

Commodity	Parts per million
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	10
Canistel	1.2
Canola, seed ¹	0.03
Citrus, dried pulp	8.0
Citrus, oil	340
Fruit, pome	1.7
Fruit, stone	2.0
Grape	2.0
Grape, raisin	3.0
Herb subgroup 19A, dried, except parsley	15.0
Herb subgroup 19A, fresh, except parsley	3.0
Juneberry	3.0
Kiwifruit	1.8
Leafy greens subgroup 4A, except spinach 35	30
Lemon	0.60
Lime	0.60
Lingonberry	3.0
Longan	2.0
Lychee	2.0
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
Pistachio	0.10
Pulasan	2.0
Rambutan	2.0
Salal	3.0
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Spanish lime	2.0
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
Turnip, greens	10.0
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugar-beet, subgroup 1B 41	0.75
Watercress	20

¹ Import only.

(2) Tolerances are established for residues of the fungicide cyprodinil, including its metabolites and degradates, in the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of cyprodinil 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine and free and conjugated CGA-304075 4-(4-cyclopropyl-6-methyl-pyrimidin-2-ylamino)-phenol, calculated as the stoichiometric equivalent of cyprodinil.

Commodity	Parts per million
Cattle, meat byproducts	0.02
Goat, meat byproducts	0.02
Horse, meat byproducts	0.02

Commodity	Parts per million
Sheep, meat byproducts	0.02

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0980; FRL-8861-1]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazifop-P-butyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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-2009-0980. All documents in the docket are listed in the docket index available at <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 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@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).
- 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 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 get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocsp> and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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-2009-0980 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be

received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0980, 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 Facility'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. Summary of Petitioned-For Tolerances

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL-8801-5), 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 petition (PP 9F7624) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide, fluzifop-P-butyl, in or on banana and plantains at 0.01 parts per million (ppm); citrus (whole fruit), citrus (oil), and citrus (juice) at 0.05 ppm; citrus (dried pulp) at 0.40 ppm; grapes at 0.01 ppm; sugarbeet (root) at 0.25 ppm; sugarbeet (top) at 1.5 ppm; sugarbeet (dried pulp) at 1.0 ppm; and sugarbeet (molasses) at 3.5 ppm.

In the **Federal Register** of February 4, 2010 (75 FR 5790) (FRL-8807-5), 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 petition (PP 9E7651) by Syngenta Crop Protection, Inc., P.O. Box

18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.411 be amended by establishing import tolerances for residues of fluzifop-P-butyl in or on potato, tuber at 1.1 ppm; potato, peel (wet) at 1.1 ppm; potato, chips at 3.0 ppm; and potato, granules/flakes at 5.0 ppm. That notice incorrectly identified fluzifop-P-butyl as an insecticide. A corrected notice, identifying fluzifop-P-butyl as an herbicide, was issued in the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL-8810-8).

Those notices referenced summaries of the petitions prepared by Syngenta Crop Protection, Inc., the registrant, which are available in the dockets (PP9F7641, docket ID number EPA-HQ-OPP-2009-0833; and PP9E7651, docket ID number EPA-HQ-OPP-2009-0980), <http://www.regulations.gov>. There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA has determined that the proposed tolerances for plantains, sugarbeet (top), and potato peel (wet) are unnecessary. EPA has also revised several of the proposed commodity terms and tolerance levels, as well as the proposed tolerance expression. The reasons for these changes are 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. * * *

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for fluzifop-P-butyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluzifop-P-butyl 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.

In characterizing the toxicity of fluzifop-P-butyl, EPA considered data on both fluzifop-P-butyl and fluzifop butyl. Fluzifop-P-butyl is the resolved, herbicidally-active isomer (R enantiomer) of fluzifop-butyl. The toxicity database for fluzifop-butyl is largely complete with sufficient toxicity data on fluzifop-P-butyl to demonstrate similar toxicity between the resolved and unresolved compounds.

Fluzifop-P-butyl has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is mildly irritating to the eye and skin and is not a skin sensitizer. In repeated-dose studies, the liver and kidney were the main target organs with toxicity expressed as liver toxicity in the presence of peroxisome proliferation and exacerbation of age-related kidney toxicity. The most sensitive endpoints were seen in the rat (decreased testes and epididymal weights in male rats and decreased pituitary and uterine weights in female rats), most likely due to the longer retention time of the major metabolite (fluzifop acid) in the rat. Fluzifop-P-butyl is classified as "Not likely to be carcinogenic to humans," based on the lack of evidence of carcinogenicity in acceptable studies in rats and hamsters. The hamster was selected for cancer study, rather than the mouse, because liver peroxisome proliferation in hamsters more closely resembles what is found for human liver cells. There is no evidence that fluzifop butyl or fluzifop-P-butyl is mutagenic.

There was no evidence of neurotoxicity or neuropathology in the available studies. Marginal increases in brain weights at termination were observed in a sub-chronic toxicity study in rats and in a carcinogenicity study performed on hamsters; however, they were only seen at higher doses not considered relevant to human exposure.

The toxicity database for fluzifop-butyl and fluzifop-P-butyl includes 7

developmental toxicity studies (5 in rats and 2 in rabbits) and a 2-generation reproduction toxicity study in rats. Fetal effects (including delayed ossification, delayed development of the urinary tract, and diaphragmatic hernias) were consistent findings across the five rat developmental toxicity studies. Maternal toxicity in these studies was observed primarily as decreased weight/weight gain, with maternal effects occurring at higher doses (100/300 milligram/kilogram/day (mg/kg/day)) than doses resulting in fetal effects (2.0/5.0 mg/kg/day). In the rabbit developmental studies, developmental effects (nominal increases in delayed ossification, total litter loss, abortions, small fetuses, and cloudy eyes in one study; and an increased incidence of 13th rib and delayed ossification in *sternebrae 2* in the second study) occurred at doses also causing maternal toxicity (abortions, death, and weight loss). Similarly, in the reproduction toxicity study in rats, offspring effects (decreased viability in the F₁ and F₂ pups during lactational day 1, 4, 11, 18, and 25; and decreased F₂ pup weight on lactational day 25) occurred at doses also resulting in parental toxicity (decreased spleen weight in males and increased absolute and relative liver and kidney weights and geriatric nephropathy in females). Reproductive

toxicity was observed in this study as decreased absolute and relative testes and epididymal weight in males and, in females, decreased pituitary and uterine weights.

For fluazifop, there were some indications of potential immunotoxicity in the form of thymic involution, altered spleen weights, lymphadenopathy and bone marrow myelogram changes in the chronic toxicity study in dogs. The significance of these effects is discussed in detail in Unit III.D.

Specific information on the studies received and the nature of the adverse effects caused by fluazifop-P-butyl 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 at <http://www.regulations.gov> in the document "Revised Fluazifop-P-Butyl. Amended Human Health Risk Assessment to Support Use on Bananas, Citrus, Grapes, Sugar Beets, and the Establishment of a Tolerance on Imported Potatoes," pg. 60 in docket ID number EPA-HQ-OPP-2009-0980.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in

evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. 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/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fluazifop-P-butyl used for human risk assessment is shown in Table 1 of this Unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZIFOP-P-BUTYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13 to 50 years of age).	NOAEL = 50 milligrams/kilograms/day (mg/kg/day) UF _A = 10x. UF _H = 10x FQPA SF = 1x	Acute RfD = 0.50 mg/kg/day aPAD = 0.50mg/kg/day	Developmental Toxicity in Rats. Developmental LOAEL = 200 mg/kg/day based on diaphragmatic hernia.
Acute dietary (General population including infants and children).	An appropriate endpoint attributable to a single dose was not identified in the available studies, including the developmental toxicity studies.		
Chronic dietary (All populations).	NOAEL= 0.74 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.0074 mg/kg/day cPAD = 0.0074 mg/kg/day	2-generation Reproduction in Rats. LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Incidental oral short-term (1 to 30 days).	NOAEL= 100 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats. Maternal LOAEL = 300 mg/kg/day based on maternal body weight gain decrement during GD 7–16.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 0.74 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZIFOP-P-BUTYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days).	Oral study NOAEL = 2.0 mg/kg/day (dermal absorption rate = 9% at 2 mg dose and 2% at 200 mg dose.) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats. Developmental LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydrourerter, and delayed ossification.
Dermal intermediate-term (1 to 6 months) and long-term (<6 months).	Oral study NOAEL= 0.74 mg/kg/day (dermal absorption rate = 9% at 2 mg dose and 2% at 200 mg dose.) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats. Developmental LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydrourerter, and delayed ossification.
Intermediate-term (1 to 6 months) and long-term (<6 months).	Oral study NOAEL = 0.74 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Cancer (Oral, dermal, inhalation).	Not likely to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluzifop-P-butyl, EPA considered exposure under the petitioned-for tolerances as well as all existing fluzifop-P-butyl tolerances in 40 CFR 180.411. EPA assessed dietary exposures from fluzifop-P-butyl 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. Such effects were identified for fluzifop-P-butyl for women of childbearing age (13 to 49 years old). In estimating acute dietary exposure, EPA used food consumption information from the U. S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that all foods contain tolerance-level residues (adjusted to account for all metabolites of concern, based on the

ratio of parent and metabolites found in plant metabolism studies) and that 100% of all crops are treated with fluzifop-P-butyl. Default processing factors were used to estimate residues in processed commodities.

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 assumed that residues were present either at tolerance or average field trial levels. As in the acute dietary exposure assessment, residue levels were adjusted to account for all metabolites of concern. Percent crop treated (PCT) data were used to refine exposure estimates for several currently registered crop uses; 100 PCT was assumed for all new crop commodities. Default processing factors were used to estimate residues in processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluzifop-P-butyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 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 require pursuant to FFDCA section 408(f)(1) 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 these tolerances.

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:

- *Condition 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 the pesticide residue.

• *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.

• *Condition 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 estimated the PCT for existing uses as follows: Asparagus 2.5%; carrot 10%; cherry 1%; cottonseed 2.5%; dry beans 1%; garlic 5%; onion (dry bulb) 15%; peach 2.5%; peanut 1%; pepper (non-bell) 1%; and sweet potato 10%.

In most cases, EPA uses available data from the U. S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. 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 reliable information on the regional consumption of food to which fluzifop-P-butyl may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluzifop-P-butyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluzifop-P-butyl. 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 the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fluzifop-P-butyl for acute exposures are estimated to be 33.4 parts per billion (ppb) for surface water and 1.56 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 6.6 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 33.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 6.6 ppb was used to assess 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).

Fluzifop-P-butyl is currently registered for the following uses that could result in residential exposures: Turfgrass and broadleaf ornamentals. EPA assessed residential exposure using the following assumptions: Homeowners that apply fluzifop-P-butyl products may be exposed to fluzifop-P-butyl for short-term durations via the dermal and inhalation routes. There is also the potential for post-application exposure of adults and children from activities on treated turf areas, such as home lawns. Short-term dermal exposure of adults and children,

as well as incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposure of children may occur. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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." EPA has not found fluzifop-P-butyl to share a common mechanism of toxicity with any other substances, and fluzifop-P-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluzifop-P-butyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for fluzifop-P-butyl includes five rat and two rabbit developmental toxicity studies as well as a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A, there was evidence of quantitative susceptibility of fetuses to fluzifop-P-butyl exposure in the rat developmental toxicity studies. The degree of concern for the increased susceptibility is low and there

is no residual uncertainty based on the following considerations: The endpoint of concern (delayed ossifications) is considered to be a developmental delay as opposed to a malformation or variation which would be considered to be more serious in nature; there were considerable variations in the incidences among the five rat studies; the NOAELs/LOAELs for this effect were well defined and consistent across these studies; and a developmental endpoint of concern (diaphragmatic hernia) is used for assessing acute dietary risk. Also, there was no evidence (quantitative or qualitative) of increased susceptibility of fetuses or offspring in the rabbit developmental studies or in the 2-generation rat reproduction toxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for fluzifop-P-butyl is adequate to assess pre- and postnatal toxicity, lacking only acute and sub-chronic neurotoxicity studies and immunotoxicity testing. Ninety-day dermal and inhalation toxicity studies are also required to confirm the PODs selected for assessing dermal and inhalation exposures based on route-to-route extrapolations from oral studies. EPA does not believe an additional uncertainty factor is needed to account for the lack of these studies for the following reasons:

a. *Ninety-day dermal and inhalation studies.* Fluzifop-P-butyl is expected to show similar toxicity by the inhalation and oral routes because of its metabolism by blood into the acid form and excretion in this manner. Further, EPA selected a conservative (protective) POD from a developmental toxicity study (NOAEL of 2.0 mg/kg/day) to assess both short-term dermal and inhalation exposures. The NOAEL from the available 28-day dermal study is considerably higher (100 mg/kg/day).

Although a POD from an oral study was used to assess residential handler inhalation risks for fluzifop-P-butyl, EPA does not believe this aggregate risk assessment is under-protective of adult handlers. Handler MOEs based on the extrapolated endpoint are quite high (14,000 to 1.1 million), and the contribution of residential exposure to aggregate risk is small. Therefore, even if an inhalation study were to provide a lower POD than the oral study, it's not expected to have a significant impact on aggregate risk.

b. *Neurotoxicity.* There was no evidence of neurotoxicity or

neuropathology in the available studies. Marginal increases in brain weights at termination were observed in a sub-chronic toxicity study in rats, and in a carcinogenicity study performed on hamsters; however, they were only seen at higher doses not considered relevant to human exposure.

c. *Immunotoxicity.* There were some indications of potential immunotoxicity in the form of thymic involution, altered spleen weights, lymphadenopathy and bone marrow myelogram changes in the chronic toxicity study in dogs. EPA's concern for these effects is low, based on the following considerations: Thymic involution was of slight severity in only 1 female treated with the mid-dose; the response was equivocal in the males, as there was no dose-response relationship (incidence and severity) and controls also exhibited thymic involution. One control dog had severe thymic involution; the statistical and biological significance of the alterations in spleen weights could not be assessed because of the large variation in the weights of control dogs. Also, the alterations were inconsistent between dogs that died (these dogs displayed increased adrenal weights) and dogs that survived (these dogs displayed decreased adrenal weights); lymphadenopathy was observed only at the high dose (125 mg/kg/day) and the response is questionable, since the colony of dogs used in the study had excessive health problems that included lymphadenopathy; the bone marrow myelogram changes were small and variable and not considered dose-related; and none of the potential immunological signs in the dog were seen in the rat, the most sensitive species. For these reasons, EPA considered the results of the chronic dog study to be unreliable. The colony of dogs used in the study had excessive health problems that may have impacted normal immune status, so that apparent immunotoxic effects were observed even in some untreated control animals. Moreover, no immunotoxic effects were observed in the sub-chronic dog study, a study where healthy animals were used. EPA therefore concludes that the available data do not warrant an additional uncertainty factor (UF) to account for the lack of an immunotoxicity study.

ii. As noted previously in this unit, there is no indication that fluzifop-P-butyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of increased quantitative susceptibility in *in utero* rats in the prenatal

developmental studies, the degree of concern for developmental effects is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of fluzifop-P-butyl.

iv. There are no significant residual uncertainties identified in the exposure databases. A citrus processing study and data on the stability of fluzifop-P-butyl in processed potato commodities are required; however, EPA does not expect these data to have a measurable impact on exposure estimates for fluzifop-P-butyl. Data are available which demonstrate fluzifop-P-butyl is stable in a wide variety of frozen crop commodities, including potatoes. As such, EPA expects fluzifop to be stable in frozen potato processed commodities but is requiring data to confirm its stability in these fractions. The submitted citrus processing study was determined to be inadequate and EPA is, therefore, requiring that another study be conducted. In the interim, EPA is establishing tolerances for processed citrus commodities using worst-case concentration factors that will not underestimate residues of fluzifop-P-butyl in these commodities.

The acute dietary food exposure assessment was performed based on tolerance-level residues and 100 PCT. The chronic assessment was refined for some commodities using reliable PCT information and anticipated residues values calculated from guideline field trial studies. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluzifop-P-butyl in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluzifop-P-butyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluzifop-P-butyl will occupy 13% of the aPAD for females 13 to 49 years old, the only population group for which an acute dietary endpoint of concern was identified.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluzifop-P-butyl from food and water will utilize 40% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluzifop-P-butyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluzifop-P-butyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluzifop-P-butyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 150 for adults and 250 for children. The MOE for adults includes chronic exposure from food and water plus short-term residential handler and post-application exposure of adult females (the adult population with the highest estimated exposure). The MOE for children includes chronic exposure from food and water plus combined dermal and incidental oral short-term, post-application exposures. Because EPA's level of concern for fluzifop-P-butyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, fluzifop-P-butyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-

term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluzifop-P-butyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluzifop-P-butyl is not expected to pose a 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 fluzifop-P-butyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultra-Violet Spectrometry (HPLC/UV)) is available to enforce the tolerance expression. The method is available in *Pesticide Analytical Methods (PAM)*, Volume II or 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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fluzifop-P-butyl.

C. Revisions to Petitioned-For Tolerances

EPA has determined that the proposed tolerances for plantains, sugarbeet (top), and potato peel (wet) are unnecessary. Residues of fluzifop-P-butyl on plantains will be covered by the tolerance for banana (40 CFR 180.1); and tolerances are no longer required for sugarbeet tops, which were removed from the Table I (Significant Feedstuffs Derived from Agricultural Crops Fed to Beef, Dairy, Poultry, and Swine) of the residue chemistry guidelines (860.1000 OPPTS Harmonized Test Guidelines) in June, 2008. A tolerance is not needed for potato peel, since processing data demonstrate that residues do not concentrate in the peel. Residues in the peel will, therefore, be covered by the tolerance for potato.

EPA has also revised several of the proposed commodity terms and tolerances levels. Commodity terms were revised as follows to comply with the Agency's Food and Feed Vocabulary: "Citrus (whole fruit)," "grapes," "potato tuber," "sugarbeet (roots)," "sugarbeet (dried pulp)," and "sugarbeet (molasses)" were revised to read "fruit, citrus, group 10;" "grape;" "potato;" "beet, sugar, roots;" "beet, sugar, dried pulp;" and "beet, sugar, molasses;" respectively.

The proposed tolerance for citrus was reduced from 0.05 ppm to 0.03 ppm, the limit of quantitation (LOQ) of the residue analytical method, since all field trial residues were below the LOQ. The citrus processing study was inadequate for determining appropriate tolerances in processed citrus commodities. Therefore, maximum theoretical concentration factors were used in conjunction with the citrus field trial results (all <0.03 ppm) to derive tolerances for citrus oil and juice (proposed at 0.05 ppm) of 30.0 ppm and 0.06 ppm, respectively. A maximum theoretical concentration factor is not available for citrus pulp; however, a recent analysis of data for 27 different pesticides showed concentration of residues in citrus pulp of between 2x and 13x. EPA, therefore, used a concentration factor of 13x in conjunction with field trial results to derive an appropriate tolerance of 0.40 ppm for citrus pulp, the same level proposed by the petitioner.

Finally, EPA is revising the requested tolerance expression for fluzifop-P-butyl in accordance with current Agency guidance. EPA is also making this change for the existing fluzifop-P-butyl tolerances. The revised tolerance expression makes clear that the tolerances cover residues of the

herbicide fluzifop-P-butyl, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only the sum of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluzifop, in or on the commodity. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of fluzifop-P-butyl, including its metabolites and degradates, in or on banana at 0.01 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 3.5 ppm; beet, sugar, roots at 0.25 ppm; citrus, dried pulp at 0.40 ppm; citrus, juice at 0.06 ppm; citrus, oil at 30.0 ppm; fruit, citrus, group 10 at 0.03 ppm; grape at 0.01 ppm; potato at 1.0 ppm; potato, chips at 2.0 ppm; and potato, granules/flakes at 4.0 ppm. Compliance with the tolerance levels is to be determined by measuring only the sum of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluzifop, in or on the commodity.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 9, 2000) do not apply to this final rule. In addition, this final 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) (Pub. L. 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: January 18, 2011.

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 180.411 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodities to the table in paragraph (a) and revising paragraph (c) the introductory text to read as follows:

§ 180.411 Fluzifop-P-butyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fluzifop-P-butyl, including its metabolites and degradates, in or on the following commodities in the table. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluzifop, in or on the commodity.

Commodity	Parts per million
Banana	0.01
* * * * *	*
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	3.5
Beet, sugar, roots	0.25
* * * * *	*
Citrus, dried pulp	0.40
Citrus, juice	0.06
Citrus, oil	30.0

Commodity	Parts per million
* * * * *	*
Fruit, citrus, group 10	0.03
* * * * *	*
Grape	0.01
* * * * *	*
Potato ¹	1.0
Potato, chips ¹	2.0
Potato, granules/flakes ¹	4.0
* * * * *	*

¹ No U.S. registrations.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide fluzifop-P-butyl, including its metabolites and degradates, in or on the following commodities in the table. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluzifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluzifop, in or on the commodity.

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[FR Doc. 2011-1779 Filed 2-1-11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0125; FRL-8860-1]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfentrazone in or on multiple commodities. Additionally, this regulation deletes existing tolerances on commodities superseded by the establishment of crop subgroups. This regulation also deletes a time-limited tolerance on bean, succulent seed without pod (lima bean and cowpea), as the tolerance expired on December 31, 2007. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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-2008-0125. All documents in the docket are listed in the docket index available at <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 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 305-7390; *e-mail address:* nollen.laura@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).
- 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 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 get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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-2008-0125 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2008-0125, 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 Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays).