Inert ingredients	Limits	Uses
Lignosulfonic acid, ammonium salt (CAS Reg. No. 8061–53–8).	.....	Do.
Lignosulfonic acid, ammonium sodium salt (CAS Reg. No. 166798–73–8).	.....	Do.
Lignosulfonic acid, calcium magnesium salt (CAS Reg. No. 55598–86–2).	.....	Do.
Lignosulfonic acid, calcium salt (CAS Reg. No. 8061–52–7) ..	.....	Do.
Lignosulfonic acid, calcium sodium salt (CAS Reg. No. 37325–33–0).	.....	Do.
Lignosulfonic acid, ethoxylated, sodium salt (CAS Reg. No. 68611–14–3).	.....	Do.
Lignosulfonic acid, magnesium salt (CAS Reg. No. 8061–54–9).	.....	Do.
Lignosulfonic acid, potassium salt (CAS Reg. No. 37314–65–1).	.....	Do.
Lignosulfonic acid, sodium salt (CAS Reg. No. 8061–51–6) ...	.....	Do.
Lignosulfonic acid, sodium salt, oxidized (CAS Reg. No. 68855–41–4).	.....	Do.
Lignosulfonic acid, sodium salt, polymer with formaldehyde and phenol (CAS Reg. No. 37207–89–9).	.....	Do.
Lignosulfonic acid, sodium salt, sulfomethylated (CAS Reg. No. 68512–34–5).	.....	Do.
Lignosulfonic acid, zinc salt (CAS Reg. No. 57866–49–6)	.....	Do.
* * *	* *	* * *
Sulfite liquors and cooking liquors, spent, oxidized (CAS Reg. No. 68514–09–0).	.....	Surfactant, related adjuvants of surfactants
* * *	* *	* * *

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[FR Doc. 05–14887 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0184; FRL–7725–5]

Pinoxaden; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pinoxaden in or on barley and wheat. Syngenta Crop Protection, Inc., 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 July 27, 2005. Objections and requests for hearings must be received on or before September 26, 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–2005–0184. 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: 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**.

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 November 19, 2004 (69 FR 67731) (FRL–7686–5), 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 4F6817) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the herbicide pinoxaden, 8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate, in or on wheat, grain at 0.70 parts per million (ppm), wheat, forage at 3.0 ppm, wheat, hay at 1.75 ppm, wheat, straw at 1.5 ppm, barley, grain at 0.70 ppm, barley, hay at 1.25 ppm, and barley, straw at 0.60 ppm. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

Based on the Agency's review the tolerances for pinoxaden are being revised to reflect the CAS chemical name. Additionally, the Agency's review of the residue chemistry data indicated that the tolerance levels needed to be raised as follows: Wheat, forage to 3.5 ppm; wheat, grain to 1.3 ppm; wheat, hay to 2.0 ppm; barley, grain to 0.9 ppm; barley, hay to 1.5 ppm; and barley, straw to 1.0 ppm. Finally, EPA concluded that tolerances were needed on barley, bran; cattle, fat; cattle, meat; cattle, meat byproducts; egg; milk; poultry, fat; poultry, meat; poultry, meat byproducts; and wheat, bran. The registrant did not propose tolerances for meat, milk, poultry, and egg (MMPE) commodities since feeding studies resulted in residues less than limit of quantitation (LOQ). However, the Agency determined that tolerances are needed on MMPE since the feeding studies were not conducted at ≥ 10X and the livestock metabolism studies indicated that residues are concentrated in some livestock tissues (liver and kidney). The tolerances for pinoxaden will be as follows:

1. The combined residues of the herbicide pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), and 4-(7,9-dioxo-hexahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-8-yl)-3,5-diethyl-benzoic acid (M6), calculated as pinoxaden in/on barley, bran at 1.6 ppm; barley, grain at 0.9 ppm; barley, hay at 1.5 ppm; barley, straw at 1.0 ppm; egg at 0.06 ppm; poultry, fat at 0.06 ppm; poultry, meat at 0.06 ppm; poultry, meat byproducts at 0.06 ppm; wheat, bran at 3.0 ppm; wheat, forage at 3.5 ppm; wheat, grain at 1.3 ppm; wheat, hay at 2.0 ppm; and wheat, straw at 1.5 ppm.

2. The combined residues of pinoxaden,(8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), calculated as pinoxaden, in/on cattle, fat at 0.04 ppm; cattle, meat at 0.04 ppm; cattle, meat byproducts at 0.04 ppm; and milk at 0.02 ppm.

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.

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 pinoxaden 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-gavage	NOAEL = 300/100 Male/Female (M/F) milligrams/kilogram/day (mg/kg/day) LOAEL = 300 mg/kg/day based on increased water consumption and urinary volume in females. A LOAEL was not observed in males

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

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity—rat-diet	NOAEL = 466/537 (M/F) mg/kg/day LOAEL = 900/965 (M/F) mg/kg/day based on decreased body weight and body weight gain and increased incidence of renal lesions in both sexes; decreased food consumption and increased water consumption in males; and increased urine volume in females
870.3100	13-Week oral toxicity—mice-gavage	NOAEL = 700 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased incidence of piloerection and decreased body weight gain in both sexes, and increased incidence of renal tubular basophilia in males
870.3100	90–Day oral toxicity—mice-diet	NOAEL = 365 mg/kg/day in males. NOAEL not observed in females. LOAEL = 708.2/165.9 (M/F) mg/kg/day based on decreased body weight and body weight gain in females, and decreased food efficiency in males
870.3150	90–Day oral toxicity—non-rodents	NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on clinical signs of toxicity fluid feces, (vomit, pale and thin appearance, decreased activity, dehydration, cold to touch, and regurgitation in both sexes, and mucus in feces in the males) and decreased body weights, body weight gains, and food consumption in both sexes
870.3200	28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day (limit dose) LOAEL = was not observed
870.3700	Prenatal developmental toxicity—rabbit	*Maternal*: NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on increased mortality, abortion, clinical signs of toxicity, and decreased body weights, body weight gains and food consumption *Developmental*: NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on increased incidence of complete early litter resorption
870.3700	Prenatal developmental—rat	*Maternal*: NOAEL = 30 mg/kg/day LOAEL = 300 mg/kg/day based on decreased body weight gains and food consumption *Developmental*: NOAEL = 30 mg/kg/day LOAEL = 300 mg/kg/day based on delays in skeletal ossification in the skull and hind digits
870.3800	Reproduction and fertility effects	*Parental*: NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day based on increased water consumption, renal tubular atrophy, and chronic nephropathy in both sexes, and increased incidence of renal pelvic dilatation in the males *Reproductive*: NOAEL = 500 mg/kg/day LOAEL = was not observed *Offspring*: NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weights and body weight gains in the F_1 pups, and decreased body weights in the F_2 males
870.4100	Chronic toxicity—dogs	NOAEL = 125 mg/kg/day LOAEL = was not observed
870.4200	Carcinogenicity—mice-diet	NOAEL = 216.5/181.2 (M/F) mg/kg/day LOAEL = was not observed
870.4200	Carcinogenicity—mice-gavage	Study could not be interpreted due to gavage errors and lung involvement.
870.4300	Chronic toxicity/Carcinogenicity—rats-gavage	NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on mortality, clinical signs, and increased serum urea and creatinine in males, and decreased body weights and body weight gains, increased water consumption and incidence of urinalysis findings, kidney surface granulation, and microscopic renal lesions in both sexes
870.5100	*In vitro* bacterial gene mutation *S. typhimurium/E. coli*	No marked increases in the number of revertants were observed at any concentration in any strain in either trial. [negative]

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

Guideline No.	Study Type	Results
870.5300	*In vitro* mammalian gene mutation (L5178YTK$^{+/-}$)	No reproducible substantial (≥ 2x solvent controls) and/or concentration-dependent increases in mutant colonies per 10^6 cells were observed at any dose level in the presence or absence of S9. [negative]
870.5375	*In vitro* mammalian cytogenetics in V79 Chinese Hamster lung fibroblasts (2001)	Although there was not a clear dose-response and several of the increases in percent aberrant cells were within the historical control range (0.0–4.0%), there was sufficient reproducible evidence of a positive mutagenic effect in the presence and absence of S9. [positive]
870.5375	*In vitro* mammalian cytogenetics in V79 Chinese Hamster lung fibroblasts (2002)	There was an increase in the percent aberrant cells that exceeded the historical control range with/without S9 metabolic activation. [positive]
870.5395	*In vivo* mammalian cytogenetics micronucleus—mice	There were no marked increases observed in mean net nuclear grains (NNG) or percent cells in repair (NNG≥ 5) at 2 or 16 hours post-dosing compared to controls. [negative]
870.5550	Unscheduled DNA synthesis (UDS) in mammalian cells (2001)	There were no marked increases observed in the mean grains per nucleus or mean NNG in either trial. Negative for increased UDS up to limit dose. [negative]
870.5550	UDS in mammalian cells (2002)	There were no marked Increases observed in mean NNG or percent cells in repair (NNG≥5) at 2 or 16 hours post-dosing compared to controls. [negative]
870.6200	Acute neurotoxicity screening battery in rats-gavage	NOAEL = 2,000 mg/kg/day LOAEL = was not determined
870.6200	Subchronic neurotoxicity screening battery in rats-gavage	NOAEL = 500 mg/kg/day LOAEL = was not determined
870.7485	Metabolism—rat	Approximately 90% of the orally gavaged dose was absorbed from the gastrointestinal tract. Approximately, 90% of the absorbed dose was excreted in the urine and feces in 72 hours and excretion was nearly complete in 7 days. Excretion in the urine ranged from 59–78% and in feces 20–25%. Tissue distribution data indicated no significant accumulation in the body. Billiary excretion study did not indicate enterohepatic circulation. No parent compound was detected in the urine, feces or bile. Major metabolite in the urine and feces was the hydrolysis product M2. Major metabolites in the urine were M2 (65%–85%) and M4 (5–13%) and in the feces 50%–70%) and M4 (25%–35%) depending up on the dose. There were no sex related differences in the absorption, distribution, excretion or qualitative profile of the metabolites.
870.7600	*In vivo* dermal penetration—rat	Low dose = 4%, 14%, 18% at 4, 10, 24 hours Mid dose = 1%, 2%, 4% at 4, 10, 24 hours High dose = 17%, 30%, 36% at 4, 10, 24 hours

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 (MOE_{cancer} = point of departure/exposures) is calculated.

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

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

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any Traditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age)	NOAEL = 30 mg/kg/day UF = 100 Acute RfD = 0.30 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/ Special FQPA SF = 0.30 mg/kg/day	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on increased incidence of complete early litter resorption.
Acute dietary (General population including infants and children)	N/A	N/A	An endpoint of concern attributable to a single-dose effect was not identified in the database.
Chronic dietary (All populations)	NOAEL= 30 mg/kg/day UF = 100 Chronic RfD = 0.30 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.30 mg/kg/day	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Incidental Oral Short-term (1–30 days)	NOAEL = 30 mg/kg/day	LOC for MOE = 100 (Residential includes FQPA SF)	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Incidental Oral Intermediate-term (1–6 months)	NOAEL = 30 mg/kg/day	LOC for MOE = 100 (Residential includes FQPA SF)	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Dermal Short-term (1–30 days)	NOAEL = 30 mg/kg/day (Dermal absorption rate = 40%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational) = 100	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Dermal Intermediate-term (1– months)	NOAEL = 30 mg/kg/day (Dermal absorption rate = 40%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational) = 100	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Dermal Long-term (> 6 months)	NOAEL = 30 mg/kg/day (Dermal absorption rate = 40%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational) = 100	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.

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

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any Traditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Short-term inhalation (1 to 30 days)	NOAEL = 30 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational) = 100	Developmental toxicity-rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Intermediate-term inhalation (1–6 months)	NOAEL = 30 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational)= 100	Developmental toxicity-rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Long-term inhalation (> 6 months)	NOAEL = 30 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential includes FQPA SF) LOC for MOE (occupational) = 100	Developmental toxicity—rabbit LOAEL = 100 mg/kg/day based on morbid condition in one rabbit (mortality), clinical signs of toxicity in a morbid rabbit, abortion, decreased body weights, body weight gains, and food consumption.
Cancer (Oral, dermal, inhalation)	Not likely to pose a cancer risk.		

Although an acceptable cancer study in rats was submitted, the dietary cancer study in the mouse was found to be unacceptable due to the failure to test at high enough doses. Nonetheless, based on the following weight-of-evidence, a repeat carcinogenicity study in mice is not required at this time:

- No evidence of carcinogenicity was observed in an acceptable/guideline carcinogenicity study in rats.
- The gavage carcinogenicity study in mice was conducted at doses as high as 750 mg/kg/day. No tumors were observed in other organs except adenomas/carcinomas in the lungs. However, the interpretation of the adenomas/carcinomas in the lungs was confounded by the gavage errors that may have introduced the dosing solution in to the trachea and lungs, and perhaps leading to lung tumors and excessive mortality.
- No tumors were seen in the mouse dietary carcinogenicity study, however, the dosing was considered to be inadequate due to the lack of significant systemic toxicity at doses up to 181.2 mg/kg/day (the study, performed under the Organization for Economic Cooperation and Development (OECD) and EPA guidelines, was terminated early for humanitarian reasons due to excessive decreases in body weight gain in the high-dose animals).
- In the 90–day feeding study in mice, pinoxaden was tested up to 7,000 ppm (1,311 mg/kg/day; limit dose), and did not produce any tumors or severe toxicity.
- Pinoxaden was considered to be non-mutagenic.

This evidence convinces EPA that repeating the dietary mouse cancer study is unlikely to provide additional useful information for the risk assessment, and that pinoxaden is not likely to pose a cancer risk.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No Tolerances have been established (40 CFR part 180) previously for the combined residues of pinoxaden on any commodities. Risk assessments were conducted by EPA to assess dietary exposures from pinoxaden 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (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 acute exposure assessments: For the acute analyses, tolerance-level residues were assumed for all food commodities with recommended pinoxaden tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent crop treated (PCT) and anticipated residues were not used in the acute risk assessment.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994 –1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for all food commodities with recommended pinoxaden tolerances, and it was assumed that all of the crops included in the analysis were treated. The PCT and the anticipated residues were not used in the chronic risk assessment.

iii. *Cancer.* Because EPA concluded that pinoxaden is not likely to pose a cancer risk, a cancer exposure assessment was not conducted.

2. *Dietary exposure from drinking water.* Pinoxaden has never been registered in the United States so drinking water concentration estimates are made by reliance on simulation or

modeling taking into account data on the physical characteristics of pinoxaden.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD.

To better evaluate aggregate risk associated with exposure through food and drinking water, OPP is no longer comparing EECs generated by water quality models with Drinking Water Levels of Comparison (DWLOC). Instead, OPP is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentrations into our aggregate assessments relies on actual CSFII-reported drinking water consumptions and more appropriately reflects the full distribution of drinking water concentrations. This is further discussed in the aggregate risk section in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of pinoxaden for acute exposures are estimated to be 0.76 parts per billion (ppb) for surface water (90th percentile annual daily maximum) and 0.13 ppb for ground water. The EECs for chronic exposures are estimated to be 0.47 ppb for surface water (90th percentile annual mean) and 0.13 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pinoxaden 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 pinoxaden and any other substances and pinoxaden 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 pinoxaden 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 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 ten-fold 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 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 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 are no concerns and no residual uncertainties with regard to pre- and/or postnatal toxicity based on the following reasons:

- There is no evidence of qualitative and/or quantitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to pinoxaden.
- There is no evidence of increased qualitative and/or quantitative evidence of increased susceptibility to pinoxaden following prenatal exposure in a 2-generation reproduction study in rats.
- There is no evidence of increased susceptibility to pinoxaden following prenatal exposure in a 2-generation reproduction study in rats.

3. *Conclusion*. There is a complete toxicity database for pinoxaden and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Additionally, the data show no concerns for pre- or postnatal sensitivity. Accordingly, EPA concludes that it is safe for infants and children to remove the additional 10X FQPA safety factor.

E. Aggregate Risks and Determination of Safety

For pinoxaden, no residential uses are proposed. Therefore, aggregate risk will consist of exposure from food and drinking water sources. Acute and chronic aggregate risks were calculated.

To better evaluate aggregate risk associated with exposure through food and drinking water, OPP is no longer comparing EECs generated by water quality models with DWLOC. Instead, OPP is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentrations into our aggregate assessments relies on actual CSFII-reported drinking water consumptions and more appropriately reflects the full distribution of drinking water concentrations.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to pinoxaden will occupy 1.5 % of the aPAD for females 13–49 years old. Drinking water was incorporated directly into the dietary

assessment using the annual peak concentration for surface water generated by the PRZM-EXAMS model as a high-end estimate (0.76 ppb; 90th percentile annual daily maximum), and therefore the aggregate exposure for food and water for females 13–49 is 1.5% of the aPAD.

An endpoint of concern attributable to a single-dose effect was not identified in the database for the general population, therefore, the only acute risk that pinoxaden poses is as a result of prenatal exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pinoxaden from food will utilize 0.9 % of the cPAD for the U.S. general population, and 2.1 % of the cPAD for children 1–2 years old, the highest exposed population subgroup. Drinking water was incorporated directly into the dietary assessment using the annual mean concentration for surface water generated by the PRZM-EXAMS model as a high-end estimate (0.47 ppb; 90th percentile annual mean), and therefore the aggregate exposure for food and water is 0.9% of the cPAD for the general population, and 2.1% of the cPAD for children 1–2 years old. There are no residential uses for pinoxaden that result in chronic residential exposure to pinoxaden.

3. *Aggregate cancer risk for U.S. population.* As explained in Unit III.B., EPA has concluded that exposure to pinoxaden is not likely to pose a cancer risk. Therefore, an aggregate cancer risk assessment was not conducted.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of pinoxaden and its metabolites.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (117–01) high performance liquid chromatography-mass spectrometry (HPLC-MS/MS) is available to enforce the tolerance expression for the combined residues of pinoxaden and M2 (as M2), and residues of M4 and M6 for plants. 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*.

The proposed enforcement methodology (T001530–03) for livestock is adequate for the determination of two major pinoxaden metabolites, M4 and M6. Based on its similarities to the plant enforcement method, the Agency expects that the proposed livestock method will be adequate for quantification of pinoxaden and M2.

B. International Residue Limits

U.S. tolerances for pinoxaden have been harmonized with Canada on the following commodities: Barley, bran at 1.6 ppm; barley, grain at 0.9 ppm; cattle, fat at 0.04 ppm; cattle, meat at 0.04 ppm; cattle, meat byproduct at 0.04 ppm; egg at 0.06 ppm; milk at 0.02 ppm; poultry, fat at 0.06 ppm; poultry, meat at 0.06 ppm; poultry, meat byproduct at 0.06 ppm; wheat, bran at 3.0 ppm; and wheat, grain at 1.3 ppm.

In addition to the harmonized tolerances, the United States has established tolerances on the following commodities: Barley, hay at 1.5 ppm; barley, straw at 1.0 ppm; wheat, forage at 3.5 ppm; wheat, hay at 2.0 ppm; and wheat, straw at 1.5 ppm.

C. Conditions

The following are confirmatory data required as conditions of registration:

1. Additional storage stability data for wheat and barley processed fractions.

2. Additional validation data for pinoxaden and M2 residues in livestock commodities (ruminant and poultry).

V. Conclusion

Therefore, tolerances are established for:

1. The combined residues of pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), and 4-(7,9-dioxo-hexahydro-pyrazolo[1,2-d] [1,4,5]oxadiazepin-8-yl)-3,5-diethyl-benzoic acid (M6), calculated as pinoxaden in/on barley, bran at 1.6 ppm; barley, grain at 0.9 ppm; barley, hay at 1.5 ppm; barley, straw at 1.0 ppm; egg at 0.06 ppm; poultry, fat at 0.06 ppm; poultry, meat at 0.06 ppm; poultry, meat byproducts at 0.06 ppm; wheat, bran at 3.0 ppm; wheat, forage at 3.5 ppm; wheat, grain at 1.3 ppm; wheat, hay at 2.0 ppm; and wheat, straw at 1.5 ppm.

2. The combined residues of pinoxaden,(8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), calculated as pinoxaden, in/on cattle, fat at 0.04 ppm; cattle, meat at 0.04 ppm; cattle, meat byproducts at 0.04 ppm; and milk 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–2005–0184 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 September 26, 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(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the

information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0184, 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. 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 18, 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 180.611 is added to read as follows:

§ 180.611 Pinoxaden; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), and 4-(7,9-dioxo-hexahydro-pyrazolo[1,2-d] [1,4,5]oxadiazepin-8-yl)-3,5-diethyl-benzoic acid (M6), calculated as pinoxaden, in/on the following commodities:

Commodity	Parts per million
Barley, bran	1.6
Barley, grain	0.9
Barley, hay	1.5
Barley, straw	1.0
Egg	0.06
Poultry, fat	0.06
Poultry, meat	0.06
Poultry, meat byproducts	0.06
Wheat, bran	3.0
Wheat, forage	3.5
Wheat, grain	1.3
Wheat, hay	2.0
Wheat, straw	1.5

(2) For the combined residues of pinoxaden, 8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites M2, 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione, and free and conjugated forms of M4, 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione, calculated as pinoxaden, in/on the following commodities:

Commodity	Parts per million
Cattle, fat	0.04
Cattle, meat	0.04
Cattle, meat byproducts	0.04
Milk	0.02

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

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

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

[FR Doc. 05–14896 Filed 7–26–05; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WT Docket No. 05–211; FCC 05–123]

Implementation of the Commercial Spectrum Enhancement Act

AGENCY: Federal Communications Commission.

ACTION: Declaratory ruling.

SUMMARY: In order to implement the auction revenue requirement in Commercial Spectrum Enhancement Act (CSEA) for any auction of frequencies subject to CSEA, the Commission interprets the meaning of the term ''total cash proceeds'' as used in CSEA to mean winning bids net of any applicable bidding credit discounts.

DATES: Effective August 26, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. People with Disabilities: Contact the FCC to request materials in accessible formats (Braille, large print, electronics files, audio format, etc.) by e-mail at *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0531 (voice), 202–418–7365 (TTY).

FOR FURTHER INFORMATION CONTACT: Audrey Bashkin or Gary Michaels, Auctions and Spectrum Access Division, Wireless Telecommunications Bureau, (202) 418–0660.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Declaratory Ruling* in WT Docket No. 05–211 adopted June 9, 2005, and released June 14, 2005. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Declaratory Ruling is also available on the FCC's Web site at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–05–123A1.doc* or *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–05–123A1.pdf*. The Commission will send a copy of this Declaratory Ruling in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

1. CSEA establishes a mechanism to use spectrum auction proceeds to reimburse Federal agencies operating on ''eligible frequencies'' (the 216–220 MHz, 1432–1435 MHz, 1710–1755 MHz, and 2385–2390 MHz bands, and certain other frequency bands) that may be reallocated from Federal to non-Federal use, for the cost of relocating operations. CSEA requires that the ''total cash proceeds'' from any auction of eligible frequencies equal at least 110 percent of estimated relocation costs of eligible Federal entities. CSEA prohibits the Commission from concluding any auction of eligible frequencies that falls short of this revenue requirement. CSEA requires the Commission, if it is unable to conclude an auction for this reason, to cancel the auction, return any deposits from participating bidders held in escrow, and absolve such bidders from any obligation to bid in any subsequent reauction of the spectrum.

2. In order to implement CSEA's revenue requirement, the Commission must determine the meaning of the term ''total cash proceeds'' as used in the statute. For the following reasons, the Commission interprets ''total cash proceeds'' for purposes of CSEA to mean winning bids net of any applicable bidding credit discounts. Under the Commission's competitive bidding rules, winning bids in an auction do not necessarily translate into amounts actually owed by bidders. The discrepancy between gross and net winning bid amounts arises from the award of bidding credits—*i.e.*, discounts on gross winning bids—to eligible designated entities, new entrants into the broadcast marketplace, and winning bidders that undertake to serve previously underserved tribal lands. In this context, the plain language of the statute appears to refer to an auction's net winning bids rather than gross