens 7%; grass <1%; peach 43%; pear 62%; plum 37%; spinach 39%; turnip 14%, and wheat 2%.

EPA estimates an upper bound of projected percent crop treated (PPCT) for a new pesticide use by assuming that the percent crop treated (PCT) during the pesticide's initial 5 years of use on a specific crop will not exceed the average PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that crop over the three most recent surveys. EPA calls this the market leader PPCT estimate. The average market leader PCTs may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCTs may be based on a cross-section of state PCTs. Comparisons are only made initially among pesticides of the same pesticide type (e.g., leading insecticides on the crop compared with the new insecticide), or, for more refined estimates, comparisons may be made among pesticides in a subcategory of the same pesticide type (e.g., leading pyrethroid insecticides compared with the new pyrethroid insecticide). 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 each year selected. Typically, EPA uses U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data because it is publicly available. When a specific crop is not surveyed by USDA/NASS, EPA uses other sources including proprietary data and calculates the estimated PCT.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the use of cyfluthrin on apples, cabbage, cauliflower, collards, grapes, kale, mustard greens, pasture/rangeland, peaches, pears, peas, plums, spinach, turnip greens, and wheat. It is

unlikely that actual PCTs for cyfluthrin will exceed the corresponding estimated PPCTs during the next 5 years because cyfluthrin shares many pest control attributes and constraints with other members of the pyrethroid class and will likely replace or be used in a similar manner to currently registered pyrethroids.

The Agency believes that the three conditions listed above have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 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 environmental fate characteristics of cyfluthrin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on survey of all the currently registered and proposed uses of cyfluthrin, it was determined that cyfluthrin use on alfalfa and cotton would lead to the highest surface water and ground water estimated groundwater concentrations (EDWCs), respectively. Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the

estimated environmental concentrations (EECs) of cyfluthrin are estimated to be 3.677 parts per billion (ppb) and 0.155 ppb for acute and chronic exposure in surface water respectively. The EEC for chronic groundwater exposure is 0.457 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 3.677 ppb was used to access the contribution of residues in drinking water to dietary risk. For chronic dietary risk assessment, the water concentration of value 0.457 ppb was used to access the contribution to drinking 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 products are registered for use at residential sites including indoor (total release fogger, and crack and crevice spray), and outdoor uses (spray fogger, and lawn 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. Exposure for outdoor handlers was assessed via the Inhalation and dermal routes. 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 homeowner that would result from outdoor lawn treatments.

Residential MOEs were assessed for indoor and outdoor uses for application and post-application exposures. This is considered a conservative assessment assuming the lawn and carpet uses happen on the same day.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Cyfluthrin and beta-cyfluthrin are members of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids interact with sodium channels, there are multiple types of sodium channels and it is currently unknown whether the pyrethroids have similar effects on all channels. The Agency does not have a clear understanding of effects on key downstream neuronal function e.g.,

nerve excitability, nor does the Agency understand how these key events interact to produce their compound specific patterns of neurotoxicity. There is ongoing research by EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When the results of the research become available, the Agency will consider the findings and make a determination of common mechanism as a basis for assessing cumulative risk. Information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism can be found on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCFA provides that EPA shall apply an additional ("10X") 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility of rats or rabbits *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 showed increased susceptibility of rats and mice from postnatal exposure to cyfluthrin. A clear NOAEL was established for the offspring effects in every case. No residual uncertainties were identified.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicology databases for cyfluthrin and beta-cyfluthrin together are considered complete and 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.

ii. 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.

iii. The NOAEL used for short-term inhalation exposure scenarios is protective of the effects seen in the developmental studies via the inhalation route.

iv. 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.

v. The NOAEL used to establish the cPAD for all populations is protective of the effects seen in the young in the reproduction studies.

vi. A beta-cyfluthrin developmental neurotoxicity study has been submitted for review and indicated both the LOAEL and NOAEL from this study are higher than the LOAEL and NOAEL chosen for risk assessment purposes.

vii. There are no residual uncertainties identified in the exposure databases. Although the acute and chronic food exposure assessments are refined, EPA believes that the assessments are based on reliable data and will not underestimate exposure/risk. The drinking water estimates were derived from conservative screening models. The residential exposure assessment utilizes reasonable high-end variables set out in EPA's Occupational/Residential Exposure SOPs (Standard Operating Procedures). The aggregate assessment is based upon reasonable worst-case residential assumptions, and is also not likely to underestimate exposure/risk to any subpopulation, including those comprised of infants and children.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and

long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyfluthrin will occupy 53% of the aPAD for the population group children 1 to 2 years old receiving the greatest exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyfluthrin from food and water will utilize 17% of the cPAD for the population group children 1 to 2 years old receiving the greatest exposure. Based on the use pattern, chronic residential exposure to residues of cyfluthrin is not expected. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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(s) 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, water, and residential exposures aggregated result in aggregate MOEs of 320 for children 1 to 2 years old; 400 for infants < 1 year old; and 420 for the U.S. population. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short-term aggregate exposures to exceed the Agency's level of concern.

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

Cyfluthrin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for cyfluthrin. Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated

result in aggregate MOEs of 220 for the U.S. population; 240 for infants < 1 year old; and 230 for children 1 to 2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect intermediate-term aggregate exposures to exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* EPA has classified cyfluthrin as "not likely to be carcinogenic to humans" and concludes that it poses no greater than a negligible cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC)/electron-capture detection (ECD)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

With regard to international MRLs for cyfluthrin, harmonization of the proposed tolerances is not an issue for grass forage, grass hay, sugar beet roots, and sugar beet dried pulp, as there are no established or proposed Canadian, Mexican or Codex MRLs for cyfluthrin residues on grass or sugar beet commodities.

C. Explanation of Tolerance Revisions

1. *Grasses.* The available field trial data support the use of up to four broadcast foliar applications of cyfluthrin (EC) to grasses grown throughout the United States at a maximum single application rate of 0.044 lb active ingredient/Acre (ai/A), with a minimum RTI of 5 days, for a maximum of 0.178 lb ai/A/season. The data also support a 0-day preharvest interval for cutting of both forage and hay. The available data support tolerances of 50 ppm on grass hay and 12 ppm on grass forage.

2. *Sugar beets.* The available field trial data are adequate. The number and geographic distribution of the field trials are adequate, and the appropriate samples were collected at normal crop

maturity. The samples were analyzed using an adequate analytical method and the sample storage intervals are supported by the available storage stability data. The available data support the use of cyfluthrin (suspoemulsion) as a seed treatment for sugar beets at a rate of 0.035 lb ai/100,000 seeds. The residue data on roots support a tolerance of 0.10 ppm. For both roots and tops, most of the field trial values were below the LOQ. As a result, EPA's statistical tolerance generator was not used to determine tolerances.

D. Response to Comments

Comments were received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated in the **Federal Register** of January 7, 2005 (70 FR 1349).

V. Conclusion

Therefore, the tolerances are established for residues of cyfluthrin, cyano(4-fluoro-3-phenoxy phenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on grass, forage, fodder and hay, group 17, forage at 12 ppm; grass, forage, fodder and hay, group 17, hay at 50 ppm; beet, sugar, roots at 0.10 ppm; and beet, sugar, dried pulp at 1.0 ppm.

VI. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: February 14, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.436 is amended by adding alphabetically commodities to the table in paragraph (a)(1), and by removing and reserving paragraph (c) to read as follows:

§ 180.436 Cyfluthrin: tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Beet, sugar, roots	0.10
Beet, sugar, dried pulp	1.0
* * * * *	*
Grass, forage, fodder and hay, group 17, forage	12
Grass, forage, fodder and hay, group 17, hay	50
* * * * *	*

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

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[FR Doc. E8-3393 Filed 2-26-08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0182; FRL-8341-4]

Dibasic Esters (DBE); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of dibasic esters (DBE; CAS Reg. No. 95481-62-2) when used as an inert ingredient solvent and/or anti-freeze microencapsulated at 10% weight/weight (W/W) or less in

pesticide formulations with the active ingredient cyfluthrin. Whitmire Micro-Gen Research Laboratories, Inc. submitted a pesticide petition 5E4442 to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting exemptions from the requirement of a tolerance. EPA published in the **Federal Register** on August 29, 2007 (72 FR 49689) a proposed rule for this petition in order to provide the public with an opportunity to comment on data that submitted to the Agency after the publication of the petition's Notice of Filing.

DATES: This regulation is effective February 27, 2008. Objections and requests for hearings must be received on or before April 28, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0182. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Tracy Ward, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9361; e-mail address: ward.tracyh@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0182 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 April 28, 2008.