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 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 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: February 17, 2006.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.495 is amended:

■ i. In paragragh (a), in the table, by removing: Corn, forage at 1.0 ppm; corn, hay at 1.0 ppm; corn stover at 1.0 ppm; corn straw at 1.0 ppm; grass, forage, fodder and hay, group 17 at 0.02 ppm; sorghum, forage at 1.0 ppm; sorghum, forage, hay at 1.0 ppm; sorghum, grain, stover at 1.0 ppm; sorghum, straw at 1.0 ppm; wheat, forage at 1.0 ppm; wheat, hay at 1.0 ppm and wheat, straw at 1.0 ppm; and by alphabetically adding the commodities as set forth below.

■ ii. In paragraph (b), in the table, by removing: All commodities in connection with the quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance in is not already established at 0.02 ppm; alfalfa, forage at 4.0 ppm; alfalfa, hay at 4.0 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut, hay at 10 ppm and onion, dry bulb at 0.10 ppm.

The additions read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Alfalfa, seed	0.15
Alfalfa, seed screenings	2.0
Animal feed, nongrass, group, 18, forage	35.0
Animal feed, nongrass, group, 18, hay	30.0
* * * * *	
Banana	0.25
Food commodities	0.02
Grain, cereal, group 16, forage, except rice	2.5
Grain, cereal, group 16, hay, except rice	10.0
Grain, cereal, group, 16, stover, except rice	10.0
Grain, cereal, group, 16, straw, except rice	1.0
* * * * *	
Grass, forage, fodder and hay, group 17, forage	10.0
Grass, forage, fodder and hay, group 17, hay	5.0
* * * * *	
Onion, green	2.0
* * * * *	
Peanut, hay	11.0
Peppermint, tops	3.5
* * * * *	
Spearmint, tops	3.5
* * * * *	
Vegetable, bulb, group 3, except green onion	0.10
* * * * *	

* * * * *

[FR Doc. 06–1939 Filed 3–7–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0311; FRL–7764–1]

Flumiclorac Pentyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumiclorac pentyl in or on undelinted cottonseed and cotton gin byproducts. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 8, 2006. Objections and requests for hearings must be received on or before May 8, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the**SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0311. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

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@epamail.epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*,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 on E-CFR Beta Site Two 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/*.

II. Background and Statutory Findings

In the **Federal Register** of November 30, 2005 (70 FR 71844) (FRL–7747–3), 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 3F6767) by Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596–8025. The petition requested that 40 CFR 180.477 be amended by establishing tolerances for residues of the herbicide, flumiclorac pentyl, [2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)phenoxy]-acetate, in or on cotton undelinted seed at 0.1 parts per million (ppm) and cotton gin by products at 2.0 ppm. That notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. The Notice of Availability of the Flumiclorac Pentyl Tolerance Reassessment (TRED) was published in the **Federal Register** on October 19, 2005 (70 FR 60824) (FRL–7740–4). The flumiclorac pentyl TRED stated that the residues should be expressed as flumiclorac pentyl, *per se*, and that the tolerances for cotton undelinted seed be increased to 0.2 ppm, and that cotton gin by products be increased to 3.0 ppm. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

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. . . .''

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 *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of flumiclorac pentyl on cotton undelinted seed at 0.2 ppm and cotton gin by products at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by flumiclorac pentyl 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 Assessment
870.3100	90–Day oral toxicity--rodents (rat)	NOAEL = 1,359 milligrams/kilogram/day (mg/kg/day)males (M) and 1,574 mg/kg/day females (F) - Highest Dose Tested(HTD) LOAEL was not established
870.3150	90–Day oral toxicity--nonrodents (dog)	NOAEL = 100 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased clotting time in females
870.3200	21/28–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day (limit dose)
870.3700	Prenatal developmental--rodents (rat)	Maternal NOAEL = 1,500 mg/kg/day - HDT Maternal LOAEL was not established Developmental NOAEL = 1,500 mg/kg/day - HDT Developmental LOAEL was not established
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 16/18mg/kg/day (M/F) Parental/Systemic LOAEL = 781/925mg/kg/day (M/F) based on increased kidney weight in males andfemales and nephropathy in males Reproductive NOAEL = 1610/1869 mg/kg/day (M/F) - HDT Reproductive LOAEL was not established Offspring NOAEL = 781/925mg/kg/day (M/F) Offspring LOAEL = 1610/1869mg/kg/day (M/F) based on decreasedbody weight/body weight in F_2 pups
870.4100	Chronic toxicity--dogs	NOAEL = 100 mg/kg/day LOAEL = 1,000 mg/kg/day based on decreased body weight gain in male; increased clotting time, increased globulin levels, and increasedalpha-2 fraction of the serum protein electrophoresis in females
870.4200	Chronic toxicity/Carcinogenicity--rats	NOAEL = 744.9/919.4 mg/kg/day(M/F) - HDT LOAEL was not established No evidence of carcinogenicity
870.4300	Carcinogenicity--mice	NOAEL = 731.4/ 850.2 mg/kg/day(M/F) - HDT LOAEL was not established No evidence of carcinogenicity
870.5100	Gene mutation	Negative up to 5,000 μg/plate withand without metabolic activation
870.5375	Cytogenetics	Negative for chromosome aberrationup to 400 μg/mL with metabolic activation; weak,positive response without activation
870.5395	Micronucleus - mouse	Negative at concentration up to300 μg/mL in cultured rat hepatocytes
870.5550	Unscheduled DNA Synthesis	Negative at doses up to 5,000 mg/kg
870.7485	Metabolism and pharmacokinetics	Rapid absorption and excretion; majormetabolic route is deesterification to a phenoxyaceticacid derivative followed by cleavageof the imide moiety or hydroxylationand/or sulfonation reactions

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 flumiclorac pentyl used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUMICLORAC PENTYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49)	An endpoint of concern for the females 13 -49 attributable to a single dose was not identified in the hazard data base.		
Acute Dietary (General population including infants and children)	An endpoint of concern for the general population attributable to a single dose was not identified in the hazard data base		
Chronic Dietary (All populations)	NOAEL= 100 mg/kg/day UF = 100 Chronic RfD = 1.0 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/Special FQPA SF = 1.0 mg/kg/day	Chronic dog LOAEL = 1,000 mg/kg/day based on decreased body weight gain (males), increased clotting time (males and females), and increased globulin levels and increased alpha-2 fraction of the serum protein electrophoresis (females)
Short-Term Incidental Oral Exposure (1 to 30 days) (Residential)	inhalation (or oral) study NOAEL = 100 mg/kg/day) UF = 100 Chronic RfD = 1.0 mg/kg/day	FQPA SF = 1 cPAD = 1.0 mg/kg/day 1 = 1.00 mg/kg/day MOE = 100 (residential)	Chronic - dog LOAEL = 1,000 mg/kg/day based on LOAEL = mg/kg/day based on decreased body weight gain (males), increased clotting time (males and females), and increased globulin levels and increased alpha-2 fraction of the serum protein electrophoresis (females)
Cancer (oral, dermal, inhalation)	No evidence of carcinogenicity in the hazard data base		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.477) for the residues of flumiclorac pentyl, in or on field corn and soybeans. Risk assessments were conducted by EPA to assess dietary exposures from flumiclorac pentyl 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.

No such effects were identified in the toxicological studies for flumiclorac pentyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the 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: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed flumiclorac pentyl tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the chronic risk assessment.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flumiclorac pentyl 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 flumiclorac pentyl.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %Reference dose or %Population adjusted dose.

Based on the FIRST and SCI-GROW models, the EECs of flumiclorac pentyl for chronic exposures are estimated to be 0.24 parts per billion (ppb) for surface water and 0.002 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).

Flumiclorac pentyl is currently registered for use on the following residential non-dietary sites: Non-agricultural settings which include golf course, parks, recreation areas as well as schools. The risk assessment was conducted using the following residential exposure assumptions: The short-term incidental oral exposures was assessed for toddlers, the most sensitive population possibly exposed to flumiclorac-pentyl from residential use. Residential Exposure Assessments for the exposure scenarios described in Table 3 which are the most likely to result in highest possible exposure by toddlers to the herbicide.

TABLE 3.—SHORT-TERM RESIDENTIAL EXPOSURE ESTIMATES AND MOES FOR FLUMICLORAC-PENTYL TREATED TURF

Resident	Activity	Days After Treatment (DAT)	Body Weight	Average Daily Dose (ADD) (mg/kg/day)	NOAEL	MOE
toddler	hand to mouth	0	15	0.0017	100	58,230
toddler	object to mouth (turf)	0	15	0.00043	100	233,000
toddler	soil ingestion	0	15	0	100	1.75 E^{7}

All MOEs, including the total toddler ingestion MOE, are well above 100 and therefore exposures to toddlers from flumiclorac-pentyl are not of concern.

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.''

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 flumiclorac pentyl and any other substances and flumiclorac pentyl 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 flumiclorac pentyl has a commonmechanism 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/pesticidesca/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of 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 based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or

special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to flumiclorac pentyl. There is no concern for neurotoxicity.

3. *Conclusion*. There is a complete toxicity data base for flumiclorac pentyl, there is no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to flumiclorac pentyl, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The dietary food exposure assessment utilizes tolerance level residues and 100% crop treated (CT) information for all commodities. By using these screening-level assumptions, chronic exposures/risks will not be underestimated. The dietary drinking water assessment utilizes values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. Accordingly, the additional 10X factor for the protection of infants and children is removed.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. An endpoint of concern attributable to a single exposure was not identified in the hazard data base and therefore no acute risk is expected from exposure to flumiclorac pentyl.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flumiclorac pentyl from food and drinking water will utilize <0.01% of the cPAD for the U.S. population, <0.01% of the cPAD for the most highly exposed population subgroup, Children 3-5 years old. Based the use pattern, chronic residential exposure to residues of flumiclorac pentyl is not expected.

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

Flumiclorac pentyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for flumiclorac pentyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, drinking water and residential exposures aggregated result in aggregate MOE of 46,000 for Children 3-5 years old. This aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food and residential uses.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FLUMICLORAC PENTYL

Population	NOAEL mg/kg/day	Level of Concern	Maximum Exposure mg/kg/day	Average Food + Water Exposure mg/kg/day	Residential Exposure mg/kg/day	Aggregate MOE (food and residential)
Children, 3-5 years old	100	≤100	1	0	0.0017	46,000

4. *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 flumiclorac pentyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas-liquid chromatography with thermionic-specific detector) 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 currently no established Codex, Canadian, or Mexican maximum residue limits for flumiclorac pentyl.

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 flumiclorac pentyl, 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, January 7, 2005 (70 FR 1349, 1354) (FRL–7691–4); October 29, 2004 (69 FR 63083, 63096) (FRL–7681–9).

V. Conclusion

Therefore, the tolerance is established for residues of flumiclorac pentyl on cotton undelinted seed at 0.2 ppm and cotton gin by products at 3.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 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 EPA–HQ–OPP–2005–0311 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 May 8, 2006.

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 issue(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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0311, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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 **ADDRESSES**. 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 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 issue(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 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 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 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: February 27, 2006.

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 180.477 is amended by revising paragraph (a) to read as follows:

§ 180.477 Flumiclorac pentyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide flumiclorac pentyl, [2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)phenoxy]-acetate, in or on the raw agricultural commodities listed below.

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Cotton gin by products	3.0
Cotton, undelinted seed	0.2
Soybean, hulls	0.02
Soybean, seed	0.01

* * * * *

[FR Doc. 06–2151 Filed 3–7–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 271 and 272

[EPA–R08–RCRA–2006–0047; FRL–8035–4]

South Dakota: Final Authorization of State Hazardous Waste Management Program Revision and Incorporation by Reference of Approved State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule and response to comments.

SUMMARY: The EPA is granting final authorization to the hazardous waste program revisions submitted by South Dakota. The Agency published a Proposed Rule on September 27, 2005, and provided for public comment. The comment period ended on October 27, 2005. No comments were received regarding Resource Conservation and Recovery Act (RCRA) program issues. There was one comment from South Dakota State Attorney General regarding Indian country language. No further opportunity for comment will be provided. This final rule also codifies and incorporates by reference the authorized provisions of the South Dakota regulations in Title 40 of the Code of Federal Regulations (CFR) part 272.

DATES: This final rule is effective on March 8, 2006. The incorporation by reference of authorized provisions in the South Dakota regulations contained in this rule is approved by the Director of the Federal Register as of March 8, 2006, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–RCRA–2006–0047. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at: EPA Region 8, from 8 a.m. to 3 p.m., 999 18th Street, Suite 300, Denver, Colorado 80202–2466, contact: Kris Shurr, phone number: (303) 312–6139, e-mail address: *shurr.kris@epa.gov,* or SDDENR, from 9 a.m. to 5 p.m., Joe Foss Building, 523 E. Capitol, Pierre, South Dakota 57501–3181, contact: Carrie Jacobson, phone number (605) 773–3153.

FOR FURTHER INFORMATION CONTACT: Kris Shurr, 8P–HW, U.S. EPA, Region 8, 999 18th Street, Suite 300, Denver, CO 80202–2466, phone number: (303) 312–6139 FAX number: (303) 312–6341; e-mail address: *shurr.kris@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Authorization of Revisions to South Dakota's Hazardous Waste Program and Correction

On October 25, 2004, South Dakota submitted final complete program revision applications seeking authorization of their changes in accordance with 40 CFR 271.21. We now make a Final decision that South Dakota's hazardous waste program revisions satisfy all of the requirements necessary to qualify for Final authorization. For a list of rules that become effective with this Final Rule, please see the Proposed Rule published in the September 27, 2005 **Federal Register** at 70 FR 56419. EPA is making one correction to the Proposed Rule. In the list of authorized provisions for Checklists 154 through 154.6 (Column 1, page 56421), the effective date for ''74:36:11:01'' is January 2, 2005.

Response to Comments: EPA proposed to authorize South Dakota's State Hazardous Waste Management Program Revisions on September 27, 2005 (70 FR 56419). EPA received only one comment from the State of South Dakota, objecting to EPA's definition of Indian country, where the State is not authorized to administer its program. Specifically, the State disagreed that all ''trust land'' in South Dakota is Indian country. However, in the comment letter, the State of South Dakota conveyed to EPA that ''while we [the State] continue to object and disagree on this issue, the state will accept EPA's authorization of the hazardous waste program revisions as described in EPA's September 27, 2005 notice in the **Federal Register**.''

EPA maintains the interpretation of Indian country in South Dakota as described in the September 27, 2005 **Federal Register** notice of proposed rulemaking. Further explanation of this interpretation of Indian country can be found at 67 FR 45684 through 45686 (July 10, 2002).

II. Incorporation by Reference

In the Proposed Rule published on September 27, 2005 (70 FR 56419), EPA also proposed to codify EPA's authorization of South Dakota's base hazardous waste management program