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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 12, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.368 is amended by alphabetically adding commodities to the table in paragraph (a)(2) to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Asparagus	0.10
* * * * *	
Carrot, roots	0.20
* * * * *	
Horseradish	0.20
Onion, green	0.20
* * * * *	
Rhubarb	0.10
* * * * *	
Swiss chard	0.10
* * * * *	

* * * * *

[FR Doc. 03–24014 Filed 9–16–03; 4:08 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0166; FRL–7325–4]

Flufenpyr-Ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], in or on field corn, soybeans, and sugarcane, and the combined residues of flufenpyr-ethyl and its metabolite, S-3153 acid-4-OH; [2-chloro-4-hydroxy-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated, in or on field corn forage and field corn stover. Valent USA Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0166, must be received on or before November 18, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), 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 pest manufacturer. Potentially affected

categories and entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0166. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/4 0cfr180_00.html,* a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of June 25, 2003 (68 FR 37813) (FRL–7307–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (0F6164) by Valent USA Corporation, 1333 North Carolina Blvd, Suite 600, P.O. Box 8025, Walnut Creek, CA 94596–8025. That notice included a summary of the petition prepared by Valent USA Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180 be amended by establishing tolerances for flufenpyr-ethyl; ethyl[2-chloro-4-fluoro-5-(5-methyl-6-oxo-4-trifluoromethyl-1,6-dihydropyridazin-1-yl)phenoxy]acetate, in or on corn, field grain; soybean, seed; and sugarcane, cane at 0.01 parts per million (ppm) and the combined residues of flufenpyr-ethyl and its metabolite S-3153 acid 4-OH; [2-chloro-4-hydroxy-5-(5-methyl-6-oxo-4-trifluoromethyl-1,6-dihydropyridazin-1-yl)phenoxy]-acetic acid in or on corn, field, forage and corn, field, stover at 0.05 ppm.

Section 408(b)(2)(A)(i) of the 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 the 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 the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of the herbicide, flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester in or on corn, field, grain; soybean, seed; and sugarcane, cane at 0.01 ppm and the combined residues of flufenpyr-ethyl and its metabolite, 2-chloro-4-hydroxy-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated in or on corn, field, forage and corn, field, stover at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by flufenpyr-ethyl are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL >1,434/1,591 milligrams/kilogram/day (mg/kg/day) male/female LOAEL not identified
870.3100	90–Day oral toxicity in non-rodents	NOAEL >1,195/1,378 mg/kg/day M/F LOAEL not identified
870.3100	90–Day oral toxicity rodents (mouse)	NOAEL = 395 mg/kg/day (M) LOAEL = 908 mg/kg/day, based on increased absolute and relative liver weights and increased incidence of hepatic centrilobular vacuolation in male mice
870.3100	28–Day oral toxicity rodents (mouse)	NOAEL = 448/629 mg/kg/day M/F LOAEL = 1,009/1,213 M/F mg/kg/day, based on increased incidence of hepatic centrilobular vacuolation
870.3150	90–Day oral toxicity in non/rodents (dog)	NOAEL = 300 mg/kg/day M/F LOAEL = 1,000 M/F mg/kg/day, based on decreased body weight gains, food consumption, and food efficiency and increased incidence of vomiting
870.3200	21–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day M/F LOAEL not identified
870.3250	90–Day dermal toxicity	NA
870.3465	90–Day inhalation toxicity	NA
870.3700	Prenatal developmental in rodents (rat)	*Maternal* NOAEL >1,000 mg/kg/day LOAEL was not established *Developmental* NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL not identified
870.3700	Prenatal developmental in non-rodents (rabbit)	*Maternal* NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day, based on increased maternal mortality, clinical signs, decreased food consumption and necropsy findings *Developmental* NOAEL = 1,000 mg/kg/day LOAEL not identified
870.3700	Prenatal developmental in non-rodents (rabbit)	*Maternal* NOAEL = 100 mg/kg/day LOAEL = 200 mg/kg/day, based on increased mortality *Developmental* NOAEL = 1,000 mg/kg/day HDT LOAEL not identified
870.3800	2-Generation reproduction and fertility effects (rat)	*Parental/systemic* NOAEL = 1,463 - 1,914 mg/kg/day LOAEL not identified *Reproductive* NOAEL = 1,463 - 1,914 mg/kg/day LOAEL not identified *Offspring* NOAEL = 1,463 - 1,914 mg/kg/day LOAEL not identified
870.3800	1-Generation reproduction and fertility effects (rat)	*Parental/systemic* NOAEL = 6.4 - 7.5 mg/kg/day LOAEL not identified *Reproductive* NOAEL = 6.4 - 7.5 mg/kg/day LOAEL not identified *Offspring* NOAEL = 6.4 - 7.5 mg/kg/day LOAEL not identified

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	1-Generation reproduction and fertility effects (rat)	*Parental/systemic* NOAEL = 139.4 - 151.7 mg/kg/day LOAEL not identified *Reproductive* NOAEL = 139.4 - 151.7 mg/kg/day LOAEL not identified *Offspring* NOAEL = 139.4 - 151.7 mg/kg/day LOAEL not identified
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL = 778.8/1024.7 mg/kg/day M/F LOAEL was not established No evidence of carcinogenicity
870.4200	Carcinogenicity rodents (mouse)	NOAEL = 39.9 - 43.7 mg/kg/day M/F LOAEL = 401.8 - 447.9 mg/kg/day M/F, based on liver toxicity in both sexes and mild anemia in males No evidence of carcinogenicity
870.5100	Bacterial gene mutation assay	Flufenpyr-ethyl was tested up to concentrations limited by cytotoxicity. There was no evidence of mutagenicity at any dose levels tested. Positive controls induced appropriate response
870.5100	Bacterial gene mutation assay S-3153 acid-4-OH	There was no evidence of a cytotoxic, mutagenic or dose-response trend in any tester system ± S9. Positive controls induced appropriate response
870.5300	*In vitro* mammalian cell gene mutation assay	The compound was tested up to an upper concentration limited by solubility and cytotoxicity. Flufenpyr-ethyl was negative for inducing mutations at the TK locus in mouse L5178Y ± S9
870.5395	Mammalian erythrocyte micronucleus assay	No clinical signs of toxicity was observed. Flufenpyr-ethyl did not induce micronucleated polychromatic erythrocytes after any treatment
870.7485	Metabolism and pharmacokinetics - rat	There is no difference in the metabolic profile of flufenpyr-ethyl attributable to gender or radiolabel position

B. Toxicological Endpoints

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD) or (cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for flufenpyr-ethyl used for human risk assessment is shown in the following Table 2:

TABLE 2.–SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUFENPYR-ETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT[1]

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF[2] and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = None mg/kg/day UF = N/A Acute RfD = None	Special FQPA SF = 1x aPAD = acute RfD Special FQPA SF = None	A dose and endpoint of concern attributable to a single dose was not available in the data base including the developmental toxicity studies
Acute dietary (general population including infants and children)	NOAEL = None mg/kg/day UF = N/A Acute RfD = None	FQPA SF = 1x aPAD = acute RfD Special FQPA SF = None	A dose and endpoint of concern attributable to a single dose was not available in the data base including the developmental toxicity studies
Chronic dietary (all populations)	NOAEL = 40 mg/kg/day UF = 100 Chronic RfD = 0.4 mg/kg/day	Special FQPA SF = 1x cPAD = chronic RfD Special FQPA SF = 0.4 mg/kg/day	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Short-term Incidental oral (1–30 days)	NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Developmental toxicity study - rabbit LOAEL = 300 mg/kg/day, based on clinical signs, decreased food consumption and necropsy findings
Intermediate-term Incidental oral (1–6 months)	NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Developmental toxicity study - rabbit LOAEL = 300 mg/kg/day, based on clinical signs, decreased food consumption and necropsy findings
Dermal all durations	HIARC concluded quantitation of dermal risk is not required due to lack of systemic toxicity at the limit-dose following repeated dermal exposures as well as lack of concern for developmental toxicity		
Short-term inhalation (1–30 days)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Intermediate-term inhalation (1–6 months)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Long-term inhalation (>6 months)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Cancer (oral, dermal, inhalation)	Flufenpyr-ethyl classified as ''not likely to be carcinogenic to humans.''		

[1] UF = uncertainty factor, FQPA SF = Special FQPA safety factor, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

[2] The reference to the Special FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have been previously established for the residues and the combined residues of flufenpyr-ethyl, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from flufenpyr-ethyl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. An endpoint of concern attributable to a single oral dose was not identified for either the general U.S. population (including infants and children) and all population subgroups, or the females 13–50 years old population subgroup for flufenpyr-ethyl; therefore, an acute dietary exposure analysis was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: An unrefined, chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. Proposed tolerance-level residues and 100 percent crop treated (%CT) information were used for all

proposed commodities. The submitted corn grain, soybean, and sugarcane processing studies indicate that flufenpyr-ethyl residues do not concentrate in corn, soybean, and sugarcane processed commodities. Therefore, processing factors were set to 1 for all corn, soybean, and sugarcane processed commodities.

The chronic dietary exposure estimates are below EPA's level of concern (<100% cPAD) for the general U.S. population and all population subgroups (<1% of the cPAD). The chronic assessment was highly conservative, using several upper-end assumptions. Additional refinements, such as inclusion of anticipated residues (ARs) and %CT data, could be made in order to refine the chronic assessment.

iii. *Cancer*. A quantitative cancer aggregate risk assessment was not performed because flufenpyr-ethyl is classified as ''not likely'' to be carcinogenic based on lack of evidence of carcinogenicity in mice and rats.

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

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent reference dose (%RfD) or percent population adjusted dose (%PAD). Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses.

Based on FIRST and SCI-GROW models, the EECs of flufenpyr-ethyl and its metabolite S-3153 acid 4-OH for acute exposures are estimated to be 3.76 parts per billion (ppb) for surface water and 0.05 ppb for ground water. The EECs for chronic exposures are estimated to be 1.504 ppb for surface water and 0.05 ppb for ground water.

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

Flufenpyr-ethyl is not registered for use on any sites that would result in residential exposure.

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

EPA does not have, at this time, available data to determine whether flufenpyr-ethyl has a common mechanism of toxicity with other substances. 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 flufenpyr-ethyl and any other substances, and flufenpyr-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that flufenpyr-ethyl 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*

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no evidence of quantitative and/or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to flufenpyr-ethyl. There is no evidence of increased qualitative and/or quantitative evidence of increased susceptibility to flufenpyr-ethyl following prenatal exposure in a 2-generation reproduction study(s) in rats or 1-generation reproduction studies.

3. *Conclusion*. There is a complete toxicity data base for flufenpyr-ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The FQPA Safety Factor (SF) was reduced to 1x based on toxicological considerations, the conservative residue assumptions used in the chronic dietary exposure risk assessment, the completeness of the toxicity, residue chemistry and environmental fate data base and the lack of the potential for residential exposures.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model

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

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

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

1. *Acute risk*. No endpoint of concern attributable to a single oral dose was identified for either the general U.S. population (including infants and children) or females 13–50 years old population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flufenpyr-ethyl from food will utilize less than 1% of the cPAD for the U.S. population, less than 1% of the cPAD for all infants less than 1 year old and less than 1% of the cPAD for for children 3–5 years old. There are no residential uses for flufenpyr-ethyl that result in chronic residential exposure to flufenpyr-ethyl.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUFENPYR-ETHYL

Population Subgroup	cPAD (mg/kg)	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC[2] (µg/L)
U.S. population	0.4	<1%	2.0	0.07	14,000
All infants (<1 year old)	0.4	<1%	2.0	0.07	4,000
Children (1–2 years old)	0.4	<1%	2.0	0.07	4,000
Children (3–5 years old)	0.4	<1%	2.0	0.07	4,000
Children (6–12 years old)	0.4	<1%	2.0	0.07	4,000
Youth (13–19 years old)	0.4	<1%	2.0	0.07	12,000
Adults (20–49 years old)	0.4	<1%	2.0	0.07	14,000
Females (13–49 years old)	0.4	<1%	2.0	0.07	12,000
Adults (50+ years old)	0.4	<1%	2.0	0.07	14,000

3. *Short-term risk*. Short-term aggregate risk assessment was not performed because there are no registered or proposed residential non-food uses. Flufenpyr-ethyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate risk assessment was not performed because there are no registered or proposed residential non-food uses. Flufenpyr-ethyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Flufenpyr-ethyl is not carcinogenic.

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, and to infants and children from aggregate exposure to flufenpyr-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Agency has a method (Method RM-36–1) for determination of flufenpyr-ethyl per se and a method (Method RM-36–3c) for determination for free and conjugated S-3153 acid-4-OH. An enforcement (confirmatory) method capable of measuring both parent and metabolite is being requested by the Agency.

B. International Residue Limits

There are currently no established tolerances for residues of flufenpyr-ethyl in/on any plant or livestock commodities. As there are no Mexican, Canadian or Codex maximum residue limits established for flufenpyr-ethyl in/on field corn, soybeans and sugarcane, there are no compatibility issues to be reconciled.

C. Conditions

Confirmatory storage stability data for the metabolite S-3153 acid-4-OH in field corn forage and stover and an

enforcement method for measuring both parent and metabolite are required.

V. Conclusion

Therefore, the tolerance is established for residues of the herbicide flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester, in or on: Corn, field, grain; soybean, seed; and sugarcane, cane at 0.01 ppm and the combined residues of the herbicide; flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester, and its metabolite, S-3153 acid- 4-OH; [2-chloro-4-hydroxy-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated in/on: Corn, field, forage; and corn, field, stover at 0.05 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0166 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 18, 2003.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0166, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov.* Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 15, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.595 is added to read as follows:

§ 180.595 Flufenpyr-ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide, flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], in or on the following commodities:

Commodity	Parts per million
Corn, field, grain	0.01
Soybean, seed	0.01
Sugarcane, cane	0.01

(2) Tolerances are established for residues of the herbicide flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], and its metabolite, S-3153 acid-4-OH; [2-chloro-4-hydroxy-5-[5-methyl-6- oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated, in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, stover	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

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

(d) *Indirect or inadvertent residues.* [Reserved]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Modified Base (1-percent-annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified BFEs are indicated on the table below and revise the Flood Insurance Rate Maps ((FIRMs) in effect for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection.

The modifications are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

These modified BFEs are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and names of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community number
Arkansas: Sebastian, (Case No. 02–06–1094P), (FEMA Docket No. P7620).	City of Greenwood.	November 13, 2002, November 20, 2002, *Greenwood Democrat*.	The Honorable Judy Selkirk, Mayor, City of Greenwood, City Hall, 30 Bell Road, Greenwood, AR 72936.	November 25, 2002 ..	050198