informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action does not include a Federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by state and local governments, or EPA consults with state and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts state law unless the Agency consults with state and local officials early in the process of developing the proposed regulation.

EPA has concluded that this rule may have federalism implications. The only reason why this rule may have federalism implications is if in the future a CISWI unit is found within the State of New Jersey the unit will become subject to the Federal Plan until a State Plan is approved by EPA. However, it will not impose substantial direct compliance costs on state or local governments, nor will it preempt state law. Thus, the requirements of sections 6(b) and 6(c) of the Executive Order do not apply to this rule.

Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination With Indian Tribal Governments'' (65 FR 67249, November 9, 2000), 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.'' This final rule does not have tribal implications, as specified in Executive Order 13175. It 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. Thus, Executive Order 13175 does not apply to this rule.

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.

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.

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.

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Acid gases, Carbon monoxide, commercial and industrial solid waste incinerators, Intergovernmental relations, Organics, Particulate matter, Lead, Reporting and recordkeeping requirements.

Dated: September 16, 2004.

Jane M. Kenny,

Regional Administrator, Region 2.

■ Part 62, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

■ 1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart FF—New Jersey

■ 2. Part 62 is amended by adding new § 62.7604 and an undesignated heading to subpart FF to read as follows:

Air Emissions From Existing Commercial and Industrial Solid Waste Incinerator Units

§ 62.7604 Identification of plan—negative declaration.

Letter from the New Jersey Department of Environmental Protection, submitted March 4, 2004, certifying that there are no commercial and industrial solid waste incinerators in the State of New Jersey subject to part 60, subpart DDDD of this chapter.

[FR Doc. 04–21496 Filed 9–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0286; FRL–7678–6]

Penoxsulam, 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of penoxsulam 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide in or on rice,grain and rice, straw. Dow AgroSciences LLC 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 September 24, 2004. Objections and requests for hearings must be received on or before November 23, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0286. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne]@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 6, 2003 (68 FR 46609) (FRL–7320–4), 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 3F6542) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268–1054. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide penoxsulam, 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide, in or on rice, grain at 0.01 parts per million (ppm), rice, straw at 0.5 ppm, rice, hulls at 0.01 ppm, rice, bran at 0.01 ppm, and rice, polished rice at 0.01 ppm. That notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing. The tolerance for rice grain was increased to 0.02 ppm to reflect the submitted field residue data. Residues of penoxsulam do not concentrate in the processed commodities, rice hull, bran, or polished rice, therefore any residues of penoxsulam on these commodities will be covered by the tolerance on rice, grain.

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 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 FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of penoxsulam on rice, grain at 0.02 ppm and rice, straw at 0.5 ppm. No tolerances were necessary for the rice process commodities, rice hulls, bran, or polished rice, because residues will not exceed the established tolerance in rice, grain. 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 penoxsulam are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-day oral toxicity-rat	NOAEL = Male (M): 50/Female (F): 250 milligrams/kilogram/day (mg/kg/day) LOAEL = M: 250 mg/kg/day based on decease body weight/body weight gain (bw/bwg), decease food consumption, and decease RBC parameters and F:500 mg/kg/day based on increase mineralization and hyperplasia of the kidney pelvic epithelium
870.3100	90-day oral toxicity-mouse	NOAEL= M:1027 highest dose tested (HDT)/F:1029 HDT mg/kg/day LOAEL= M: Not determined, >1027 HDT/F:>1029 HDT mg/kg/day
870.3150	90-day oral toxicity- dog	NOAEL = M: 17.8/F: 19.9 mg/kg/day LOAEL = M:49.4/F:57.1 mg/kg/day based on histopathologic changes in kidney
870.3200	28-day dermal Test Material: technical	NOAEL = M:1,000/F:1,000 mg/kg/day LOAEL = M:>1,000 HDT/F: >1,000 HDT
870.3200	Test Material: 21.9% formulated GF-443 material, rat	NOAEL= M:500/F:1,000 mg/kg/day LOAEL = M:1,000 mg/kg/day based on very slight hyperplasia at test site and F:>1,000 HDT mg/kg/day
870.3700	Prenatal developmental-rat	Maternal NOAEL = 500 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decease bwg, decease food consumption, and decease kidney weights Developmental NOAEL = 1,000 HDT mg/kg/day Developmental LOAEL = >1,000 HDT
870.3700	Prenatal developmental-rabbit	Maternal NOAEL = 25 mg/kg/day Maternal LOAEL = 75 mg/kg/day based on death, clinical signs, decease bwg, and decease food consumption Developmental NOAEL = 75 mg/kg/day Developmental LOAEL = >75 HDT
870.3800	2-Generation Reproduction and fertility effects in rats	Parental/Systemic NOAEL = M:100/F:30 mg/kg/day Parental/Systemic LOAEL = M:300 mg/kg/day based on decease bw of F1 males Parental/Systemic LOAEL = F:100 mg/kg/day based on kidney lesions Reproductive/Offspring NOAEL = 30 mg/kg/day Reproductive/Offspring LOAEL = 100 mg/kg/day based on delayed preputial separation
870.4100	Chronic toxicity-dogs	NOAEL = M:14.7/F:44.8 HDT mg/kg/day LOAEL = M:46.2 mg/kg/day based on slight multifocal hyperplasia in the kidney epithelium and F:> 44.8 HDT
870.4100	Chronic toxicity- rats	NOAEL = M:50/F:50 mg/kg/day LOAEL = M:250 mg/kg/day based on decease bw/bwg, decease RBC parameters, increase BUN, increase urine volume, decease urine specific gravity, increase kidney wt., increase crystals/calculi in kidney and urinary bladder, hyperplasia of kidney pelvis epithelium and urinary bladder mucosa, and increase severity of chronic glomerulonephropathy
870.4200	Carcinogenicity- rats	LOAEL = F:250 mg/kg/day based on decease bw/bwg, increase urine volume, increase crystals/calculi in urinary bladder, hyperplasia of kidney pelvis epithelium and urinary bladder mucosa
870.4200	Carcinogenicity	Evidence of carcinogenicity in male rats based on possibly treatment related increase incidence of Large Granular Lymphocyte (LGL) Leukemia at 5, 50, & 250 mg/kg/day. Also increase severity at 250 mg/kg/day. Female rats - negative for carcinogenicity, but dosing was only marginally adequate.
870.4300	Carcinogenicity-mice	NOAEL = M:>375 HDT/F:>750 HDT mg/kg/day LOAEL = M:>375 HDT/F:>750 HDT In males, negative for carcinogenicity at doses tested. Dosing inadequate. In females, negative for carcinogenicity at the doses tested. Dosing adequate (750 mg/kg/day is sufficiently close to limit dose of 1,000 mg/kg/day).

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

Guideline No.	Study Type	Results
870.5100	MUTA-Reverse Gene mutation - *S.typhimurium*/ *E. coli*	Negative with and without rat S-9 activation
870.5300	Muta-forward gene mutation (CHO Cells/HGPRT locus)	Negative with and without rat S-9 activation
870.5375	Muta-*in vitro* Mammalian Cytogenetics (Chromosomal aberrations in primary rat lymphocytes)	Negative with and without rat S-9 activiation
870.5395	Muta-*in vivo* Micronucleus, Mice (bone marrow cells)	Negative at oral doses (once per day on two consecutive days) of up to 2,000 mg/kg
870.6200	Acute neurotoxicity screening battery	NOAEL = M/F 2,000 HDT mg/kg/day LOAEL = M/F >2,000 HDT
870.6200	Chronic neurotoxicity screening battery	NOAEL = M/F 250 mg/kg/day LOAEL = M/F >250 (HDT) mg/kg/day

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/ exposures) is calculated.

A summary of the toxicological endpoints for penoxsulam used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PENOXSULAM 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 (all populations)	None UF = N/A	Not applicable	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on penoxsulam.
Chronic Dietary (all populations)	NOAEL= 14.7 mg/kg/day UF = 100 Chronic RfD = 0.147 mg/kg/day	Special FQPA SF = 1x cPAD = chronic RfD Special FQPA SF = 0.147 mg/kg/day	1-Year Chronic Feeding Study in Dogs. LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the pelvic epithelium of the kidney.
Incidental Oral Short-Term (1 - 30 days)	NOAEL = 17.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL = 17.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Dermal Short-Term (1 - 30 days)	None	Not applicable	No dermal, systemic, neuro or developmental toxicity concerns.
Dermal Intermediate-Term (1 - 6 months)	Oral study NOAEL= 17.8 mg/kg/day (dermal absorption rate = 50%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Dermal Long-Term > 6 months)	Oral study NOAEL= 14.7 mg/kg/day (dermal absorption rate = 50%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100.	1-Year Chronic Feeding Study in Dogs. LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the pelvic epithelium of the kidney.
Inhalation Short-Term (1 - 30 days)	Oral study NOAEL= 17.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Inhalation Intermediate-Term (1 - 6 months)	Oral study NOAEL= 17.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Inhalation Long-Term (> 6 months)	Oral study NOAEL= 14.7 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	1-Year Chronic Feeding Study in Dogs. LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the pelvic epithelium of the kidney.
Cancer (oral, dermal, inhalation)	Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential		

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, N/A = Not Applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.605) for the residues of penoxsulam, in or on a variety of raw agricultural commodities. Tolerances are established in/on rice, grain at 0.02 ppm and rice, straw at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from penoxsulam 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.

EPA did not identify a treatment-related effect observed in any of the available toxicity studies on penoxsulam that could be considered to have resulted from a single dose of the test material.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the Lifeline™ Model Version 2.0, which uses food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary analysis for penoxsulam was conducted using tolerance levels and 100% Crop Treated (CT) for the use on rice.

iii. *Cancer*. The Agency has classified penoxsulam as Suggestive Evidence of Carcinogenicity, But not sufficient to assess human carcinogenic potential and, therefore, quantification of human cancer risk is not required. The weight-

of-the-evidence for this classification is as follows:

a. Evidence of carcinogenicity (mononuclear cell leukemia (MNCL)) was seen in one sex (males) of one species (rat).

b. There was an increased incidence of MNCL at all dose levels with all incidences exceeding the laboratory historical control, however, the dose-response was flat over a wide range of doses.

c. Although MNCL is recognized as a common neoplasm in Fischer rats, the mechanism of producing MNCL is not completely understood. Therefore, the significance of MNCL and its biological relevance for human cancer risk remains uncertain and cannot be discounted.

d. There is no mutagenicity concern for penoxsulam.

e. SAR data are negative for MNCL.

Note: Although dosing in the male mice was not considered to be adequate, the Agency concluded that an additional mouse carcinogenicity study was not required. This was based on the following:

1. No treatment-related effects were seen up to the limit dose of a 1,000 mg/kg/day in a subchronic mouse study;

2. No hyperplasia was seen in the mouse carcinogenicity study at 350 mg/kg/day in males and 750 mg/kg/day in females;

3. No structural alerts were seen with the SAR data;

4. Rat data indicate saturation of absorption at 250 mg/kg/day; and

5. No mutagenic activity. Based on these data, the CARC determined that a repeat of the male mouse cancer study would have no impact on the regulation of penoxsulam.

iv. *Anticipated residue and percent crop treated (PCT) information.* For this analysis the tolerance levels and 100% CT for rice commodities were used.

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

The standard models used by EPA in assessing potential high end pesticide levels in surface water are not designed to address the agricultural practices involved in rice farming. EPA has recently developed a Tier I Aquatic Exposure Assessment method of estimating screening level concentrations in surface water to support regulatory decisions for pesticides used in rice agriculture that require ecological and human health risk assessments.

Under this method estimated environmental concentrations (EEC's) and estimated drinking water concentrations (EDWCs) for the use of pesticides in rice paddies are estimated by applying the total annual application to the paddy and partitioning the pesticide between the water and the paddy sediment according to a linear or K_d partitioning model. The EEC/EDWC ($\mu g. L^{-1}$) represents the dissolved concentration occurring in the water column and the concentration in water released from the paddy. Movement of pesticide on suspended sediment is not considered. The equation to use for this calculation is:

$EEC = 10^9 M_T/V_T + m_{sed}K_d$

where M_T is the total mass of pesticide in kg applied per ha of paddy, V_T is 1.067×10^6 L ha^{-1} which is the volume of water in a paddy 4 inches (10.16 cm) deep, and includes the pore space in a 1 cm sediment interaction zone. The mass of sediment, m_{sed}, is the amount found in the top 1 cm interaction zone and is 130,000 kg ha^{-1} when the sediment bulk density was assumed to be 1.3 kg L^{-1}, a standard assumption for the bulk density of surface horizons of mineral soils (Brady, Nyle C. 1984. The Nature and Properties of Soils, Ninth Edition. Macmillan Publishing Company, New York ; Hillel, Daniel. 1982. Introduction to Soil Physics. Academic Press. Orlando, Florida). The 10^9 constant converts the units of mass from kg to µg. For chemicals that have a valid K_{oc}, the K_d can be calculated using a sediment carbon content of 2% (K_{oc}*0.02). An organic carbon content of 2% represents a typical value for a high clay soil that might be used to grow rice in the Mississippi Valley or Gulf Coast regions. Both K_d and K_{oc} should be estimated according to the methods recommended for other surface water models in EFED's Input Parameter Guidance (USEPA, 2002). References can be viewed on the EPA Pesticide Site at *http://www.epa.gov/oppefed1/models/water/input_guidance2_28_02.htm.*

This model is considered conservative, because the residues calculated by this method are screening estimates and as such are expected to exceed the true values found in the environment the great majority of the time. Based on preliminary assessment of rice monitoring data, predicted pesticide concentrations as derived above (assuming a 1 cm sediment interaction zone) exceed the observed peak pesticide concentrations. These EEC's are expected to exceed the concentrations measured in the paddy, because degradation processes and dilution with uncontaminated water outside the paddy is not considered. This calculation does not represent a concentration expected in drinking water, as it represents paddy discharge water. Rather, it represents an upper bound on the drinking water concentrations, and is therefore suitable for use in screening assessments. The concentrations found at drinking water facilities impacted by rice culture would be expected to be less than this value (in some cases much less), because of the aforementioned degradation processes, dilution by water from areas in the basin not in rice culture, and the fact that in most cases less than 100% of the rice paddies in a specific area will be treated with the pesticide.

Based on the methodology to estimate screening level concentrations of pesticides in rice and SCI-GROW models, the EECs of penoxsulam for acute and chronic exposures are estimated to be 45 parts per billion (ppb) for surface water and 5.86 ppb for combined residues of penoxsulam in 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).

Penoxsulam 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 penoxsulam and any other substances and penoxsulam 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 penoxsulam 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 OPP concerning common mechanism determinations and procedures for cumulating effects

from substances found to have a common mechanism on EPA's web site 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 quantitative or qualitative evidence of susceptibility in rats or rabbits following in utero exposures. No developmental toxicity was seen at the highest dose tested in either species. Following pre/post-natal exposure in the two-generation study, offspring toxicity was seen at the same dose that induced parental toxicity and was not more severe than maternal toxicity.

3. *Conclusion*. There is a complete toxicity data base for penoxsulam and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The uncertainty factor (UF) is 100 based on 10X for interspecies extrapolation and 10X for intraspecies variability. EPA determined that the 10X safety factor (SF) to protect infants and children should be removed based on the following:

i. There was no toxicologically significant evidence observed of neurotoxicity in either the acute or chronic neurotoxicity study.

ii. No definitive quantitative or qualitative susceptibility was observed in either of the developmental rat or rabbit studies.

iii. Significant dose-related effects in the two-generation reproduction study were limited to the delay in preputial separation. No other endpoints of reproductive toxicity or offspring growth and survival were affected by treatment.

iv. The chronic dietary food exposure assessment utilizes proposed tolerance level residues and 100% CT information for all commodities. By using these conservative assessments, actual and chronic exposures/risks will not be underestimated.

v. The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

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

When EECs for surface water and ground water are less than the calculated DWLOCs, 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*. A quantitative acute exposure/risk assessment was not performed, because no treatment-related effect was identified in any of the available toxicity studies on penoxsulam that could be considered to have resulted from a single dose of penoxsulam. Penoxsulam is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to penoxsulam from food will utilize <1 % of the cPAD for the U.S. population, <1 % of the cPAD for all infants (<1 year old), and <1 % of the cPAD for all children (1 - 12). There are no residential uses for penoxsulam that result in chronic residential exposure to penoxsulam. In addition, there is potential for chronic dietary exposure to penoxsulam in drinking water. 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 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PENOXSULAM

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb),/ CHED≤	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.147	<1	45	5.86	5,100

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PENOXSULAM—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb),/ CHED≤	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
All Infants <1 year old	0.147	<1	45	5.86	1,500
Children 1-2 years old	0.147	<1	45	5.86	1,500
Children 3-5 years old	0.147	<1	45	5.86	1,500
Children 6-12 years old	0.147	<1	45	5.86	1,500
Youth 13-19 years old	0.147	<1	45	5.86	5,100
Adults 20-49 years old	0.147	<1	45	5.86	5,100
Females 13-49 years old	0.147	<1	45	5.86	4,400
Adults 50+ years old	0.147	<1	45	5.86	5,100

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).

Penoxsulam 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).

Penoxsulam 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*. Penoxsulam is classified as Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential. A human cancer risk assessment is not required. A rational for this classification has been provided in Unit.III.C.1.iii. of this document.

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 penoxsulam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical methodology (LC/MS/MS method) has been subjected to an independent laboratory validation, and will be available for use as an enforcement method.

Adequate enforcement methodology (using LC/MS/MS) 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 International Residue Limits for penoxsulam use on rice.

C. Conditions

The modifications recommended by the independent laboratory and EPA's Analytical Chemistry Branch will be made to the final written enforcement method.

The final report of the ongoing storage stability study must be submitted in support of any future food uses. Storage stability data for future uses will require the receipt and acceptance of the final rice report as well as any data required for the additional use.

V. Conclusion

Therefore, the tolerance is established for residues of penoxsulam, 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide, in or on rice, grain at 0.02 ppm and rice, straw at 0.5 ppm. Separate rice processed commodity tolerances are not needed. Any residues of penoxsulam, per. se., in/on rice processed commoditites will be covered by the tolerance on rice, grain at 0.02 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0286 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 23, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0286, 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 **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure

''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 17, 2004.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.605 is added to read as follows:

§ 180.605 Penoxsulam; tolerances for residues.

(a) *General.* Tolerances are established for the herbicide, penoxsulam (2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide) in/on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.02
Rice, straw	0.50

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

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

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

[FR Doc. 04–21502 Filed 9–23–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0315; FRL–7680–1]

Dimethenamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of dimethenamid in or on onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish. Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the FFDCA 21 U.S.C. 346a(q), as amended by the FQPA of 1996. By law, EPA is required to reassess all tolerances in existence on August 2, 1996 by August 2006. This regulatory action will count for thirteen reassessments towards this August 2006 deadline.

DATES: This regulation is effective September 24, 2004. Objections and requests for hearings must be received on or before November 23, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0315. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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