B. Analytical Method(s)

A method for extraction and ELISA analysis of the Vip3Aa19 protein in cotton has been submitted and is under review by the Agency. For the temporary tolerance exemption, the ELISA method described with the expression data is sufficient.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the PIP *Bacillus thuringiensis* Vip3Aa19 protein and the genetic material necessary for its production in cotton.

VIII. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, this rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

IX. Congressional Review Act

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

List of Subjects in 40 CFR Part 174

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

Dated: April 26, 2007.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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

[PART 174—AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.452 is revised to read as follows:

§ 174.452 Bacillus thuringiensis Vip3Aa19 protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa19 protein in cotton are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant (PIP) in the food and feed commodities of cotton; vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit (EUP) 67979–EUP–7, which is being issued in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked May 1, 2008. However, if the EUP is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. E7–8951 Filed 5–8–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0965; FRL–8124–2]

Flufenacet; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes pesticide tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) for combined residues of flufenacet and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on grass (forage, hay), sweet corn (forage, kernel plus cob with husk removed, stover), wheat (bran, forage, grain, hay, straw), cattle kidney, goat kidney, hog kidney, horse kidney, and sheep kidney. Bayer Cropscience petitioned EPA to establish these tolerances.

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also

Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0965. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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 code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0965 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 July 9, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0965, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 20, 2006 (71 FR 76321) (FRL–8104–4), 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 0F6095) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.527 be amended by establishing a tolerance for combined residues of the herbicide flufenacet (*N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl] oxy] acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the food commodities: corn, sweet, forage at 0.4 parts per million (ppm); corn, sweet, kernel plus cob with husks removed at 0.05 ppm; corn, sweet, stover at 0.4 ppm; wheat, forage at 10.0 ppm; wheat, grain at 1.0 ppm; wheat, hay at 2.0 ppm; wheat, straw at 0.5 ppm; seed-grass, forage at 7.0 ppm; seed-grass, forage, regrowth at 0.1 ppm; seed-grass, hay, regrowth at 0.5 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

After completing a review of the submitted data, the Agency determined that additional tolerances are needed in connection with the petitioned-for tolerances for wheat bran 0.80 ppm, grass forage at 7.0 ppm, and grass hay at 0.4 ppm, cattle kidney at 0.05 ppm, goat kidney at 0.05 ppm, hog kidney at 0.05 ppm, horse kidney at 0.05 ppm, and sheep kidney at 0.05 ppm. EPA determined that tolerance levels are needed that differ from those proposed by the registrant for sweet corn forage at 0.45 ppm (0.4 ppm proposed) sweet corn stover at 0.30 ppm, (0.4 ppm proposed) wheat forage at 6.0 ppm (10.0 ppm proposed), wheat grain at 0.60 ppm (1.0 ppm proposed), wheat hay at 1.2 ppm (2.0 ppm proposed), and wheat straw at 0.35 ppm (0.5 ppm proposed). EPA determined that tolerances are not necessary for fat, meat, and meat byproducts of cattle, goat, hog, horse,

and sheep. Since permanent tolerances are being established for wheat and kidney of cattle, goat, hog, horse, and sheep, emergency exemption tolerances for these commodities are being deleted.

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 combined residues of flufenacet. 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 flufenacet as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document, entitled *Flufenacet: HED Human Health Risk Assessment for Uses on Wheat, Perennial Grasses Grown for Seed and Sweet Corn* which is in the docket for this rule.

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. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for flufenacet used for human risk assessment can be found in Table 4 (p.14) of the document, entitled *Flufenacet: HED Human Health Risk Assessment for Uses on Wheat, Perennial Grasses Grown for Seed and Sweet Corn* which is in the docket for this rule.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.527) for the combined residues of flufenacet and its metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from flufenacet in food from existing and proposed tolerances 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.

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 1988 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 acute exposure assessments: Anticipated residues for many crops (field corn, soybean, sweet corn, and wheat) were developed using field trial data. Anticipated residues for livestock commodities were derived using available feeding and metabolism studies in conjunction with the anticipated dietary burden to ruminants, swine and poultry. Tolerance level residues were used to assess flufenacet exposure from the remaining commodities (i.e., cereal grains other than wheat). Exposure estimates for all commodities were further refined using percent crop treated (PCT) data. Projected PCT data were used to refine anticipated residues for the new food uses (sweet corn and wheat). Available processing data were used to refine anticipated residues for cereal grains and corn. For all other processed commodities, DEEM (ver. 7.81) default processing factors were assumed.

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 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Anticipated residues for many crops (field corn, soybean, sweet corn, and wheat) were developed using field trial data. Anticipated residues for livestock commodities were derived using available feeding and metabolism studies in conjunction with the anticipated dietary burden to ruminants, swine and poultry. Tolerance level residues were used to assess flufenacet exposure from the remaining commodities (i.e., cereal grains). Exposure estimates for all commodities were further refined using PCT data. Projected PCT data were used to refine anticipated residues for the new food uses (sweet corn and wheat). Available processing data were used to refine anticipated residues for cereal grains and corn. For all other processed

commodities, DEEM (ver. 7.81) default processing factors were assumed.

iii. *Cancer*. A cancer aggregate exposure assessment was not performed because flufenacet is not carcinogenic.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Chronic and acute dietary exposure analyses for sweet corn were based on projected PCT when treated with flufenacet of an average of 3% (used for chronic exposure assessment) and a maximum of 10% (used for acute exposure assessment). These projected PCT estimates were based on the following. Flufenacet has been registered and used on field corn since 1998. Field corn and sweet corn are the same species and there are many weeds and herbicides used to control those weeds which are common to the two crops. Therefore the use of flufenacet on field corn was used as the basis for predicting flufenacet use on sweet corn. EPA also analyzed other factors based on available information that included more recent usage of other acetamide herbicides on both field corn and sweet corn, information on new products desired for sweet corn, including flufenacet, to combat newly invasive weeds and resistant weeds, and differences in importance of individual herbicides between field corn and sweet corn.

Chronic and acute dietary exposure analyses for wheat were based on projected PCT when treated with flufenacet of an average of 1% and a maximum of 3%. These projected PCT estimates were based on the following: Emergency exemption uses have been issued for flufenacet on wheat for several years. EPA initially estimated the PCT for wheat based on recent PCTs for winter wheat due to emergency exemption usage. EPA later examined acres treated in individual states and compared that information to the treatment acres permitted under the emergency exemptions. EPA also analyzed other factors based on available information that included usage of metribuzin on winter wheat (since a new use is the combination metribuzin and flufenacet), current and past Emergency Exemption requests for flufenacet in the Northwest and on the East Coast to control resistant Italian ryegrass, and more recent usage data.

For all other commodities, PCT estimates were based on a screening level usage analysis of pesticide usage data from the following sources:

- USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service)—pesticide usage data from 1998 to 2003.
- NCFAP (National Center for Food and Agricultural Policy—pesticide usage data from 1997 and is only used if data is not available from the other sources.
- Private pesticide market research—pesticide usage data from 1998 to 2004.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described above for flufenacet on sweet corn, wheat, and grass forage and other commodities with existing registrations for flufenacet is reliable and has a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which flufenacet may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flufenacet 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 flufenacet. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppfeed1/models/water/index*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of flufenacet (plus its degradate thiadione in surface water) for acute exposures are estimated to be 8.64 parts per billion (ppb) for surface water and 0.10 ppb for ground water. The EECs for chronic exposures are estimated to be 2.23 ppb for surface water and 0.10 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).

Flufenacet 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 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 flufenacet and any other substances and flufenacet 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 flufenacet 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 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 indication of additional susceptibility of young rats or rabbits following prenatal exposure to flufenacet in the developmental toxicity studies. There was an indication of qualitative susceptibility in the 2–generation reproduction study. Effects seen in the offspring in the reproductive toxicity studies (including increased pup death in early lactation and cannibalism) were more severe than those seen in the parental animals (increased liver weight and cytomegaly), although there was no difference in the NOAELs/LOAELS between parental animals and offspring in that study. Increased susceptibility (qualitative and quantitative) was seen in the developmental neurotoxicity study in rats. Decreased body weight was seen in pups at all dose levels, and additional effects, including decreased motor activity, delayed developmental landmarks, and decreases in morphometric measurements were seen at mid and high doses. Morphometric measurements were not made at the low dose. A slight decrease in body weight in mid and high dose dams during early lactation may have been due to palatability of test substance and was not considered adverse.

The selection of 1.7 milligrams/kilograms/day (mg/kg/day) as a LOAEL for the developmental neurotoxicity study is considered to be a conservative recommendation as to the decreased body weight effect, because the decrease in pup body weight at that dose is transient, and a similar decrease was not seen in the 2–generation reproduction study (decreased pup body weight seen in the 1–generation range-finding reproduction study occurred at higher doses than those evaluated in the developmental neurotoxicity study).

3. *Conclusion*. Several factors weighed in favor of the conclusion that no additional safety factor is needed to protect the safety of infants and children. First, there was no evidence of increased susceptibility in the developmental toxicity studies (rats and rabbits), and qualitative susceptibility seen in the rat reproduction study did not raise concerns because the pup death may be attributable to maternal cannibalism, and there was a clear NOAEL for the effect. Second, there are also no additional residual uncertainties with respect to exposure data:

- The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- Although the exposure assessment from pesticide residues in food was somewhat refined, the assessment is based on reliable data and will not underestimate exposure/risk.
- There are no residential uses for flufenacet.

Nonetheless, for several reasons EPA determined that the 10X FQPA Safety Factor should be retained. The primary reason for retaining the additional safety factor is that there is uncertainty regarding the protectiveness of selected RfDs because of a lack of comparative susceptibility data for thyroid hormone levels. Secondarily there is also some uncertainty due to the lack of a NOAEL in the DNT for the decrease in morphometric measurements and body weight effects in pups and the lack of data on comparative sensitivity to neuropathologic lesions. Concerns with regard to these latter issues are more limited given dose response data on the morphometric changes indicating that these effects would not be expected at the low dose, the transient nature of the body weight effects seen at the low dose, and the fact that neuropathologic lesions were only seen at relatively high doses.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food plus drinking water to flufenacet will occupy 30% of the aPAD for the U.S. population, 25% of the aPAD for females 13 years and older, 89% of the aPAD for all infants (< 1 year old), and 42% of the aPAD for children 1–2 years old.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flufenacet from food plus drinking water will utilize 2.9% of the cPAD for the U.S. population, 9.2% of the cPAD for all infants (< 1 year old), and 4.4% of the cPAD for children 1–2 years old. There are no residential uses for flufenacet that result in chronic residential exposure to flufenacet. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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).

Flufenacet 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 exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Flufenacet 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*. Because flufenacet is classified as a ''not likely'' carcinogen, the Agency does not expect exposure to flufenacet to result in any cancer risk.

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 flufenacet residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatographic/single ion mode (GC/SIM) common moiety method) 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

Flufenacet is not in the Codex system, i.e., there are no established or pending Codex MRLs for flufenacet. Therefore, there are no harmonization issues.

V. Conclusion

Therefore, the tolerances are established for combined residues of flufenacet, (*N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl] oxy] acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety, in or on grass forage at 7.0 ppm, grass hay at 0.4 ppm, sweet corn forage at 0.45, sweet corn kernel plus cob with husk removed at 0.05 ppm, sweet corn stover at 0.30 ppm, wheat bran at 0.80 ppm, wheat forage at 6.0 ppm, wheat grain at 0.60 ppm, wheat hay at 1.2 ppm, wheat straw at 0.35 ppm, cattle kidney at 0.05 ppm, goat kidney at 0.05 ppm, hog kidney at 0.05 ppm, horse kidney at 0.05 ppm, and sheep kidney at 0.05 ppm. Section 18 emergency exemption tolerances are deleted for flufenacet in or on wheat (forage, grain, hay, straw) and fat, kidney, meat, and meat byproducts of cattle, goat, hog, horse, and sheep.

VI. 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.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, 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 final 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: May 1, 2007.

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 180.527 is amended as follows:
■ i. By revising the section heading;
■ ii. By revising paragraph (a);
■ iii. By removing the text of paragraph (b) and reserving with heading;
■ iv. By revising the introductory text of paragraph (c) and adding commodities to the table; and
■ v. By revising the introductory text of paragraph (d).

The amendments read as follows:

§ 180.527 Flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-N-methylethyl benzenamine tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following commodities.

Commodity	Parts per million
Cattle, kidney	0.05
Corn, field, forage	0.4
Corn, field, grain ...	0.05
Corn, field, stover	0.4
Corn, sweet, forage	0.45
Corn, sweet, kernel plus cob with husks removed ..	0.05
Corn, sweet, stover	0.30
Goat, kidney	0.05
Hog, kidney	0.05
Horse, kidney	0.05
Sheep, kidney	0.05
Soybean, seed	0.1
Wheat, bran	0.80
Wheat, forage	6.0
Wheat, grain	0.60
Wheat, hay	1.2
Wheat, straw	0.35

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

(c) *Tolerances with regional registrations.* Tolerances are established for combined residues of flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide, and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety, with regional registration.

Commodity	Parts per million
Grass, forage	7.0
Grass, hay	0.4

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities when present therein as a result of application of flufenacet to the growing crops in paragraph (a) of this section.

* * * * *

[FR Doc. E7–8936 Filed 5–8–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0535; FRL–8127–2]

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of clethodim and certain of its metabolites in or on asparagus; flax, seed; herb, subgroup 19A; hop, dried cones; leafy greens subgroup 4A; safflower, meal; safflower, seed; sesame, seed; and vegetable, legume, group 6, except soybean. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0535. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*,or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to