

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: July 26, 2005.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 180.612 is added to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide topramezone, [3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.15
Corn, field, forage	0.05
Corn, field, grain	0.01
Corn, field, stover	0.05
Corn, pop, grain	0.01
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.05
Goat, kidney	0.05
Goat, liver	0.15
Horse, kidney	0.05
Horse, liver	0.15
Sheep, kidney	0.05
Sheep, liver	0.15

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

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

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

[FR Doc. 05-15604 Filed 8-9-05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0139; FRL-7724-8]

Aminopyralid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for free and conjugated residues of aminopyralid in or on grass and wheat commodities; and residues of aminopyralid in or meat; fat and meat byproducts, excluding kidney; of cattle, goat, and sheep, and milk. 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 August 10, 2005. Objections and requests for hearings must be received on or before October 11, 2005.

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-2004-0139. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 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 on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of June 2, 2004 (69 FR 31106-31110) (FRL-7359-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C.

346a(d)(3), announcing the filing of a pesticide petition (PP 4F6827, incorrectly stated as 7F4851) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the herbicide aminopyralid (XDE-750): 4-amino-3,6-dichloropyridine-2-carboxylic acid and its glucose conjugate, expressed as total parent in or on grass forage at 25 parts per million (ppm), grass hay at 65 ppm, wheat forage at 2 ppm, wheat hay at 4 ppm, wheat grain at 0.05 ppm, wheat straw at 0.5 ppm, wheat bran at 0.1 ppm, wheat middlings at 0.02 ppm, wheat shorts at 0.05 ppm, wheat flour at 0.01 ppm, wheat germ at 0.02 ppm, wheat aspirated grain fractions at 0.5 ppm. Tolerances of the parent, aminopyralid (free) were also proposed for milk at 0.02 ppm, cream at 0.02 ppm, edible animal tissues except kidney at 0.05 ppm, and kidney at 1.0 ppm. That notice included a summary of the petition prepared by Dow AgroSciences, LLC, the registrant.

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 free and conjugated residues; of aminopyralid in or on grass, forage at 25 ppm; grass, hay at 50 ppm; aspirated grain fractions at 0.2 ppm; wheat, bran at 0.1 ppm; wheat, forage at 2.0 ppm; wheat, grain at 0.04 ppm; wheat, hay at 4.0 ppm; wheat, straw at 0.25 ppm; and for a tolerance for residues of aminopyralid per se in or on cattle, fat at 0.02 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts,

except kidney at 0.02 ppm; cattle, kidney at 0.3 ppm; goat, fat at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts, except kidney at 0.02 ppm; goat, kidney at 0.3 ppm; horse, fat at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproducts, except kidney at 0.02 ppm; horse, kidney at 0.3 ppm; sheep, fat at 0.02 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts, except kidney at 0.02 ppm; sheep, kidney at 0.3 ppm; and milk at 0.03 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 aminopyralid 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.

Studies were performed using aminopyralid technical acid (XDE-750) and a formulation (GF-871) consisting of triisopropanolamine salt of aminopyralid (XDE-750 TIPA). Doses (Table 1 and Table 2 of this unit) are expressed as acid equivalents for all studies regardless of the material administered to test animals.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	2001 13-Week feeding—rat (XDE-750) with 4 week recovery period	NOAEL = 500 milligrams/kilogram/day (mg/kg/day) for males (M) and 1,000 mg/kg/day for females (F) LOAEL M = 1,000 mg/kg/day based on hyperplasia of mucosal epithelium of the ileum and cecum. F = not determined
870.3100	2004 13-Week feeding—rat (GF-871)	NOAEL = 520 mg/kg/day LOAEL = mg/kg/day: not determined
870.3100	2001 13-Week feeding—mouse (XDE-750)	NOAEL = 1,000 mg/kg/day LOAEL = mg/kg/day: not determined
870.3200	2002 28-Day dermal—rat (XDE-750)	<i>Systemic:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined <i>Dermal:</i> NOAEL = M= 100 mg/kg/day F = 1,000 mg/kg/day LOAEL = M = 500 mg/kg/day, based on histopathological changes (slight epidermal hyperplasia) F = not determined

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

Guideline No.	Study type	Results
870.3150	2002 13-Week feeding—dog (XDE-750)	NOAEL = M = 282 mg/kg/day F = 232 mg/kg/day LOAEL = M = 1,070 mg/kg/day F = 929 mg/kg/day, based on stomach histopathology (slight diffuse hyperplasia and hypertrophy of the mucosal epithelium)
870.3700	2002 Developmental tox—rabbit (XDE-750)	<i>Maternal:</i> NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day, based on decrease in body weight (GD 7–10), decreased food consumption, incoordinated gait (23/26), and ulcers and erosions of the stomach. <i>Developmental:</i> NOAEL = 500 mg/kg/day LOAEL = (mg/kg/day) not determined
870.3700	2004 Developmental tox—rabbit (GF-871)	<i>Maternal:</i> NOAEL = 104 mg/kg/day LOAEL = 260 mg/kg/day, based on severe inanition and body weight loss, decreased fecal output, and mild incoordinated gait <i>Developmental:</i> NOAEL = 260 mg/kg/day LOAEL = 520 mg/kg/day, based on decreased fetal body weight.
870.3700	2001 Developmental tox—rat (XDE-750)	<i>Maternal:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined <i>Developmental:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined
870.3700	2004 Developmental tox—rat (GF-871)	<i>Maternal:</i> NOAEL = 520 mg/kg/day LOAEL = mg/kg/day, not determined <i>Developmental:</i> NOAEL = 520 mg/kg/day LOAEL = (mg/kg/day) not determined
870.3800	2003 2-Generation reproduction—rat (XDE-750)	<i>Parental/Systemic:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined <i>Reproductive:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined <i>Offspring:</i> NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined.
870.4100	2003 1-Year feeding—dogs (XDE-750)	NOAEL = M = 99 mg/kg/day F = 93 mg/kg/day LOAEL = M = 967 mg/kg/day F = 1038 mg/kg/day, based on thickening of stomach mucosa (F), and stomach histopathology in all animals (slight diffuse hyperplasia and hypertrophy of the mucosa epithelium, slight lymphoid hyperplasia of the gastric mucosa and very slight/slight chronic mucosal inflammation).
870.4200	2003 18-Month carcinogenicity—mice (XDE-750)	NOAEL = M = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined
870.4300	2004 2-Year carcinogenicity—rats (XDE-750)	NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on cecal enlargement, slight mucosal hyperplasia (M) and slightly decreased body weights.
870.5100	2004 Bacterial reverse mutation assay (XDE-750)	Negative
870.5100	2004 Bacterial reverse mutation assay (GF-871) XDETIPA	Negative

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

Guideline No.	Study type	Results
870.5300	2004 <i>In vitro</i> mammalian cell gene mutation test	Negative
870.5300	2004 <i>In vitro</i> mammalian cell gene mutation test (GF-871)	Negative
870.5375	2004 <i>In vitro</i> mammalian cell chromosome aberration test (XDE-750)	XDE induced chromosome aberrations, but only at cytotoxic concentrations, the clastogenic response was induced secondary to toxicity.
870.5375	2004 <i>In vitro</i> Mammalian cell chromosome aberration test (GF-871)	Negative
870.5395	2002 Mammalian erythrocyte micronucleus test (XDE-750)	Negative
870.5395	2004 Mammalian erythrocyte micronucleus test (GF-871)	Negative
870.6200	Acute neurotoxicity screening battery (XDE-750)	NOAEL = 1,000 mg/kg/day LOAEL = 2,000 mg/kg/day based on fecal soiling in M and urine soiling in F.
870.6200	Chronic neurotoxicity—rat (XDE-750)	NOAEL = 1,000 mg/kg/day LOAEL = (mg/kg/day) not determined.
870.7485	2004 Metabolism and pharmacokinetics—rat (XDE-750)	Recovery after 168 hrs: 96% in low dose (urine—50%, feces— 43%, tissues—0.1%, cage wash—3%), 95% in high dose (urine—41%, feces—43%, tissues—1%, caged wash— 10%), and 95% in the repeated low dose (urine—59%, feces— 33%, tissues—0.1%, cage wash—3%). XDE-750 represented ≥96% of administered dose (AD) in urine and 100% AD in feces. Three unknown components (≥4%) found in urine were also found in dose formulations.
Non-guide-line	Triisopropanolamine Salt, Dissociation and Metabolism in Maile Fischer 344—rats (XDE-750)	¹⁴ C-XDE-750 and ¹⁴ C-XDE-750-TIPA, when administered orally to rats, were bioequivalent in terms of absorption, distribution, metabolism, and excretion of the amino-dichloropicolinate portion of the molecule(s)

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 UFs 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 UFs 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 ($\text{MOE}_{\text{cancer}} = \text{point of departure} / \text{exposures}$) is calculated.

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

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CHEMICAL FOR USE IN HUMAN RISK ASSESSMENTS

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)			No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Chronic dietary (All populations)	NOAEL= 50 mg/kg/day UF= 100 Chronic RfD=0.5 mg/kg/day	cPAD= cRfD/FQPA SF cPAD= 0.5 mg/kg/day	Chronic toxicity/carcinogenicity study LOAEL= 500mg/kg/day based on cecal enlargement, slight mucosal hyperplasia in males and slightly decreased body weights.
Incidental oral Short-term (1-30 days)	NOAEL= 104 mg /kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL=260 mg/kg/day based on severe inanition (exhaustion due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Incidental oral Intermediate-term (1–6 months)	NOAEL = 104 mg /kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL=260 mg/kg/day based on severe inanition (exhaustion due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Dermal Short-term (1–30 days)	N/A	N/A	No endpoint identified for this group. No absorption study available. No systemic toxicity seen at the limit dose (1,000 mg/kg/day) in the 28–day dermal toxicity study in rats.
Dermal Intermediate-term (1–6 months)	N/A	N/A	No endpoint identified for this group. No absorption study available. No systemic toxicity seen at the limit dose (1,000 mg/kg/day) in the 28–day dermal toxicity study in rats.
Dermal Long-term (> 6 months)	N/A	N/A	No endpoint identified for this group. No absorption study available. No systemic toxicity seen at the limit dose (1,000 mg/kg/day) in the 28–day dermal toxicity study in rats.
Inhalation Short-term (1–30 days)	NOAEL = 104 mg /kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL = 260 mg/kg/day based on severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Inhalation Intermediate-term (1–6 months)	NOAEL = 104 mg /kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL=260 mg/kg/day based on severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Inhalation Long-term (> 6 months)	N/A	N/A	N/A
Cancer (Oral, dermal, inhalation)	Classification: There was no treatment related increase in tumor incidence when compared to control. This chemical is not likely to be a carcinogen.		

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.* Currently, no tolerances have been established for the residues of aminopyralid, in or on any raw agricultural commodity. Risk assessments were conducted by EPA to assess dietary exposures from aminopyralid in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An endpoint of concern attributable to a single dose of aminopyralid was not identified. Therefore, an acute dietary exposure assessment was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Lifeline™ Model Version 2.0 software which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments. This risk assessment assumed that 100% crop treated for all food and feed commodities and tolerance level residues.

The dietary exposure was based on residues of aminopyralid in or on grass and wheat commodities treated with formulations of its triisopropanolammonium (TIPA) salt and potential drinking water exposure. Total dietary exposures for the U.S. population and all subpopulations were less than 0.0013 mg/kg/day.

iii. *Cancer.* Aminopyralid is classified as “not likely to be carcinogenic to humans” based on the lack of evidence for carcinogenicity in mice and rats. Therefore, a quantitative cancer exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it

deems appropriate. For the present action, EPA did not rely on anticipated residues or PCT information.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the Screening Concentration in Ground Water Modeling System (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Aminopyralid is relatively persistent in the environment at relevant pH's and temperatures. It is rapidly photodegraded in water under favorable light conditions. Laboratory studies found a half-life of 0.6 day. In addition to carbon dioxide, there were two major degradates, oxamic acid and malonic acid, other degradates were at least four different 2 and 3 carbon acid amides. Photodegradation is expected to be a significant route of dissipation for aminopyralid in the environment in clear shallow surface water. Aminopyralid photodegrades

moderately slowly on soil, with half-life of 72.2 days in one study.

Aminopyralid is mobile in soils and generally is not expected to bind to aquatic sediments. Based on results reported in terrestrial field dissipation studies, aminopyralid appears to be non-persistent in the field. No major degradates were identified.

Since the models used are considered to be screening tools in the risk assessment process, the Agency estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. Estimated drinking water concentration (EDWC) derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD.

Based on the PRZM/EXAMS model, the EECs of aminopyralid for chronic exposures are estimated to be 1.937 parts per billion (ppb) for surface water and 0.630 ppb for ground water. The chronic estimated water concentrations derived from surface water modeling results were significantly higher than the modeled ground water concentrations, and therefore protective of potential exposures via ground water sources of drinking water when incorporated into aggregate exposure estimates. The aminopyralid EEC's were incorporated into LifeLine™ Model Version 2.0 to determine aggregate pesticide exposures from pesticide residues in the diet.

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). Aminopyralid has no pending applications to register any use on residential sites; however, use of aminopyralid is requested on campgrounds and other natural recreation areas. Such use could result in post-application incidental oral exposures for infants and children.

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.”

Aminopyralid is a pyridinecarboxylic acids as are the pesticides picloram and clopyralid. Although these pesticides share a common herbicidal mode-of-action (auxinic growth regulation), this auxinic growth process in plants is not

present in mammals. No common mode of mammalian toxicity has been identified for auxinic herbicides. An evaluation of the mammalian toxicology databases of all three active ingredients for target organ toxicities indicates that there is no evidence that the same toxic effect occurs in or at the same organ or tissue by essentially the same sequence of major biochemical events.

For the purposes of this tolerance action, therefore, EPA has not assumed that aminopyralid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the database 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 UFs (safety) 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. *Pre-natal and post-natal sensitivity.* There is no evidence of increased qualitative or quantitative susceptibility of the fetuses in the rat or rabbit developmental toxicity studies (XDE-750 and GF-871) or in a 2-generation reproduction study (rat) after exposure to aminopyralid. The toxicology database is complete with respect to pre- and post-natal toxicity. Therefore, EPA has no residual uncertainty regarding this finding.

In an acute neurotoxicity study in rats with XDE-750, there were no treatment-

related effects on the Functional Observational Battery (FOB), motor activity, or neuropathological observations. Clinical observations of rats in the 2,000 mg/kg/day group revealed a higher incidence of fecal soiling in males and urine soiling in females compared to the controls. However, these effects were transient (most resolving within 3–4 days of treatment) and without gross or neuropathologic changes. In addition, a chronic neurotoxicity study in rats did not demonstrate effects that would suggest neurotoxicity. In developmental toxicity studies in rabbits with aminopyralid (XDE-750 and GF-871) incoordinated gait was observed in males and females in the mid- and high-dose groups. However this finding was transient, with complete reversal within 2 hours post-dosing. Incoordinated gait was not observed in any of the other toxicity studies reviewed. A developmental neurotoxicity study (DNT) is not recommended based on these studies.

3. *Conclusion.* There is a complete toxicity database for aminopyralid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA SF was reduced to 1X, based upon the following: As mentioned above, there is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to aminopyralid in developmental toxicity studies. There is no quantitative or qualitative evidence of increased susceptibility to aminopyralid following pre-/post-natal exposure in a 2-generation reproduction study. In addition, there is no concern for developmental neurotoxicity resulting from exposure to aminopyralid, and a developmental neurotoxicity study is not required. Furthermore, the chronic dietary food exposure assessment assumes 100% crops treated for all commodities. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded. Finally, for the proposed uses for aminopyralid which result in recreational exposure; default assumptions, that result in high-end estimates of exposure, were used.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and

residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EECs. The DWLOC values are not regulatory standards for drinking water, but 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). 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. When new uses are added OPP reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in

developing drinking water modeling inputs.

1. *Acute risk.* An endpoint of concern attributable to a single dose was not identified. Therefore, no acute risk is expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to aminopyralid from food plus drinking water will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for children 1–2 years old, and <1% of the cPAD for children 6–12 years old. There are no residential uses for aminopyralid that result in chronic residential exposure to aminopyralid.

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).

Although there will not be any residential uses for aminopyralid, Dow AgroSciences, LLC has pending applications for use-sites: Campgrounds and recreational areas. EPA has completed short-term risk assessment for these use-sites. The risk assessment was for the potential post-application exposure of infants and children, based on hand-to-mouth transfer of residues and ingestion of aminopyralid-contaminated grass and soil. Post-application inhalation exposure is not

expected to occur. For the risk assessment of these incidental exposures, the NOAEL of 104 mg/kg/day found in the rabbit development study, was used. The combined exposures from food and drinking water and these incidental exposures were used to estimate short-term aggregate risk for infants and children. The Table 3 of this unit gives the EPA's short-term exposure and risk estimates for aminopyralid, resulting from potential exposures from food, drinking water and the recreational uses of aminopyralid.

TABLE 3.—SHORT-TERM AGGREGATE EXPOSURE AND RISK ESTIMATES FOR AMINOPYRALID

Population sub-group	NOAEL, mg/kg/day	Exposure, mg/kg/day			Aggregate MOE
		Dietary	Total non-dietary	Total aggregate	
All infants (< 1 year)	104	0.00052	0.0021	0.00262	40,000
Children 1–2 years	104	0.00120	0.0021	0.00330	32,000
Children 3–5 years	104	0.00088	0.0021	0.00298	35,000
Children 6–12 years	104	0.00052	0.0021	0.00262	40,000

The EPA acknowledges that the aggregate exposure and risk estimates for infants and children are likely overestimates and the coincidence of such exposures will not be common.

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).

Aminopyralid has no pending registration for any sites that would result in intermediate-term exposure. While there is potential short-term exposure from the campgrounds and recreation area uses, there are no potential intermediate-term (30–180 days) exposures.

5. *Aggregate cancer risk for U.S. population.* Aminopyralid has not been shown to be carcinogenic. Therefore, aminopyralid is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to aminopyralid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, liquid chromatography and positive ion electrospray tandem spectrometry with limits of quantitation of 0.01 ppm, is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits for aminopyralid.

C. Conditions

Dow AgroScience, LLC must submit storage stability data for grass forage and hay reflecting up to approximately 15 months of frozen storage.

D. Public Comments

One comment was received. B. Sachau objected to the proposed tolerance because of the amounts of pesticides already consumed and carried by the American population. The commenter also claimed that tests conducted with animals have absolutely

no validity and are cruel to the test animals. EPA has responded to B. Sachau's generalized comments on numerous previous occasions. (See the **Federal Register** of January 7, 2005 (70 FR 1349–1354) (FRL–7691–4) and the **Federal Register** of October 29, 2004 (69 FR 63083–63096) (FRL–7681–9)).

V. Conclusion

Therefore, the tolerances are established for residues of aminopyralid, free and conjugated residues, in or on aspirated grain fractions at 0.2 ppm; grass, forage at 25 ppm; grass, hay at 50 ppm; wheat bran at 0.1 ppm; wheat, forage at 2.0 ppm; wheat, grain at 0.04 ppm; wheat, hay at 4.0 ppm; wheat, straw at 0.25 ppm; and tolerances are established for residues of aminopyralid in or on cattle, fat at 0.02 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts, except kidney at 0.02 ppm; cattle, kidney at 0.3 ppm; goat, fat at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts, except kidney at 0.02 ppm; goat, kidney at 0.3 ppm; horse, fat at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproducts, except kidney at 0.02 ppm; horse, kidney at 0.3 ppm; milk at 0.03 ppm; sheep, fat at 0.02 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts,

except kidney at 0.02 ppm; and sheep, kidney at 0.3 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-2004-0139 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 October 11, 2005.

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

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200

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

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0139 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has

been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 27, 2005.

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 180.610 is added to subpart C to read as follows:

§ 180.610 Aminopyralid; tolerances for residues.

(a) *General.* (1) Tolerances are established for free and conjugated residues of the herbicide, aminopyralid (2-pyridine carboxylic acid, 4-amino-3,6-dichloro-) calculated as aminopyralid in or on:

Commodity	Parts per million
Grass, forage	25
Grass, hay	50
Wheat, bran	0.1
Wheat, forage	2.0
Wheat, grain	0.04
Wheat, hay	4.0
Wheat, straw	0.25
Aspirated grain fractions	0.2

(2) Tolerances are established for residues of the herbicide aminopyralid in or on:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat by-products, excluding kidney	0.02
Cattle, kidney	0.3
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts, excluding kidney	0.02
Goat, kidney	0.3
Horse, fat	0.02
Horse, meat	0.02
Horse, meat by-products, excluding kidney	0.02
Horse, kidney	0.3
Milk	0.03
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat by-products, excluding kidney	0.02
Sheep, kidney	0.3

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

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

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

[FR Doc. 05–15523 Filed 8–9–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0141; FRL–7728–1]

2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5- α)pyrimidin-5-one (PP796); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the established exemption from the requirement of a tolerance under 40 CFR 180.1065 for 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5- α)pyrimidin-5-one, which is also known as "PP796", by increasing the amount that can be used to not more than 0.3 percent in formulation of paraquat dichloride. Syngenta Crop Protection submitted a pesticide petition (PP) 5E6929 requesting this amendment.

DATES: This regulation is effective August 10, 2005. Objections and requests for hearings must be received on or before October 11, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0141. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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.