as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VI. 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 12, 2009.

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 180.275 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	*
Lychee	15
* * * * *	*
Starfruit	3.0
* * * * *	*

* * * * *

[FR Doc. E9–4364 Filed 3–3–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0066; FRL–8401–1]

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 beans, dry, seed; peanut; peanut, meal and soybean, seed. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or before May 4, 2009, 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–2008–0066. 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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne @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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0066 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 May 4, 2009.

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–2008–0066, 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. Petition for Tolerance

In the **Federal Register** of February 6, 2008 (73 FR 6964) (FRL–8350–9), 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 7F7289) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, in or on dry beans at 25 parts per million (ppm); peanuts at 1.5 ppm; soybean at 2.5 ppm; soybean meal at 2.5 ppm; and soybean refined oil at 0.01 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the field trial data supporting the petition and to harmonize with the Food and Feed Commodity Vocabulary at *http://www.epa.gov/opphed01/foodfeed/index.htm*. EPA has amended the commodity listing to read: Beans, dry, seed at 50 ppm; peanut at 1.5 ppm; peanut, meal at 2.2 ppm; and soybean, seed at 2.5 ppm. EPA is also editorially combining the tolerance sections and correcting the tolerance expressions to delete references to the unresolved isomer fluazifop-butyl that is no longer a registered pesticide under FIFRA. Background information is provided in the docket associated fluazifop-P-butyl; Tolerance Reassessment Decision. The Notice of Availability was published in the **Federal Register** of October 21, 2005 (70 FR 61287) (FRL–7726–2).

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 the petitioned-for tolerances for residues of fluazifop-P-butyl on beans, dry, seed; peanut; peanut, meal; and soybean, seed at 50 ppm, 1.5 ppm, 2.2 ppm, 2.5 ppm, respectively. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

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

In characterizing the toxicity of fluazifop-P-butyl, EPA considered data on both fluazifop-P-butyl and fluazifop-butyl. Fluazifop-P-butyl is the purified (R) enantiomer of the mixed isomeric (RS) fluazifop-butyl product and the data show them to be toxicological equivalent. Fluazifop-P-butyl has shows no indication of being an eye or skin irritant in acute or 21–day dermal studies, and is not a skin sensitizer. Fluazifop-P-butyl does show similar toxicity by both the inhalation and oral routes because of its metabolization by blood into the acid form and excretion in this manner. The liver and kidney have demonstrated to be its target organs expressed for the most part as liver toxicity in the presence of peroxasome proliferation and exacerbation of age related kidney toxicity. In general, there were no carcinogenicity concerns in any acceptable studies in the rat with fluazifop-butyl or in the hamster for fluazifop-P-butyl. The hamster was selected for cancer study because liver

peroxasome proliferation more closely resembled what was found for human liver cells. There were no mutagenicity concerns evident for fluazifop-butyl or fluazifop-P-butyl. There were no concerns for neurotoxicity resulting from fluazifop-P-butyl which were evident at relevant exposure levels. There was also no evidence of clinical signs which would indicate neurotoxicity or neuropathology in the available studies as well. 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, but only at higher doses. In all, it was concluded that there is no concern for developmental neurotoxicity resulting from exposure to fluazifop-butyl or fluazifop-P-butyl.

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 *Fluazifop-P-Butyl. Amended Human Health Risk Assessment to Support Use on Dry Beans, Peanuts, and the Post-Bloom Application to Soybeans*, page 11 in docket ID number EPA–HQ–OPP–2008–0066.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 discussed at *http://www.regulations.gov* in the document *Fluazifop-P-Butyl. Amended Human Health Risk Assessment to Support Use on Dry Beans, Peanuts, and the Post-Bloom Application to Soybeans*, page 11 in docket ID number EPA–HQ–OPP–2008–0066..

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fluazifop-P-butyl, EPA considered exposure under the petitioned-for tolerances as well as all existing fluazifop-P-butyl tolerances in (40 CFR 180.411). EPA assessed dietary exposures from fluazifop-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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances (current and proposed) were treated (100% crop treated (PCT) assumption)) and contain tolerance-level residues with ratio adjustments to account for additional metabolites of concern. PCT and/or anticipated residues were not used in the acute risk assessment.

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 average residue levels observed in applicable field trials and PCT were used.

iii. *Cancer*. The Agency has determined that fluazifop-P-butyl is ''not likely to be a human carcinogen'' based on the lack of evidence of carcinogenicity in rats and hamsters and no mutagenicity concerns. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Almonds 100%, asparagus 1%, carrots 10%, nectarines 1%, onions 15%, peaches 1%, pistachios 100%, pomegranates 100%, soybeans 100%, and watermelons 100%.

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 Pesticide Use Database for the chemical/crop combination for the most recent 6 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 fluazifop-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 fluazifop-P-butyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluazifop-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 fluazifop-P-butyl for acute exposures are estimated to be 23.9 parts per billion (ppb) for surface water and 0.59 ppb for ground water. For chronic exposures assessments are estimated to be 5.1 ppb for surface water and 0.59 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 23.9 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.1 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).

Fluazifop-P-butyl is currently registered for the following uses that could result in residential exposures: Lawns, walks, driveways, and ornamental planting beds. EPA assessed residential exposure using the following assumptions: Homeowners that apply fluazifop-P-butyl products may become exposed for short-term durations via the dermal and inhalation routes. Fluazifop-P-butyl can be used in a number of residential areas which may be frequented by the general population such as on home lawns. This provides the potential for short-term dermal (adults and children) and incidental oral exposure (children) following residential applications of fluazifop-P-butyl.

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 fluazifop-P-butyl to share a common mechanism of toxicity with any other substances, and fluazifop-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 fluazifop-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 website 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 prenatal and postnatal toxicity database for fluazifop-P-butyl includes the rat and rabbit developmental toxicity studies and the 2–generation reproduction toxicity study in rats. There is some evidence of quantitative susceptibility following oral and dermal exposures to rats. Following *in-utero* exposures, developmental effects (characterized as delayed ossification) were seen in the absence of maternal toxicity in two strains of rats. There is no evidence (quantitative or qualitative) of susceptibility following *in-utero* oral exposure in rabbits or in the 2–generation reproduction toxicity study in rats. No evidence of neurotoxicity was seen.

Although increased prenatal and postnatal quantitative susceptibility was seen in rats, the Agency concluded that there is a low degree of concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of fluazifop-P-butyl because:

i. The short-term dermal and inhalation endpoint of concern (delayed ossification) is considered to be a developmental delay rather than a malformation or variation.

ii. The developmental endpoint of concern (diaphragmatic hernia) used for assessing acute dietary risk was only found in one of the five developmental rat toxicity studies conducted.

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 fluazifop-P-butyl is complete except for a confirmatory immunotoxicity study. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petition was submitted, these studies are not yet available for fluazifop-P-butyl. In the absence of specific immunotoxicity studies, EPA has evaluated the available fluazifop-P-butyl toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. The slight immunotoxicity findings in the chronic dog study are unreliable due to the fact the dogs were unhealthy and no immunotoxic effects were noted in the subchronic dog study where the dogs

were healthy. No other potential immunotoxicity effects were evident in the toxicity database for fluazifop-P-butyl. The liver and kidney are the primary target organs and the most sensitive species is the rat (due to longer retention time of the major metabolite in this species). Based on these considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a point of departure less than the NOAEL of 0.74 milligram/kilogram/day used in calculating the cPAD for fluazifop-P-butyl; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There is no indication that fluazifop-P-butyl is a neurotoxic chemical at relevant exposure levels and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There are no residual uncertainties for prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessments were performed based on reliable data on average residue levels observed in applicable field trials and PCT. Chronic exposure will not be underestimated. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluazifop-P-butyl in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluazifop-P-butyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD 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 fluazifop-P-butyl will occupy 12.1% of the aPAD for (females 13-49 years old) the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazifop-P-butyl from food and water will utilize 74.9% of the cPAD for (children 1-2 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 fluazifop-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).

Fluazifop-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 fluazifop-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 aggregated result in aggregate margins of exposure (MOEs) of 150 for the general U.S. population, 150 for adult females and 240 for children; all below EPA's level 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).

Fluazifop-P-butyl is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to fluazifop-P-butyl through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography-mass spectrometry) 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

There are no Codex Maximum Residue Limits (MRLs) established for fluazifop residues. Canada has established a 1 ppm tolerance for fluazifop-butyl calculated as the acid in soybeans, and a Mexico MRL is established for fluazifop-p-butyl in soya at 1 ppm. The proposed U.S. tolerances cannot be harmonized with the Canadian or Mexican MRLs for soybean, because higher residues were observed in the U.S. crop field trials.

C. Response to Comments

Public comments were received from B. Sachau who objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and are cruel to the test animals. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to fluazifop-P-butyl, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has responded to B. Sachau's generalized comments on numerous previous occasions, 70 FR 1349-1354 (January 7, 2005); 69 FR 63083- 63096 (October 29, 2004).

V. Conclusion

Therefore, tolerances are established for residues of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on beans, dry, seed; peanut; peanut, meal; and soybean, seed at 50 ppm, 1.5 ppm, 2.2 ppm, and 2.5 ppm, respectively.

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) (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 12, 2009.

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 the section heading and paragraphs (a) and (c) to read as follows:

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

(a) *General.* Tolerances are established for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the following commodities:

Commodity	Parts per million
Beans, dry, seed	50
Carrot, roots	2.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cotton, oil	0.2
Cotton, undelinted seed	0.1
Egg	0.05
Endive	6.0
Fruit, stone	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.05
Nut, macadamia	0.1
Onion, bulb	0.5
Peanut	1.5
Peanut, meal	2.2
Pecans	0.05
Poultry, fat	0.05
Poultry, meat	0.05

Commodity	Parts per million
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, seed	2.5
Spinach	6.0
Sweet Potato, roots	0.05

* * * * *

(c) *Tolerances with regional registrations*. Tolerances with regional registrations are established for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the following commodities:

Commodity	Parts per million
Asparagus	3.0
Coffee, bean	0.1
Pepper, tabasco	1.0
Rhubarb	0.5

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0065; FRL–8400–4]

Propoxycarbazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of propoxycarbazone and its Pr-2-OH metabolite in or on grass, forage and grass, hay. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or May 4, 2009, 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–2008–0065. 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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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