G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Protection of Children From Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

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) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective July 25, 2003.

K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 25, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, New source review, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 16, 2003.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 03–16028 Filed 6–24–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0181; FRL–7313–9]

Flufenacet (N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule. SUMMARY:

This regulation establishes a tolerance 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 corn, field, forage; corn, field, grain; corn, field, stover; and soybean, seed; and for indirect or inadvertent residues for flufenacet and its metabolites in or on alfalfa, forage; alfalfa, hay; alfalfa, seed; clover, forage; clover, hay; grain, cereal, group 15, except rice; grain, cereal, forage, fodder and straw, group 16, except rice; and grass, forage, fodder, and hay, group 17. BayerCropScience 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 June 25, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0181, must be received on or before August 25, 2003.

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

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), 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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0181. The official public

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

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the'' **Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_(_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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

II. Background and Statutory Findings

In the **Federal Register** of March 20, 2003 (68 FR 13703) (FRL–7296–5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 6F4631 and 0F6095) by BayerCropScience, P.O. Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petitions prepared by BayerCropScience, the registrant. One comment was received in response to this notice of filing by B. Sachau, 15 Elm Str., Florham Park, NJ 07932. Mr. Sachau objected generally to the presence of pesticides in food and specifically to the presence of flufenacet.

Bayer requested in petition 6F4631 that 40 CFR 180.527 (a) be amended by making the currently time-limited tolerances 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] permanent in or on the following agricultural commodities: Corn, field, forage at 0.4 ppm; corn, field, grain at 0.05 ppm; corn, field, stover at 0.4 ppm; and soybean, seed at 0.1 ppm.

Bayer requested in petition 0F6095 that the section 18 tolerances listed below in 40 CFR 180.527 (b) 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 it's metabolites containing 4-fluoro-*N*-methylethyl benzenamine moiety] be made permanent and moved to 40 CFR 180.527 (a), cattle, fat at 0.05 ppm; cattle, kidney at 0.5 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.1 ppm; goat, fat at 0.05 ppm; goat, kidney at 0.5 ppm; goat, meat at 0.05 ppm; goat, meat byproducts at 0.1 ppm; hog, fat at 0.05 ppm; hog, kidney at 0.5 ppm; hog, meat at 0.05 ppm; hog, meat, byproducts at 0.1 ppm; horse, fat at 0.05 ppm; horse, kidney at 0.5 ppm; horse, meat at 0.05 ppm; horse, meat byproducts at 0.1 ppm; sheep, fat at 0.05 ppm; sheep, kidney at 0.5 ppm; sheep, meat at 0.05 ppm; sheep, meat byproducts at 0.1 ppm; wheat, forage at 10.0 ppm; wheat, grain at 1.0 ppm; wheat, hay at 2.0 ppm; and wheat, straw at 0.50 ppm.

Bayer requested in petition 0F6095 that the currently time limited tolerances in 40 CFR 180.527 (d) be amended by establishing permanent tolerances 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 from the application of this herbicide to the raw agricultural commodities listed in 40 CFR 180.527 (a) and (b) at the levels listed below Table 1:

TABLE 1.—TOLERANCE LEVELS

Commodity	Current level in Parts per Million	Level in Parts per Million proposed by Bayer
Alfalfa, forage	0.1	0.1
Alfalfa, hay	0.1	0.1
Alfalfa, seed	0.1	0.1
Clover, forage	0.1	0.1
Clover, hay	0.1	0.1
Grain, cereal, group 15, except rice	0.1	0.4
Grain, cereal, forage, fodder, and straw, group 16, except rice	0.1	10.0
Grass, forage, fodder and hay, group 17	0.1	0.1

The Agency's current review did not include the data submitted with petition 0F6095. Therefore, the Agency is leaving the section 18 time limited tolerances listed in 40 CFR 180.527 (b) unchanged. The time limited tolerances listed in 40 CFR 180.527 (b) were issued in connection with a section 18 and were extended to July, 2005 on January 16, 2003 (68 FR 2242)(FRL–7284–8). The section 18 tolerances are not being modified in this notice but are included in the risk assessments discussed below. In addition, since the Agency's current review did not include the data submitted with petition 0F6095 and the risk assessment outlined below indicated that the risk cup was full, the tolerances for indirect or inadvertent residues listed in 40 CFR 180.527(d) will be made permanent but the levels will remain unchanged.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information..'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances 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 on corn, field, forage at 0.4 ppm; corn, field, grain at 0.05 ppm; corn, field, stover at 0.4 ppm; soybean, seed at 0.1 ppm by establishing permanent tolerances 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 metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities from the application of this herbicide to the raw agricultural commodities, listed in 40 CFR 180.527 (a) and (b), alfalfa, forage at 0.1 ppm; alfalfa, hay at 0.1 ppm; alfalfa, seed at 0.1 ppm; clover, forage at 0.1 ppm; clover, hay at 0.1 ppm; grain, cereal, group 15, except rice at 0.1 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice at 0.1 ppm; and grass, forage, fodder, and hay, group 17 at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by flufenacet are discussed in Table 2 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 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents - rat	NOAEL = <6.0 (male [m], 7.2 (female [f]) milligram/kilogram/day (mg/kg/day) LOAEL = 6.0(m) mg/kg/day based on decreased T4; 28.8 mg/kg/day (f) and on hematology and clinical chemistry findings
870.3100	90–day feeding - mouse	NOAEL(mg/kg/day)=18.2(m),24.5(f), LOAEL (mg/kg/day)=64.2 (m), 91.3(f) based on systemic toxicity and histopathology of the liver, spleen, and thyroid.
870.3150	90–Day oral toxicity in nonrodents	NOAEL (mg/kg/day)= 1.67 (m);1.70 (f). LOAEL (mg/kg/day)= 7.20 (m); 6.90 (f) based on increases in LDH, globulin, and spleen pigment in females, decreased T4 and ALT values in both sexes, decreased albumin in males, and decreased serum glucose in females
870.3200	21/28–Day dermal toxicity	Dermal irritation NOAEL(mg/kg/day)=1000 (m and f) Systemic toxicity NOAEL mg/kg/day) = 20(m); 150(f) LOAEL(mg/kg/day)= 150(m);1,000(f) based on decreased T4 and FT4 levels in both sexes and histopathological findings in females
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 25 mg/kg/day LOAEL = 125 mg/kg/day based on decreased BWG initially Developmental NOAEL = 25 mg/kg/day LOAEL = 125 mg/kg/day based on decreased fetal body weight, delayed ossificaition in skull, vertebrae, sternebrae, and appendages, and increased extra ribs.
870.3700	Prenatal developmental toxicity in nonrodents (rabbits)	Maternal NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on histopathological findings in liver. Developmental NOAEL = 25 mg/kg/day LOAEL = 125 mg/kg/day based on increased skeletal variations.
870.3800	Reproduction and fertility effects - rat	Parental/Systemic NOAEL = 1.4 (m), 1.5(f) mg/kg/day LOAEL = 7.4 (m), (8.2 (f) mg/kg/day based on increased liver weight in F1 females and hepatocytomegaly in F1 males Reproductive NOAEL = 1.3 mg/kg/day LOAEL = 6.9 mg/kg/day based on increased pup death in early lactation (including cannibalism) for F1 liters and the same effects in F1 and F2 pups at 36 mg/kg/day.

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4100	Chronic toxicity dogs	NOAEL = 1.29(m), 1.14(f) mg/kg/day LOAEL = 27.75 (m), 26.82(f) mg/kg/day based on increased alkaline phosphatase, kidney, and liver weight in both sexes, increased cholesterol in males, decreased T3, T4, and ALT values in both sexes, and increased incidences of microscopic lesions in the brain, eye, kidney, spinal cord, sciatic nerve, and liver.
870.4300	Chronic toxicity/ oncogenicity in rodents (rat)	NOAEL =1.2 (m), 1.5 (f) mg/kg/day LOAEL = 19.3 (m), 24.4(f) mg/kg/day based on methemoglobinemia and multi-organ effects in blood, kidney, spleen, heart, brain, eye, liver and uterus. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = <7.4 ((m), 9.4 (f) mg/kg/day LOAEL = 7.4 (m), 38.4 (f) mg/kg/day based on increased incidence and severity of cataracts. No evidence of carcinogenicity
870.5100 870.5395 870.5375 870.5375 870.5550	Gene Mutation Cytogenetics Other Effects	Ames Assay *S. typhimurium* not mutagenic *In vivo* mammalian cytogenetics—micronucleus assay (mouse) not mutagenic. *In vitro* mammalian cytogenetics- Chinese hamster lung fibroblasts (V79) cells not mutagenic. *In vitro* cytogenetics chromosomal analysis of cultured CHO cells-not mutagenic. Unscheduled DNA synthesis in rat hepatocytes *in vitro*-not mutagenic.
870.6200	Acute neurotoxicity screening battery	NOAEL = <75 (m and f) mg/kg/day LOAEL = 75 (m and f) mg/kg/day based on clinical signs in females (uncoordinated gait and decreased activity) and decreased motor activity in males.
870.6200	Subchronic neurotoxicity screening battery	NOAEL = 7.30 (m), 8.40 (f) mg/kg/day LOAEL = 38.1 (m), 42.6 (f) mg/kg/day based on microscopic lesions (including axonal swelling in brain and spinal cord).
870.6300	Developmental neurotoxicity	Maternal NOAEL = 40.8 mg/kg/day LOAEL = not determined (no adverse effects seen). Offspring NOAEL = <1.7 mg/kg/day LOAEL = 1.7 mg/kg/day based on decreased pre- weaning body weight and body weight gain.
870.7485	Metabolism and pharmacokinetics	Rapidly absorbed and metabolized following oral exposure to either single or multiple doses. The urine was the major route of excretion with small amount excreted via feces. Significant amounts of radiolabel were eliminated as CO_2 and CH_4. A maximum of 7% of the total recovered radiolabel was found in the tissues and residual carcass. Twenty-five metabolites arising from the fluorophenyl portion of the molecule were detected in excreta, and 17 of these were identified. The total amount of radiolabel identified ranged from [Fluorophenyl-UL-^{14}C] FOE 5043 67%-86%; [Thiadiazole-2-^{14}C] FOE 5043 84%-92%; and [Thiadiazole-5-^{14}C] FOE 5043 53%-69%. All unidentified residues in excreta were characterized .
n/a	Metabolism/Mechanism	Hypothesis of an extrathyroidal mechanism of action for FOE 5043 (flufenacet) Hypothesis of an extrathyroidal mechanism of action for FOE 5043-supplement to above.
n/a	Metabolism/Metabolite	Evaluated a hypothesis that the neurotoxicity observed in dogs dosed with high levels of FOE 5043 was caused by metabolic limitations.

B. Toxicological Endpoints

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

The Agency imposed an additional 10X safety factor to account for uncertainties arising because available data support the possibility of decreases in thyroid hormones at dose levels similar to those used in the submitted rat developmental neurotoxicity study (DNT) as well as the lack of a NOAEL in the rat developmental neurotoxicity study. To address these concerns the Agency will require a special comparative assay on thyroid hormone levels in neonatal and adult rats as a condition of registration. The Agency also had a concern for a lack of a NOAEL in the rat developmental neurotoxicity study and for the decrease in morphometric measurements in adult females which were not measured at the lowest dose. The doses and endpoints for various risk assessments and the uncertainty factors applied are expected to adequately address uncertainties

arising from the missing data and a lack of a NOEL in the DNT study.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF. For flufenacet, the Agency concluded that the Special FQPA Safety Factor could be reduced to 1X, based on the low degree of concern and lack of residual uncertainties for pre- and post-natal toxicity as outlined in Unit III.D.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenicity 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 flufenacet used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUFENACET FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	LOAEL = 1.7 mg/kg/day UF = 1,000X Acute RfD = LOAEL/UF = 0.0017 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.0017 mg/kg/day	Developmental Neurotoxicity study in rats. LOAEL = 1.7 mg/kg/day based on decreased body weight/body weight gain, and missing morphometric measurements in caudate/putamen, in pups.
Chronic Dietary (All populations)	LOAEL= 1.7 mg/kg/day UF = 1,000 Chronic RfD = LOAEL/UF = 0.0017 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/ FQPA SF = 0.0017 mg/kg/day	Developmental Neurotoxicity study in rats. LOAEL = 1.7 mg/kg/day based on decreased body weight/body weight gain in pups.
Cancer (oral, dermal, inhalation)	Classifed as 'Not Likely' to be a carcinogen.		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect- level, LOAEL = lowest-observed-adverse-effect-level, PAD = population-adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable/Not Required.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.527) for the 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 a variety of raw agricultural commodities. Tolerances have been established on meat, fat, kidney, and meat byproducts of cattle, goats, hogs, horses, and sheep, wheat grain, forage, hay, and straw in connection with a section 18. These tolerances expire July, 2005 and have been included in the risk assessments. Risk assessments were conducted by EPA to assess dietary exposures from flufenacet in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA [1994–1996 and 1998] nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated expoure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments:

a. Anticipated-residue estimates were assumed for some commodities (field corn, soybeans, and wheat);

b. Tolerance-level residues were assumed for some crops (cereal grains); and

c. Percent crop-treated estimates were utilized for all crops.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the 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:

a. Anticipated-residue estimates were assumed for some commodities (field corn, soybeans, and wheat);

b. Tolerance-level residues were assumed for some crops (cereal grains); and

c. Percent crop-treated estimates were utilized for all crops.

iii. *Cancer.* Flufenacet is not carcinogenic, therefore a quantitative cancer risk assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the 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 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. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the 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 the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows.

Based on current use, the Agency used the following percent crop treated estimates: Field corn 2%, soybeans1%, and wheat 1%,. For crops planted in rotation (cereal grains), 2% crop treated was assumed as this is the highest estimate for the primary crops. For livestock commodities, a percent crop treated estimate of 1%, corresponding to the use on wheat, was utilized. The Agency has previously concluded that secondary residues of flufenacet in livestock commodities would not result from the use of flufenacet on corn or soybeans but would result from the section 18 use on wheat.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. 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.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of flufenacet for acute exposures are estimated to be 9.9 parts per billion (ppb) for surface water and 0.21 ppb for ground water. The EECs for chronic exposures are estimated to be 1.3 ppb for surface water and 0.21 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 exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether flufenacet has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. No increase in susceptibility was seen in rat and rabbit developmental studies, but qualitative and/or quantitative increases in susceptibility were seen in the rat reproduction study and in the rat developmental neurotoxicity studies.

3. *Conclusion*. The toxicology data base for flufenacet is complete except for a special comparative assay on thyroid hormone levels in neonatal and adult rats and a 28-day inhalation toxicity study in rats. The exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The Agency evaluated the potential for increased susceptibility of infants and children from exposure to flufenacet. The Agency concluded that there is a low degree of concern and lack of residual uncertainties for pre- and post-natal toxicity in the rat reproduction study and the rat and rabbit developmental toxicity studies. The Agency determined that the concern is also low for susceptibility seen in the developmental neurotoxicity (DNT) study. Multiple offspring effects were seen at the mid- and high doses, and no adverse maternal effects were seen at any dose. However, the only effect seen at the lowest dose in offspring was a transient decrease in body weight. The concern for the decrease in the offspring weights was reduced because no decrease in body weight was seen in the offspring in the reproduction study .

The Agency considered the lack of comparative data for thyroid hormone levels in adult and neonatal animals. Available data support the possibility of decreases in thyroid hormones in adult animals (decreases were observed in several studies conducted in rats, mice, rabbits, and dogs) at dose levels similar to those used in the submitted DNT study. Because of the above concern, a special comparative study on thyroid hormone levels in neonatal and adult rats is being requested by the Agency as a condition of registration. The Agency also noted that morphometric measurements could be incorporated into the comparative thyroid assay to confirm the findings observed in adult female offspring in the DNT (data for this endpoint were not available at the low dose).

Due to the concerns regarding the possibility of decreases in thyroid hormones and the need for comparative susceptibility data on this issue as well as the lack of a NOAEL in the DNT, EPA found no basis to remove the 10X FQPA safety for the protection of infants and children. EPA considers this additional 10X factor to be an uncertainty factor to address the deficiencies in the database.

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to flufenacet will occupy 23% of the aPAD for the U.S. population, 17 % of the aPAD for females 13 years and older, 23% of the aPAD for all infants and 48% of the aPAD for children 1-2 years. In addition, there is potential for acute dietary exposure to flufenacet in drinking water. Table 4 of this unit presents the EECs and DWLOCs for the major populations subgroups.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUFENACET

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.0017	23	9.9	0.21	46
All Infants	0.0017	23	9.9	0.21	13
Children (1-2 yrs)	0.0017	48	9.9	0.21	9
Children (3-5 yrs)	0.0017	42	9.9	0.21	10
Children (6-12 yrs)]	0.0017	29	9.9	0.21	12
Youth (13-19 yrs)	0.0017	21	9.9	0.21	41
Adults (20-49 years)	0.0017	20	9.9	0.21	47
Females (13-19 years)	0.0017	17	9.9	0.21	42

The EECs are less than calculated DWLOCs for acute exposure to flufenacet in drinking water, except for the population subgroup, children 1-2 years old, where the EEC marginally exceeds the DWLOC.

In evaluating the acceptability of these estimated risks, EPA has taken into account that the risk assessment was performed by estimating exposure at the 99.9th percentile of exposure. As EPA has explained in its policy regarding use of population percentiles in estimating exposure, EPA generally uses the 95th percentile when conducting an exposure assessment with unrefined residue values (i.e. assuming all covered food contains tolerance level residues) and the 99.9th percentile when using highly refined residue values (i.e. monitoring values). See U.S. EPA, Office of Pesticide Programs, Choosing A Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern 17 (March 16, 2000) (*http://www.epa.gov/pesticides/trac/science/trac2b054.pdf*). The residue values used in the flufenacet risk assessment fall somewhere between highly refined and unrefined. Although the Agency did use data bearing on percent crop treated, three other aspects of the assessment made it not particularly refined, and therefore, somewhat conservative (i.e. tending to overstate exposure). First, EPA assumed tolerance level residues for all crops covered by tolerances designed to address the possibility of flufenacet residues being present in crops grown at a later date in the same field as the treated crop. These rotational crop tolerances include rice and sorghum. Further, compounding this conservative assumption, EPA assumed that two percent of all of the crops covered by rotational crop tolerances would contain flufenacet residues even though the treatment rate for wheat and soybeans was at a one percent level (only corn was at the two percent level) and it is unlikely, in any event, that the crops covered by the rotational crop tolerances would, in their entirety, be grown in a rotational program.

Second, and probably most important, for those crops for which EPA did not assume tolerance level residues (corn, wheat, and soybeans) EPA did not use monitoring data (i.e. data collected from food as it moves in the channels of trade) but data from crop field trials. Crop field trials are studies conducted to determine the maximum residue levels that can occur under the limits imposed by the pesticide's label. Accordingly, such studies involve applying the pesticide, pursuant to its label, the maximum number of times at the maximum application rate and harvesting the crop as promptly as soon as permitted following the last pesticide treatment. These studies overstate the residue levels that consumers are exposed to for two reasons. First, in crop field studies, residue levels are measured at harvest and thus do not reflect the degradation that generally occurs during the production, shipping, and storage of food prior to sale to the consumer. Second, farmers are not required to apply pesticides in the manner used in crop field trials but generally may use lower amounts than those specified on the label, apply the pesticide less frequently than the number of applications permitted by the label, and wait longer to harvest the crop than the minimum pre-harvest interval prescribed by the label. See 7 U.S.C. 136a(ee). Such practices reduce residue values, normally by significant amounts. With flufenacet, the decrease will be even more significant than usual because some of the field trial data are based upon an application rate of 0.9 lbs. a.i. acre per season v.s. the label rate of 0.79 lbs. a.i. acre per season for field corn and 0.9 lbs. a.i. acre per season v.s. the label rate of 0.45 lbs. a.i. per acre per season for soybeans.

A third aspect of the flufenacet exposure assessment that overstated residue levels was the fact that EPA did not use processing reduction factors. Processing studies are performed in order to show whether or not residues concentrate in processed commodities of the RAC. For example wheat grain, may be processed into bran, flour, middlings, shorts and germ. Processing studies frequently show residues decreasing in the processed commodities. If the residues decrease in the processed commodity, we may be able to determine a reduction factor. The concentration and/or reduction factors are directly applied to the residue level used in the dietary exposure assessment for that commodity. The processing studies for flufenacet treated corn and soybeans showed no detectable residues. However, the Agency for this risk assessment assumed the residues in the raw agricultural commodity were carried through undiminished to the processed commodities.

As EPA has made clear, even when an exposure assessment is based on highly refined data, an indication that exposure at the 99.9th percentile poses a risk of concern is merely the starting point for assessing the ultimate safety of the pesticide. EPA has detailed a number of steps that are important to assess the accuracy of any 99.9th percentile estimate including sensitivity analyses and scrutiny of data inputs. When an assessment does not rely on highly refined exposure data there is an even greater need for close examination of

any risk estimates. As outlined above, there are several aspects of the flufenacet exposure assessment that are likely to significantly inflate exposure, and thus risk, estimates. Taking this into account as well as the fact that a risk analysis using a 99.8th population percentile raises the DWLOC for children between 1 and 2 years old to 12 ppb and thus above the EEC of 9.9 ppb, EPA concludes that flufenacet does not show a acute risk of concern.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flufenacet from food will utilize <1 % of the cPAD for the U.S. population, <1 % of the cPAD for all infants and 1.0 % of the cPAD for children (1-2 yrs). In addition, there is potential for chronic dietary exposure to flufenacet in drinking water. There are no residential uses for flufenacet and therefore, no chronic residential exposure to flufenacet. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUFENACET

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0017	<1.0	1.3	0.21	59
All Infants	0.0017	<1.0	1.3	0.21	17
Children (1-2 yrs)	0.0017	1.0	1.3	0.21	17
Youth (13-19 yrs)	0.0017	<1.0	1.3	0.21	51
Adults (20-49 yrs)	0.0017	<1.0	1.3	0.21	59

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*. Flufenacet is not carcinogenic, therefore no aggregate cancer risk is expected.

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 chromotography /mass spectrometry with selected ion monitoring) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances for flufenacet on corn, soybeans, wheat or livestock commodities.

C. Conditions

The following studies are required as a condition of registration.

1. A special comparative sensitivity study on thyroid hormone levels in neonatal and adult rats.

2. 28-day inhalation toxicity study in rats.

V. Comments

One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. Mr. Sachau objected generally to the presence of pesticides in food and specifically to the presence of flufenacet. Mr. Sachau also proposed that the U.S. establish testing on humans instead of dogs and rats.

Mr. Sachau comment 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 flufenacet, including all anticipated dietary exposures and all other exposures for which there is reliable information.

VI. Conclusion

Therefore, the tolerance is 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] on corn, field, forage at 0.4 ppm; corn, field, grain at 0.05 ppm; corn, field, stover at 0.4 ppm; soybean, seed at 0.1 ppm by establishing permanent tolerances 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 from the application of this herbicide to the raw agricultural commodities, listed in 40 CFR 180.527 (a) and (b), alfalfa, forage at 0.1 ppm; alfalfa, hay at 0.1 ppm; alfalfa, seed at 0.1 ppm; clover, forage at 0.1 ppm; clover, hay at 0.1 ppm; grain, cereal, group 15, except rice at 0.1 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, at 0.1 ppm; and grass, forage, fodder and hay, group 17 at 0.1 ppm. These tolerances replaced currently expiring tolerances in § 180.527 (a) and (d).

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0181 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 August 25, 2003.

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

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

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0181, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. 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 record keeping requirements.

Dated: June 12, 2003.

Peter Caulkins,

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), 346(a) and 371.

■ 2. Section 180.527 is amended by revising paragraphs (a) and (d) to read as follows:

§ 180.527 N-(4-fluorophenyl)-N-(1-methylethyl)-2-[(5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl)oxy]acetamide; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide *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:

Commodity	Parts per million
Corn, field, forage	0.4
Corn, field, grain	0.05
Corn, field, stove	0.4
Soybean, seed	0.1

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide *N*-(4-fluroophenyl)-*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 raw agricultural commodities listed in paragraph (a) of this section.

Commodity	Parts per million
Alfalfa, forage	0.1
Alfalfa, hay	0.1
Alfalfa, seed	0.1
Clover, forage	0.1
Clover, hay	0.1
Grain, cereal, group 15, except rice	0.1
Grain, cereal, forage, fodder, and straw, group 16, except rice	0.1
Grass, forage, fodder, and hay, group 17	0.1

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0179; FRL–7311–5]

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II. of the **SUPPLEMENTARY INFORMATION.** These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective June 25, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0179, must be received by EPA on or before July 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand