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 by 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 other 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4).

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. Submission to Congress and the Comptroller General

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: April 2, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.434 is amended by revising the section heading, and in the table to paragraph (a) by removing the entries for corn, forage; and corn, grain; by adding an entry for corn, field, stover; corn, field, forage; corn, field, grain; and by revising the entries for corn, sweet, kernel plus cob with husks removed; peanuts; peanuts, hay; pineapple; and pineapple, fodder, to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million	Expiration Date
* * * * *		
Corn, field, forage	12	3/30/04
Corn, field, grain ...	0.1	3/30/04
Corn, field, stover	12	3/30/04
Corn, sweet (kernel plus cob with husks removed)	0.1	3/30/04
* * * * *		
Peanut	0.2	3/30/04
Peanut, hay	20	3/30/04
* * * * *		
Pineapple	0.1	3/30/04
Pineapple, fodder ..	0.1	3/30/04
* * * * *		

* * * * *

[FR Doc. 01–9366 Filed 4–17–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301116; FRL–6778–5]

RIN 2070–AB78

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerances for residues of flumioxazin in or on soybean seed and peanuts. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 18, 2001. Objections and requests for hearings, identified by docket control number OPP–301116, must be received by EPA on or before June 18, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please

follow the detailed instructions for each method as provided in Unit VI.. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301116 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180._00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301116. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of February 14, 2001 (66 FR 10292) (FRL–6765–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP 7F4841 and OF6171) for tolerances by Valent U.S.A. Corporation, 1333 North California, Boulevard, Suite 600, Walnut Creek, CA 94596–8025. This notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on soybean seed and peanuts at 0.01 part per million (ppm). Valent U.S.A. Corporation subsequently amended the petition to request tolerances in or on soybean seed and peanut nutmeat at 0.02 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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) 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 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), 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), for a tolerances for residues of flumioxazin on soybean seed and peanut nutmeat at 0.02 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 flumioxazin are discussed in the following Table 1 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
870.1000	Acute Oral - rat	LD_{50}>5,000 mg/kg (M and F); no clinical signs
870.1100	Acute Dermal - rat	LD_{50}>2,000 mg/kg; no clinical signs
870.1200	Acute Inhalation - rat	LC_{50} = 3.93 mg/L
870.2400	Primary Eye Irritation - rabbit	No corneal irritation; mild irritation of iris cleared by 24 hours; mild irritation of conjunctival cleared by 48 hours
870.2500	Primary Skin Irritation - rabbit	No erythema or edema
870.2600	Dermal sensitization - guinea pig	Not a dermal sensitizer
870.3100	90-Day oral toxicity - rat	NOAEL = mg/kg/day: 69.7 (M), 71.5 (F) LOAEL = mg/kg/day: 243.5 (M), 229.6 (F) based on a decrease in MCV both sexes; increase in platelets F only
870.3100	90-Day oral toxicity - rat	NOAEL = mg/kg/day: 65.0 (M), 72.9 (F) LOAEL = mg/kg/day: 196.7 (M), 218.4 (F) based on hematology changes
870.3150	90-Day capsule - dog	NOAEL = mg/kg/day: 10 (M and F) LOAEL = mg/kg/day: 100 (M and F) based on dose dependent increase in total cholesterol, phospholipid and alkaline phosphatase
870.3100	90-Day oral toxicity - mouse	NOAEL = mg/kg/day: 429 (M and F) LOAEL = mg/kg/day: 1429 (M and F) based on increased liver weight in males
870.3100	4-Week oral toxicity - mouse	NOAEL = mg/kg/day: 151.5 (M), 164.5 (F) LOAEL = mg/kg/day: 419.9 (M), 481.6 (F) based on increased absolute and/or relative liver weights in M and F
870.3200	21-Day dermal toxicity - rat	NOAEL = mg/kg/day: 1,000 (LIMIT DOSE) LOAEL = mg/kg/day: ≤1,000 based on no effects
870.3700a	Prenatal developmental - rat (oral)	Maternal NOAEL = 30 mg/kg/day (HDT) LOAEL = >30 mg/kg/day (HDT) Developmental NOAEL = 3 mg/kg/day LOAEL = 10 mg/kg/day based on cardiovascular effects (especially ventricular septal defects)
870.3700a	Prenatal developmental - rat (dermal)	Maternal NOAEL = 300 mg/kg/day (HDT) LOAEL = >300 mg/kg/day (HDT) Developmental NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on cardiovascular effects (especially ventricular septal defects)
870.3700b	Prenatal developmental - rabbit (oral)	Maternal NOAEL = 1,000 mg/kg/day LOAEL = 3,000 mg/kg/day (HDT) based on decrease in body weight and food consumption during dosing Developmental NOAEL = 3000 mg/kg/day (HDT) LOAEL = >3,000 mg/kg/day
870.3800	Reproduction and fertility effects - rat	Parental/Systemic NOAEL = mg/kg/day: males = 12.7, females = 15.1 LOAEL = mg/kg/day: males = 18.9, females = 22.7 based on increase in clinical signs (red substance in vagina) and increased female mortality as well as decreased body weight, body weight gain and food consumption Reproductive NOAEL = mg/kg/day: males = 18.9 (HDT), females = 22.7 (HDT) LOAEL = mg/kg/day: males = >18.9 (HDT), females = >22.7 (HDT) Offspring NOAEL = mg/kg/day: males = 6.3, females = 7.6 LOAEL = mg/kg/day: males = 12.7, females = 15.1 based on a decrease in the number of liveborn and a decrease in pup body weight
870.4100	12-Month capsule - dog	NOAEL = 100 mg/kg/day (M and F) LOAEL = 1,000 mg/kg/day (M and F), (LIMIT DOSE) based on the following for males and females: increased absolute and relative liver weights; 300% increase in alkaline phosphatase values
870.4200	Carcinogenicity - mouse	NOAEL = mg/kg/day: males = 754.1, females = 859.1 (LIMIT DOSE) LOAEL = no systemic effects at LIMIT DOSE in males or females No evidence of carcinogenicity

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

Guideline No.	Study type	Results
870.4300	Combined chronic carcinogenicity - rat	NOAEL = mg/kg/day: males = 1.8, females = 2.2 LOAEL = mg/kg/day: males = 18.0, females = 21.8 based on increased chronic nephropathy in males and decreased hematological parameters in females (Hgb, MCV, MCH and MCHC) No evidence of carcinogenicity
870.5100	Gene mutation in *S. typhimurium* and *E. coli*	Neither cytotoxic nor mutagenic up to 2,000 μg/plate. There were reproducible increases in revertant colonies of *S. typhimurium* strains TA1538 and TA98 in S9 activated phases of the preliminary cytotoxicity and both mutation assays. Results considered to be equivocal.
870.5375	Gene mutation in chinese hamster ovary cells	Precipitation at ≥200 μM. Cytotoxicity at 500 μM. Positive +S9 ≥100 μM and negative at 30-500 μM -S9. Aberrations were chromatid breaks and exchanges.
870.5395	*In vivo* rat bone marrow	Negative in male (up to 5,000 mg/kg) and female rats (up to 4,400 mg/kg) when tested orally.
870.5550	UDS assay	Negative up to 5,000 mg/kg.
870.7485	Metabolism and pharmacokinetics - rat (oral)	Gastrointestinal tract absorption >90% at 1 mg/kg and up to 50% at 100 mg/kg. At least 97% recovery in feces and urine 7 days after dosing. Highest levels of residues (36-49 ppb) in blood cells at low dose and 2800-3000 ppg at high dose (RBC levels > plasma). In addition to untransformed parent, 7 metabolites identified in urine and feces (38-46% for low dose and about 71% at high dose).
870.7600	Dermal penetration - rat	Males dosed with suspension of 50 WDG formulation in water at 0.02, 0.20 or 1.0 mg/rat (0.002, 0.020 or 0.100 cm^2. At 0.02 mg/rat, absorption ranged from 0.48% at 0.5 hours to 5.46% at 24 hours. At 0.2 mg/rat, absorption ranged from 0.007% at 0.5 hours to 0.74% at 24 hours. At 1.0 mg/rat, absorption ranged from 0.004% at 0.5 hours to 10.47% at 24 hours.
870.7600	Dermal penetration - rat	Females dosed with 200 or 800 mg/kg b.w. Dermal absorption for 200 and 800 mg/kg was 3.9 and 8.0% by 48 hours after initiation of treatment for 6 hours. Blood levels at 6-24 hours after dermal dosing with 200 mg/kg were similar to those obtained at 2-6 hours after oral dosing with 1 mg/kg. Blood levels at 6-24 hours after dermal dosing with 800 mg/kg were similar to those obtained at 2-6 hours after oral dosing with 30 mg/kg.
	Special Study - Rat Developmental: Critical Time for Defects	Pregnant females were administered 400 mg/kg by gavage on gestation day 11 or 12 or 13 or 14 or 15. Day 12 administration showed: largest incidence of embryonic death, lowest fetal body weights and greatest incidence of ventricular spetal defects.

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 intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA 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 is expressed as 1×10^{-6} or one in a million). 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 flumioxazin used for human risk assessment is shown in the following Table 2:

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute Dietary Females 13-50	NOAEL = 3 mg/kg/day Acute RfD = 0.03 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.003 mg/kg/day	Oral developmental and supplemental prenatal studies in the rat LOAEL = 10 mg/kg/day based on cardiovascular effects (especially ventricular septal defects in fetuses)
Acute Dietary General Population	An endpoint attributable to a single dose (exposure) was not identified from the available studies, including the developmental toxicity studies in rats and rabbits.		
Chronic Dietary all populations	NOAEL = 2 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.002 mg/kg/day	2-Year Chronic/Carcinogenicity Study in the rat LOAEL = 18 mg/kg/day based on increased chronic nephropathy in males and decreased hematological parameters in females (Hgb, MCV, MCH and MCHC)
Incidental Oral (short and intermediate term)	NOAEL = 65 mg/kg/day	Target MOE = 1,000 (Residential)	90-Day Toxicity Studies in the rat LOAEL = 196.7 mg/kg/day based on hematology changes (decrease in MCV and increase in female platelets)
Dermal (all durations)	NOAEL = 30 mg/kg/day	Target MOE = 1,000 (Residential)	Dermal Developmental Study in the rat LOAEL = 100 mg/kg/day based on cardiovascular effects (especially ventricular septal defects in fetuses)
Short-term Inhalation	NOAEL = 3 mg/kg/day	Target MOE = 1,000 (Residential)	Oral Developmental Study in the rat LOAEL = 10 mg/kg/day based on cardiovascular effects (especially ventricular septal defects in fetuses)
Intermediate- and Long-term Inhalation	NOAEL = 2 mg/kg/day	Target MOE = 1,000 (Residential)	2-Year Chronic/Carcinogenicity Study in the rat LOAEL = 18 mg/kg/day based on increased chronic nephropathy in males and decreased hematological parameters in females (Hgb, MCV, MCH and MCHC)
Cancer (oral, dermal, inhalation)	Not likely to be a carcinogen for humans based on the lack of carcinogenicity in a 2-year rat study, an 18-month mouse study and a battery of mutagenic studies.		

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No previous tolerances have been established for the residues of flumioxazin. Risk assessments were conducted by EPA to assess dietary exposures from flumioxazin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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 this acute analysis the assumption was made that 100% of the crops with flumioxazin tolerances are treated with flumioxazin. In addition, the assumption was made that all commodities contain tolerance level residues when consumed, with the exception of those with default processing factors. Default processing factors were used for peanuts-butter (1.89x) and for soybeans-sprouted seeds (0.33x). As the exposure and risk estimates were low, no further refinements were made to this analysis.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For this chronic analysis the assumption was made that 100% of the crops with flumioxazin tolerances are treated with flumioxazin. In addition, the assumption was made that all commodities contain tolerance level residues when consumed, with the exception of those with default processing factors. Default processing factors were used for peanuts-butter (1.89x) and for soybeans-sprouted seeds (0.33x). As the exposure and risk estimates were low, no further refinements were made to this analysis.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground

Water (SCI-GROW), which predicts pesticide concentrations in groundwater. 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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

The hydrolysis study for flumioxazin indicates that flumioxazin forms the metabolite 482-HA, which can further hydrolyze to metabolites APF and THPA. The rates of the two hydrolytic reactions are very pH dependent, but the parent is not very stable at any likely environmental pH. Additional data indicated that THPA and APF are likely to be very mobile. Although THPA can comprise a major portion of the total residue in water, it does not possess the phenyl ring and is thus considered significantly less toxic than parent, APF, and 482-HA, thus THPA needs not be included in the residue of concern for drinking water. Therefore, parent flumioxazin and the metabolites 482-HA and APF are the residues of concern in drinking water.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of flumioxazin and its metabolites of concern in water for acute exposures are estimated to be 2.4 parts per billion (ppb) for surface water and 6.3 ppb for ground water. The EECs for chronic exposures are estimated to be 0.67 ppb for surface water and 6.3 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).

Flumioxazin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether flumioxazin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, flumioxazin 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 flumioxazin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The data for flumioxazin indicate that there is both quantitative and qualitative evidence of increased susceptibility to flumioxazin from prenatal or postnatal exposures. Quantitative susceptibility is observed when the young respond more than the adults at a given dose, and qualitative susceptibility is observed when there is a unique biological target, such as the developing brain, that predisposes the individual.

The quantitative and qualitative evidence of increased susceptibility is observed with the rat fetuses to *in utero* exposure to flumioxazin in the oral and dermal developmental studies. In both studies, there was an increased incidence in fetal cardiovascular anomalies (especially ventricular septal defects). In the oral study, no maternal effects were seen at the highest dose tested (HDT) (30 milligrams/kilograms (mg/kg/day)); whereas, the effects in the fetuses were observed at 10 mg/kg/day. In the dermal study, no maternal effects were noted at the HDT (300 mg/kg/day); whereas, the effects in the fetuses were observed at 100 mg/kg/day. Regarding the 2-generation rat reproduction study, parental effects (red substance in vagina and increased mortality in females as well as decreases in male and female body weights, body weight gains, and food consumption) were noted at 18.9 mg/kg/day in males HDT and 22.7 mg/kg/day in females HDT. Based on the results of the study, no apparent reproduction effects were attributed to test article administration. The effects observed regarding the offspring were a decrease in both the number of liveborn and pup body weights at 12.7 mg/kg/day for males and 15.1 mg/kg/day for females. Therefore, it was considered that there was both a quantitative and qualitative increase in susceptibility.

3. *Conclusion*. There is a complete toxicity data base for flumioxazin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA safety factor (as required by the Food Quality Protection Act of August 3, 1996) has been retained at 10x for all population subgroups for all exposure durations (acute and chronic) in assessing the risk posed by this chemical. The reasons for retaining the 10x safety factor are as follows. First, there is evidence of increased susceptibility of the rat fetuses to *in utero* exposure to flumioxazin by the

oral and dermal route in the prenatal developmental toxicity studies in rats. In addition, there is evidence of increased susceptibility of young animals exposed to flumioxazin in the 2-generation reproduction toxicity study in rats. Finally, there is concern for the severity of the effects observed in fetuses and young animals when compared to those observed in the maternal and parental animals (dose- and treatment-related increase in the incidence of cardiovascular abnormalities, particularly ventricular septal defect, in the developmental studies; and decreases in the number of live born pups and pup body weights in the absence of parental toxicity in the reproduction study).

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure to the subgroup of concern, the acute dietary exposure from food to flumioxazin will occupy 0.72% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to flumioxazin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUMIOXAZIN

Population subgroup	aPAD (mg/kg)	% aPAD (food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
Females (13+ years)	0.003	0.72	2.4	6.3	90

2. *Chronic risk*. Using the exposure assumptions described inthis unit for chronic exposure, EPA has concluded that exposure to flumioxazin from food will utilize 0.5% of the cPAD for the U.S. population, 2.3% of the cPAD for all infants (< 1 year) and 1.2% of the cPAD for children (1-6 years). There are no residential uses for flumioxazin that result in chronic residential exposure to flumioxazin. In addition, there is potential for chronic dietary exposure to flumioxazin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUMIOXAZIN

U.S population subgroup	cPAD mg/kg/day	% cPAD (food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.002	0.5	0.67	6.3	70
Infants (< 1 year)	0.002	2.3	0.67	6.3	20
Females (13+ years)	0.002	0.4	0.67	6.3	60
Males (13 - 19 years)	0.002	0.6	0.67	6.3	70

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).

Flumioxazin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure

plus chronic exposure to food and water (considered to be a background exposure level).

Flumioxazin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *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 flumioxazin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established on soybeans or peanuts.

V. Conclusion

Therefore, the tolerances are is established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on soybean seed and peanuts at 0.02 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301116 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 June 18, 2001.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301116, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). 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 FFDCA section 408(d), such as the exemption 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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: April 7, 2001.

Joseph J. Merenda,

Acting 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), 346(a) and 371.

2. Section 180.568 is added to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) *General.* Tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on the following raw agricultural commodities:

Commodity	Parts per million
Peanuts	0.02
Soybean seed	0.02

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

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

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

[FR Doc. 01–9597 Filed 4–17–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301117; FRL–6778–8]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the ovicide/miticide hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent) in or on tree nuts (nutmeat), plums, fresh prunes, dried prunes, pistachios, peppermint (tops), spearmint (tops), and caneberries. Gowan Company and the Interregional Research Project No. 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective April 18, 2001. Objections and requests for hearings, identified by docket control number OPP–301117, must be received by EPA on or before June 18, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301117 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703)–308–8587; and e-mail address: sproat.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301117. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

Hexythiazox is the active ingredient in Savey Ovicide/Miticide 50 WP (EPA Reg. No. 10163–208). Permanent tolerances are established under 40 CFR 180.448(a) for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent) in/on apples at 0.50 parts per million (ppm), wet apple pommace at 0.80 ppm; hops at 2.0 ppm, and pears at 0.3 ppm; milk, fat, and meat by-products of cattle, goats, horses, sheep, and swine at 0.02 ppm; almonds at 0.30 ppm and almond hulls at 10 ppm; and strawberries at 3.0 ppm. Tolerances with regional registrations are established for cotton gin by-products (California only) at 3.0 ppm and undelinted cotton seed (California only) at 0.20 ppm.

In the **Federal Register** of July 31, 1996 (61 FR 39971) (FRL–5384–6); April 30, 1997 (62 FR 23455) (FRL–5600–8); January 28, 1998 (63 FR 4252) (FRL–5763–6); and December 28, 2000 (65 FR 82349) (FRL–6761–6), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA of 1996 (Public Law 104–170) announcing the filing of pesticide petitions for tolerances by Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569, and the Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ, 08902–3390. These notices included summaries of the petitions prepared by Gowan Company, the registrant. There were no comments received in response to the notice of filings.

The petition(s) requested that 40 CFR 180.448 be amended by establishing tolerances for residues of the insecticide