United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-R-05-005 September 2005

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Fluazifop-P-butyl

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for Fluazifop-P-butyl," which was approved on September 13, 2005. This document is also known as a Tolerance Reassessment Decision, or TRED. A Notice of Availability of this tolerance reassessment decision published in the *Federal Register*. Because relatively few comments were received in previous public comment opportunities, no additional comment period is planned. The TRED, supporting risk assessments, and response to comments for fluazifop-P-butyl are available to the public in EPA's Pesticide Docket **OPP-2004-0347** at: http://www.epa.gov/edockets.

The fluazifop-P-butyl TRED was developed through EPA's public participation process, published in the Federal Register on May 14, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Through the public participation process, EPA is making a commitment to both involve the public and meet statutory deadlines.

Background

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the enactment of FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made, the tolerances are considered reassessed. Existing tolerances associated with fluazifop-P-butyl must be reassessed in accordance with FFDCA, as amended by FQPA.

There are 37 tolerances established under 40 CFR 180.411 for residues of fluazifop-butyl, fluazifop-P-butyl, and free and conjugated fluazifop. There are currently no active products containing fluazifop or free and conjugated fluazifop. Fluazifop-P-butyl (Case Number 2285, active ingredient number 122809) is the resolved isomer of fluazifop-butyl. Because fluazifop-butyl has been canceled and fluazifop-P-butyl is the only registered active ingredient supported for reregistration, only fluazifop-P-butyl is addressed in this TRED document. In addition, the Agency is establishing a tolerance on cotton gin byproducts. The current tolerance expressions will be consolidated and expressed as "fluazifop."

Table 1. Chemicals in Case Number 2285

PC Code	**Chemical Name**	**Status**
122805	fluazifop, a.k.a. fluazifop-butyl	Canceled
122809	fluazifop-P-butyl, a.k.a. propanoic acid, 2-(4-((5-(trifluoromethyl)-2-pyridinyl)oxy)phenoxy)-, butyl ester, (R)-]	Active

Fluazifop-P-butyl is a selective, post-emergent herbicide registered for the control of perennial and annual grass weeds. Fluazifop-P-butyl is currently registered for food/feed use on asparagus, carrot, coffee, cotton, endive (escarole), garlic, macadamia nut, onion, pecan, pepper, rhubarb, soybeans, stone fruits, sweet potato, and yam. It is also registered for use on lawns/turf. The estimated total domestic use (annual average) is approximately 250,000 lbs. active ingredient per year. More than 90% of fluazifop-P-butyl's total usage is on cotton and soybeans. Fluazifop-P-butyl is typically applied as a broadcast, banded, directed or spot treatment with groundboom sprayers and aerial equipment. Applications are made as pre-plant, at-plant, post-emergence foliar or soil applications, and/or post-harvest applications to the plant.

EPA has completed its review of the dietary and residential risks and is issuing its risk management decision for fluazifop-P-butyl.

Regulatory Decision

EPA has evaluated the dietary and residential risks from the supported registered uses and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to fluazifop-P-butyl. The acute dietary exposure estimates (food + water) for the U.S. population and all population subgroups are <1% of the acute Population Adjusted Dose (aPAD) and are below the Agency's level of concern at the 95th exposure percentile. The chronic dietary exposure estimates (food + water) for the U.S. population are 15% of the chronic Population Adjusted Dose (cPAD) and for the most highly exposed population subgroup, children 1-2 years of age are, 46% cPAD and are below the Agency's level of concern at the 95th exposure percentile. This assessment is considered conservative since tolerance level residues and screening level water estimates were included in the dietary assessment.

The current tolerances established at 40 CFR 180.411 for residues of fluazifop-P-butyl in/on raw agricultural commodities are now considered reassessed under section 408(q) of the FFDCA (see Table 6).

Cumulative Risk Assessment

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency considers other substances because low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually.

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluazifop-P-butyl and any other substances, and fluazifop-P-butyl does not appear to produce a toxic metabolite that is also produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluazifop-P-butyl has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Human Health Effects

(For a complete discussion, see section 4:1 of the *"Fluazifop-P-butyl: Revised HED Chapter of the TRED,"* dated August 29, 2005.)

The database for fluazifop-butyl and fluazifop-P-butyl is adequate for FQPA evaluation. Acceptable developmental toxicity studies in rats and rabbits on fluazifop-P-butyl are available in addition to an acceptable two-generation reproduction study in rats. There is no need for a special FQPA safety factor (i.e., reduced to 1X) given the robust database and since there are no residual uncertainties for pre-and/or post-natal toxicity. The Agency has determined that the exposure estimates are conservative and unlikely to underestimate the potential exposure or risk for infants and children.

Fluazifop-P-butyl has low acute toxicity (Toxicity Category III) by the oral, dermal and inhalation routes, is mildly irritating (Toxicity Category IV) to the eye and skin, and is not a skin sensitizer. Available data in rats show that the kidney and liver are the target organs. Toxicity is expressed as exacerbation of age-related kidney toxicity and liver toxicity in the presence of peroxasome proliferation.

In accordance with EPA's Guidelines for Carcinogen Risk Assessment, Fluazifop-P-butyl is classified as "not likely to be carcinogenic to humans." No mutagenic potential was observed in adequate *in vivo* and *in vitro* studies with fluazifop-P-butyl.

There is evidence of pre/post-natal toxicity resulting from exposure to fluazifop-butyl and fluazifop-P-butyl. There was quantitative evidence of increased susceptibility in the fetuses of rats exposed *in utero* to fluazifop-butyl and fluazifop-P-butyl. Developmental toxicity, characterized as delays in skeletal ossifications, was seen in the absence of maternal toxicity consistently in two strains of rats. There was no evidence (quantitative or qualitative) of increased susceptibility following *in utero* exposures to rabbits or following pre-and/or post-natal exposure in the two-generation reproduction toxicity study in rats. The degree of concern is low for the increased susceptibility seen in the rats 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 is considered to be more serious in nature; there were considerable variations in the incidences among the five studies; the NOAEL and LOAEL were well defined and consistent across these studies; and a developmental endpoint of concern (diaphragmatic hernia) is used for assessing acute dietary risk. Therefore, there is no residual uncertainty for pre and/or post natal toxicity.

The acute dietary endpoint for females 13-49 is based on diaphragmatic hernia observed in a rat developmental toxicity study at the LOAEL of 200 mg/kg/day. The NOAEL in this study was 50 mg/kg/day. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variation) was applied to the NOAEL resulting in an acute Reference Dose (aRfD) of 0.50 mg/kg/day. There is no aRfD for the general population because an endpoint attributable to a single dose was not seen in the database including the developmental toxicity studies.

The chronic dietary endpoint for all populations is based on decreased spleen, testes, and epididymal weights in males and decreased uterine and pituitary weights in females observed in a two-generation reproduction study in rats at the LOAEL of 5.8 mg/kg/day in males and 7.1 mg/kg/day in females. The NOAEL in this study was 0.74 mg/kg/day. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variation) was applied to the NOAEL resulting in a cRfD of 0.0074 mg/kg/day.

A summary of the toxicological dose and endpoints for fluazifop-P-butyl that were used in the dietary risk assessment is shown below in Table 2.

Table 2. Toxicological Dose and Endpoints used in the Dietary Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-49 years of age)	NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.50 mg/kg	FQPA SF = 1X aPAD = acute RfD / FQPA SF = 0.50 mg/kg	Developmental Toxicity in rats 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 = 100 Chronic RfD = 0.0074 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD / FQPA SF = 0.0074 mg/kg/day	Two-Generation Reproduction in rats LOAEL = 5.8 mg/kg/day in males and 7.1 in females based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females

Drinking Water Exposure and Risk Assessment

(For a complete discussion, see the "*Tier 2 Drinking Water Assessment,*" dated May 11, 2005.)

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Since limited monitoring data were available for fluazifop-P-butyl, estimated drinking water environmental concentrations (EDWECs) were calculated from models. The EDWECs were incorporated directly into the acute and chronic dietary exposure assessment model (DEEM-FCID™) for fluazifop-P-butyl. The EDWECs are based on application methods, rates and use sites that would likely yield the highest drinking water concentrations.

Fluazifop-P-butyl is rapidly (less than one day) degraded in soil to fluazifop acid, which is much more stable in soil and water environments than the parent. EPA used the physical properties of fluazifop acid in its modeling because it is the form expected to be present in drinking water. The tree fruit scenarios were modeled in the drinking water assessment because they have the highest labeled use rates.

Surface Water - In the Tier 2 surface water assessment, maximum application rates, minimum application intervals, and the default percent cropped area (PCA) factor of 87%, were incorporated into the PRZM-EXAMS model to yield the EDWECs in raw (untreated) drinking water, using the Index Reservoir scenario.

Ground Water - In the Tier 1 ground water assessment, maximum application rates, minimum application intervals, and the default PCA factor of 87%, were incorporated into SCIGROW model to yield the EDWECs in raw (untreated) drinking water. The model predicts the impact on ground water from a single season's use of a chemical.

Table 3. Estimated Drinking Water Environmental Concentrations for Fluazifop Acid

Fluazifop Acid		
Duration of Exposure	**Surface Water EDWECs**	**Ground Water EDWECs**
Acute	7.5 ppb	0.1 ppb
Chronic (non-cancer)[a]	3.0 ppb	0.02 ppb

[a] Values represent 1-in-10 year return frequencies

Acute and Chronic Dietary (Food + Water) Exposure and Risk Assessment

(For a complete discussion, see section 6:1 of the *"Fluazifop-P-butyl: Revised HED Chapter of the TRED,"* dated August 29, 2005.)

Acute and chronic dietary risk assessments for fluazifop-P-butyl were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03, which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

An acute dietary exposure analysis (food + water) was performed to determine the acute exposure and risks which result from the registered uses of fluazifop-P-butyl. Tolerance level residues with a ratio adjustment for additional metabolites of concern, 100% crop treated (CT), and default processing factors were used in this assessment. A screening level point estimate was used to assess the dietary exposure and risks from residues in water. No refinements were included for the acute dietary exposure analysis; therefore this is considered to be a conservative assessment. Dietary risk estimates are provided for the only population subgroup with an acute dietary endpoint, females 13-49 years of age. This assessment concludes that for all supported registered commodities, the acute dietary risk estimates are below the Agency's level of concern for the U.S. population and all population subgroups (<1 % aPAD) at the 95th exposure percentile.

A chronic dietary exposure analyses was performed to determine the chronic exposure and risks which result from the registered uses of fluazifop-P-butyl. Tolerance levels with a ratio adjustment for additional metabolites of concern, percent crop treated estimates, and default processing factors were used in the chronic assessment. A screening level point estimate was used to assess the dietary exposure and risks from residues in water. No additional refinements were included. Dietary risk estimates are provided for the U.S. population (total) and various population subgroups. The chronic dietary exposure estimates (food + water) for the U.S. population (15% cPAD) and the most highly exposed population subgroup, children 1-2 years of age (46% cPAD), are below the Agency's level of

concern at the 95th exposure percentile.

Fluazifop-P-butyl is classified as "not likely to be carcinogenic to humans;" therefore, no dietary cancer assessment was performed. Results of the dietary exposure and risk assessment are listed below.

Table 4. Summary of Dietary (Food + Water) Exposure and Risk for Fluazifop-P-butyl

Population Subgroup*	Acute Dietary		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	NA	NA	0.001085	15
Children 1-2 years old			0.003410	46
Females 13-49 years old	0.004638	<1	<1	11

Residential Risk

(For a complete discussion, see section 6.3 of the "*Fluazifop-P-butyl: Revised HED Chapter of the TRED,"* dated August 29, 2005.)

At this time, products containing fluazifop-P-butyl are registered for residential use on turfgrass and broadleaf ornamentals; for total grass weed control for lawn renovations; and around driveways, fence lines, sidewalks, and similar areas. Exposure to residential handlers can occur when they mix, load or apply fluazifop-P-butyl for use in a low pressure hand wand, hose-end sprayer or ready-to-use sprayer. In the residential handler scenarios assessed, margins of exposure (MOEs) ranged from 240 to 4300 and do not exceed the Agency's level of concern. Intermediate- and long-term exposures are not anticipated for residential handlers.

EPA assessed short-term dermal and inhalation risks using a NOAEL of 2 mg/kg/day based on an endpoint of reduced fetal weight, hydroureter and delayed ossification at the LOAEL of 5 mg/kg/day in a rat developmental toxicity study. Selecting a short-term dermal (non cancer) endpoint from an oral study requires the use of a dermal absorption factor. Based on a dermal absorption study in humans, the Agency determined that a dermal absorption factor of 9% should be used to assess risks from low exposures (e.g., golfing or mowing residential lawns) and a dermal absorption factor of 2% should be used to assess risks from high exposure activities. Although a 21-day rabbit dermal toxicity study was available with a NOAEL of 100 mg/kg/day and a LOAEL of 500 mg/kg/day, the Agency chose to use the rat developmental study with a lower NOAEL of 2 mg/kg/day and the dermal absorption rates noted above for the residential short-term dermal risk assessment because the effects observed in the rat developmental toxicity study would not be observable in the 21-day rabbit dermal toxicity.

Postapplication exposure can occur when individuals are in or near a residential area that has been previously treated with fluazifop-P-butyl (e.g., home lawns). The postapplication scenarios

assessed for adults included activities such as lawn renovation, mowing or golfing, MOEs ranged from 380 to 26,000. The postapplication scenario assessed for children age 10-12 was golfing, the MOEs ranged from 8,600 to 10,000. The postapplication scenarios for toddlers were assessed for separate postapplication activities (i.e. dermal contact, oral hand to mouth, oral object to mouth, and oral incidental soil ingestion); MOEs ranged from 260 to 26,000,000. In addition, the separate postapplication scenarios for toddlers were assessed as if all those activities occurred simultaneously (i.e. dermal contact + oral hand to mouth + oral object to mouth + oral incidental soil ingestion = combined MOE); MOEs ranged from 250 to 32,000. All postapplication scenarios for adults, children and toddlers had MOEs that do not exceed the Agency's level of concern.

Aggregate Risk

(For a complete discussion, see section 7:0 of the "*Fluazifop-P-butyl: Revised HED Chapter of the TRED,"* dated August 29, 2005.)

In accordance with the FQPA, EPA must consider and aggregate pesticide exposures and risks from all potential sources including food, drinking water, and residential exposures. In an aggregate assessment, exposures are combined and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD). When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. In general, exposures from various sources are aggregated only when the toxic effects determined by the endpoint selected for that route, are the same. In the case of fluazifop-P-butyl, an aggregate assessment was performed using high-end exposures and conservative endpoints. Further refinements would have been incorporated into the risk assessment if exposures of concern had been identified. Since the screening level aggregate assessment did not show risks of concern, the Agency concludes with reasonable certainty that combined residues of fluazifop-P-butyl from food, drinking water and residential exposures would not likely result in an aggregate risk of concern to any population subgroup.

Acute aggregate risk estimates include contributions to exposures from acute dietary (food + water) only. The estimated acute dietary risk is <1 % of the aPAD for females 13-49 years of age and does not exceed the Agency's level of concern for any population sub-group. No acute dietary endpoint was selected for the U.S. population and therefore, no dietary risk assessment was conducted for that population.

Short-term aggregate risk estimates include contributions to exposures from chronic dietary (food + water) and short-term residential sources for adult, children and toddlers from dermal, oral and inhalation exposures. The estimated short-term aggregate risk (MOEs) ranged from 150 to 250 and do not exceed the Agency's level of concern for any population sub-group.

Table 5. Short-Term Aggregate Risk

Population	EPA's Aggregate LOC[1]	Short-Term Scenario				
		MOE food + water[2]	MOE incidental oral[3]	MOE dermal[4]	MOE inhalation[5]	Aggregate MOE (food + water + residential)[6]
U.S. Pop.	100	92,000	NA	150	14,000	150
Adult Female	100	119,000	NA	150	14,000	150
Child	100	29,000	5,500	260	NA	250

[1] *Level of Concern (LOC) is 100 based on 10X for inter-species extrapolation and 10X for intra-species variation.*

[2] MOE food + water = [(short-term oral NOAEL 100 mg/kg/day)/(chronic dietary exposure)]

Chronic dietary exposure: U.S. Pop.=0.0011 mg/kg/day; Females 13-49 yrs = 0.00084 mg/kg/day; Children 1-2 yrs. = 0.0034 mg/kg/d

[3] MOE incidental oral = [(short-term incidental oral NOAEL 100 mg/kg/day)/(child residential exposure)]

Child residential exposure: Hand-to-mouth = 0.015 mg/kg/day; Object-to-mouth = 0.0037 mg/kg/day; Incidental soil ingestion = 0.000049 mg/kg/day

[4] MOE dermal = [(short-term dermal NOAEL 2 mg/kg/day)/(high-end dermal residential exposure)]

Dermal exposure: Adults = handler 0.0081 mg/kg/day + postapp 0.0053 mg/kg/day; Child = 0.0076 mg/kg/day

[5] MOE inhalation = [(inhalation NOAEL 2 mg/kg/day)/(high-end inhalation residential exposure)]

Inhalation exposure: Adult = handler 0.00014 mg/kg/day

[6] Aggregate MOE (food + water + residential) = 1÷[[(1÷MOE food+water) + (1÷MOE incidental oral) + (1÷MOE dermal) + (1÷MOE inhalation)]]

Intermediate-term aggregate risk estimates were not calculated because no intermediate-term residential exposures are expected.

Long-term (non cancer) aggregate risk estimates were calculated based on the contribution from chronic dietary sources alone (food + water), since no long-term or chronic residential exposures are expected. The chronic dietary exposure estimates (food + water) for the U.S. population (15% cPAD) and the most highly exposed population subgroup, children 1-2 years of age (46% cPAD) are below the Agency's level of concern at the 95th exposure percentile.

Aggregate cancer risk was not assessed because fluazifop-P-butyl is classified as "not likely to be carcinogenic to humans."

Tolerance Reassessment Summary

Tolerances for the residues of fluazifop butyl, fluazifop-P-butyl, and free and conjugated fluazifop are established under 40 CFR 180.411. Because the resolved isomer of fluazifop butyl is the only registered active ingredient, the tolerance expressions, which are currently expressed in terms of mixture of isomers for some commodities and in terms of the resolved isomer for other commodities, will be consolidated as tolerances 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. A summary of the fluazifop-P-buytl tolerance reassessment is presented in Table 6.

Table 6. Tolerance Reassessment Summary for Fluazifop-P-Butyl

Commodity	Current Tolerance (ppm)	Range of Residues (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.411(a)(1):				
Cattle, fat	0.05	--	0.05 [2]	
Cattle, meat	0.05	--	0.05 [2]	
Cattle, meat byproducts	0.05	--	0.05 [2]	
Cotton, undelinted seed	0.1	--	0.10 [2]	
Cotton, oil	0.2	--	0.20 [2]	
Egg	0.05	--	0.05 [2]	
Goat, fat	0.05	--	0.05 [2]	
Goat, meat	0.05	--	0.05 [2]	
Goat, meat byproducts	0.05	--	0.05 [2]	
Hog, fat	0.05	--	0.05 [2]	
Hog, meat	0.05	--	0.05 [2]	
Hog, meat byproducts	0.05	--	0.05 [2]	
Horse, fat	0.05	--	0.05 [2]	
Horse, meat	0.05	--	0.05 [2]	
Horse, meat byproducts	0.05	--	0.05 [2]	
Milk	0.05	--	0.05 [2]	
Poultry, fat	0.05	--	0.05 [2]	
Poultry, meat	0.05	--	0.05 [2]	
Poultry, meat byproducts	0.05	--	0.05 [2]	
Sheep, fat	0.05	--	0.05 [2]	
Sheep, meat	0.05	--	0.05 [2]	
Sheep, meat byproducts	0.05	--	0.05 [2]	
Soybean	1.0	--	1.0	
Soybean, meal	2.0	--	2.0 [2]	
Soybean, refined oil	2.0	--	2.0 [2]	
Tolerances Listed Under 40 CFR §180.411(a)(2):				
Carrots, roots	2.0	--	2.0 [3]	
Endive	6.0	--	TBD [1]	
Fruit, stone	0.05	<0.03	0.05 [2]	*Fruit, stone, group 12*
Nut, macadamia	0.1	<0.1	0.10	
Onion (bulb)	0.5	--	0.50	*Onion, dry bulb*
Pecans	0.05	<0.03	0.05	*Pecan*

Commodity	Current Tolerance (ppm)	Range of Residues (ppm)	Tolerance Reassessment (ppm)	Comment/*[Correct Commodity Definition]*
Spinach	6.0	--	Revoke	There are currently no registered uses on spinach.
Sweet potato, roots	0.5	#0.5	0.50 [3]	
Tolerances to Be Proposed under 40 CFR 180.411(a):				
Cotton, gin byproducts	--	--	TBD [1]	
Tolerances Listed Under 40 CFR §180.411(c)(1):				
Pepper, tabasco	1.0	--	1.0	
Tolerances Listed under 40 CFR 180.411(c)(2):				
Asparagus	3.0	0.14-2.7	TBD [1]	
Coffee, bean	0.1	<0.1	0.10	
Rhubarb	0.5	<0.5	0.50 [3]	

[1] To be determined when additional crop field trial data have been submitted.

[2] Tentative until additional information is received to upgrade the existing data.

[3] Confirmatory data are required.

Additional Generic Data Requirements

Table 7 lists the generic data requirements for fluazifop-P-butyl. For a detailed description of the following data requirements, refer to the Residue Chemistry chapter dated August 11, 2004 and the HIARC Report dated June 15, 2004. In addition, the Agency has no data to assess exposures from applications using a sprinkling can, therefore, Outdoor Residential Exposure Task Force (ORETF) hose-end data were used in the assessment.

Table 7. Data Requirements for Fluazifop-P-butyl

Guideline	**Study Title**
870.3465	28-Day Inhalation Toxicity
860.1200	Directions for Use
860.1300	Nature of the Residue - Plants
860.1300	Nature of the Residue - Livestock
860.1340	Residue Analytical Method
860.1380	Storage Stability Data
860.1480	Magnitude of the Residue - Meat, Milk, Poultry, Eggs
860.1500	Crop Field Trials: carrot, sweet potato, endive, rhubarb, asparagus, cotton seed and gin byproducts

860.1520	Processed Food/Feed: coffee, soybean
860.1650	Submittal of Analytical Reference Standards
860.1850	Confined Accumulation in Rotational Crops

Required Label Changes

The following label amendments are needed. In addition, the registrant must submit translated copies of labels for all foreign uses of fluazifop-P-butyl on coffee destined for import into the U.S.

- All product labels that contain use directions for Florigraze perennial peanuts must be amended to refer to this crop as "'Florigraze' rhizoma peanuts" or "'Florigraze' perennial (rhizoma) peanuts."
- All labels that include uses on nonbearing ginseng, olive, and/or small fruits must be modified to specify that the crop may not be harvested for food/feed use within one year of treatment.
- All labels that include uses for soybean must specify a maximum seasonal application rate of 0.5 lb ai/A to soybeans.
- All labels that include uses for pecans must specify a 30-day PHI for pecans.
- For EPA Reg. No. 100-1071 and 100-1116, the rotational crop restriction that prohibits the grazing of rotated small grain crops and the harvesting of these crops for livestock forage and straw is impractical and must be removed.

This document summarizes the Agency's decision on the tolerance reassessment for fluazifop-P-butyl. A generic data call-in (DCI) and product-specific DCI including instructions for submitting the necessary label changes will be issued as soon as possible after publication of this TRED. Please contact Lance Wormell of my staff with any questions regarding this decision. He may be reached by phone at (703) 603-0523 or by e-mail at wormell.lance@epa.gov.

Sincerely,

Debra Edwards, Ph.D., Director
Special Review and Reregistration Division

Technical Support Documents
for the Fluazifop-P-Butyl TRED

1. Diana Locke (USEPA/OPPTS/OPP/HED). Fluazifop-P-butyl: Revised HED Chapter of the Tolerance Reassessment Eligibility Document (TRED). August 29, 2005

2. Sherrie L. Kinard (USEPA/OPPTS/OPP/HED). Fluazifop-P-butyl. REVISED TRED - Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decisions. Residue Chemistry Considerations. Case No. 2285. August 17, 2005.

3. Sherrie L. Kinard (USEPA/OPPTS/OPP/HED). Fluazifop-p-butyl. Revised Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision (TRED). August 18, 2005.

4. William P. Eckel (USEPA/OPPTS/OPP/EFED). Tier 2 Drinking Water Assessment for Fluazifop-P-butyl and its Major Degradate Fluazifop-acid: Response to Phase 3 Comments. May 11, 2005.

5. Ken Dockter (USEPA/OPPTS/OPP/HED). Fluazifop-P-butyl. List B Reregistration Case 2285. PC Code 122809. Product Chemistry Chapter for the Reregistration Eligibility Decision [RED] Document. February 25, 2004.

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