13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). 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* August 10, 1999 (64 FR 43255). 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).

X. 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: September 21, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.1001, the table in paragraph (d) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d)* * *

Inert ingredients	Limits	Uses
* * *	*	*
Yucca extract from Yucca schidigera.	.....	Wetting agent
* * *	*	*

* * * * *

[FR Doc. 00–24946 Filed 9–28–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301061; FRL–6746–5]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance 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 wet apple pomace, almonds, strawberries, stone fruit (excluding plums), milk, fat and meat byproducts in cattle, goats, horses, swine, and sheep. It also increases the tolerance in apples and establishes a tolerance with regional registration in cotton. Gowan Company 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 September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301061, must be received by EPA on or before November 28, 2000.

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–301061 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	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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.gpo.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301061. 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 0.02 parts per million (ppm), hops at 2.0 ppm, and pears at 0.3 ppm. Time-limited tolerances established under 40 CFR 180.448(b) for residues in/on undelinted cotton seed and cotton gin byproducts at 0.1 and 2.0 ppm expired on October 10, 1999. Additional time-limited tolerances for residues in/on dates (0.1 ppm), hops (2.0 ppm), and strawberries (3.0 ppm) established under 40 CFR 180.448(b) are set to expire on September 15, 2000.

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 August 26, 1998, 63 FR 45487, (FRL–6023–5), 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 a pesticide petition (PP 6F4738, 8F4985) for tolerance by Gowan Company, P.O. Box 5569, Yuma AZ 85366-5569. This notice included a summary of the petition prepared by Gowan Company, the registrant. There were no comments received in response to the notice of filing.

The petition(s) requested that 40 CFR 180.448 be amended by establishing a tolerance for residues of the insecticide hexythiazox, in or on various food commodities as follows: (1) On July 31, 1996 PP 6F4738 proposed the establishment of tolerances for stone fruits (except plums) at 1 ppm; almond nutmeat at 0.2 ppm and almond hulls at 10 ppm; milk, cattle meat, and cattle fat at 0.05 ppm, and cattle meat by products at 0.1 ppm. On April 30, 1997, the petitioner refiled the petition pursuant to the Food Quality Protection Act (FQPA). On January 28, 1998, the petitioner amended the tolerance petition by proposing to establish a tolerance for stone fruits including plums at 1 ppm; prunes at 5 ppm; and all tree nuts at 0.2 ppm. Based upon EPA's review of the field residue data, the tolerance for almonds was changed from 0.2 ppm to 0.3 ppm. Also, the commodity terms almonds, nutmeat and almond hulls was changed to almond and almond, hulls. EPA was unable to complete its review of the field residue data for tree nuts and plums (prunes) and therefore is limiting tolerances to stone fruits (except plums) and almond at this time. Also, the commodity term Stone Fruits (except plums) was corrected to read Fruit, stone group (except plums). Based upon data from a ruminant feeding study, the tolerances proposed in milk, cattle fat and meat byproducts are too high and are reduced to 0.02 ppm. Tolerances for meat are not required. The petition was amended to specify tolerances in cattle, goats, horses, swine, and sheep fat and meat byproducts and milk at 0.02 ppm. (2) On August 26, 1998, PP 8F4985 proposed the establishment of tolerances for strawberries at 3.0 ppm; the increase of tolerances in apples from 0.02 ppm to 0.40 ppm; wet apple pomace at 0.70 ppm; cotton, undelinted seed at 0.20 ppm; and cotton gin byproducts at 3.0 ppm, geographically limited to California only. Based upon apple processing studies, the pomace tolerance of 0.70 ppm is too low and is revised to 0.80 ppm. The use on cotton is limited to California based on the geographical representation of the residue data submitted. Additional residue data would be required to expand the area of usage.

Hexythiazox is currently proposed for use on stone fruits (except plums) to control European red mites, Twospotted spider mites, McDaniel spider mite, Strawberry spider mites, Pacific spider mites, Pecan leaf scorch mites, and Willamette mites; almonds to control European red mites, Twospotted spider mites, McDaniel spider mites, Strawberry spider mites, Pacific spider mites, Pecan leaf scorch mites, and Willamette mites; strawberries to control Twospotted spider mites; apples to control European red mites, Twospotted spider mites, McDaniel spider mite, Pacific spider mites, and Willamette mites; and in cotton to control Twospotted spider mites, Strawberry spider mites, Pacific spider mites, and Carmine spider mites.

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 tolerance for residues of hexythiazox on stone fruits (except plums) at 1 ppm; almonds at 0.3 ppm and almond hulls at 10 ppm; milk at 0.02 ppm; fat of cattle, goats, horses, swine and sheep at 0.02 ppm; meat by-products of cattle, goats, horses, swine and sheep at 0.02 ppm; strawberries at 3.0 ppm; wet apple pomace at 0.80 ppm; cotton, undelinted seed (CA only), at 0.20 ppm; and cotton gin byproducts (CA only) at 3.0 ppm. This regulation also increases the tolerance on apples from 0.02 ppm to 0.50 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 hexythiazox 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
870.3100	90–Day oral toxicity rodents	NOAEL = 8.1/5.4 mg/kg/day males, females LOAEL = 58.6/38.1 mg/kg/day, males, females based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zona fasciculata.
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = 240 mg/kg/day LOAEL = 720 mg/kg/day based on decreased maternal body weight gain and decreased food consumption. Developmental NOAEL = ≥ 2,160 mg/kg/day LOAEL > 2,160 mg/kg/day.
870.3700b	Prenatal developmental in nonrodents	Maternal NOAEL = ≥ 1080 mg/kg/day LOAEL = > 1,080 mg/kg/day. Developmental NOAEL = ≥ 1,080 mg/kg/day LOAEL = > 1,080 mg/kg/day.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 29.73/34.77 mg/kg/day, males/females LOAEL = 180.67/207.67 mg/kg/day, males/females based on decreased body weight gain and increased absolute and relative liver, kidney, and adrenal weights. Reproductive NOAEL = > 180.67/207.67mg/kg/day, males/females LOAEL >180.67/207.67 mg/kg/day, males/females. Offspring NOAEL = 29.73/34.77 mg/kg/day, males/females LOAEL = 180.67/207.67 mg/kg/day, males/females based on decreased pup body weight during lactation, and delayed hair growth and/or eye opening.
870.4100b	Chronic toxicity dogs	NOAEL = 2.5 mg/kg/day LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology.
870.4300	Chronic Toxicity/Carcinogenicity rats	NOAEL = 23/29 mg/kg/day, males/females LOAEL = 163/207 mg/kg/day, males/females based on decreased body weight and body weight gain and increased absolute and relative liver weights. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 41.6/51.2 mg/kg/day, males/females LOAEL = 267/318 mg/kg/day, males/females based on decreased male body weight and body weight gain and increased absolute and relative liver weights in both sexes. Evidence of carcinogenicity (causes liver tumors in females)
870.5100	Gene Mutation (*Salmonella typhimurium* and *Escherichia coli* reverse gene mutation assay)	The test was negative up to the highest dose tested (6400 micrograms/plate +/- S9)

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

Guideline No.	Study Type	Results
870.5300	Gene Mutation (*In vitro* mammalian cell forward gene mutation assay in CHO cells)	Independently performed trials were negative up to precipitating doses (≥ micrograms/mL) and severely cytotoxic concentrations (200 micrograms/mL -S9; 400 micrograms/mL + S9)
870.5375	Cytogenetics (*In vitro* mammalian cell cytogenetic assay in CHO cells)	The test was negative up to precipitating doses accompanied by severe cytotoxicity (≥ 167 micrograms/mL +/-S9)
870.5395	Cytogenetics (*In vivo* mouse micronucleus assay)	The results were inconclusive because a positive response, which was within the wide range of historical background data, was recorded for female mice at the mid-and high- doses (500 and 10,000 mg/kg). The assay should be repeated to confirm or refute the equivocal results.
870.5550	Other Effects (*In vitro* UDS assay in primary rat hepatocytes	The test was negative up to a lethal dose (250 micrograms/mL).
870.7485	Metabolism and pharmacokinetics	Absorption and distribution of dosed radioactivity were rapid. The radioactive material was rapidly eliminated in the urine and feces; the majority of the radioactivity was eliminated within 24 hours. There were no observable differences in the total elimination of NA-73 between male and female rats. The major route of elimination in both the male and female rats was by fecal excretion. The major metabolite found, PT-1-8 (cis), accounted for 8-12% of the administered radioactivity in the low dose groups. Approximately 11-20% and 65-69% of the dosed radioactivity was identified as unchanged NA-73 in the low-dose and high-dose groups, respectively. All other metabolites were present at low concentrations (<2%). There was no apparent sex difference in metabolite formation. Significant levels of NA-73 equivalent ^{14}C- residues were detected in the fat, liver, and adrenals. A sex-related difference in the residue levels of all tissues was observed, with residues in female tissues being two-fold higher than those found in male tissues.
870.7485	Metabolism and pharmacokinetics	Total recovery of radioactivity 72 hours after treatment accounted for 101.9-103% of the dose. The distribution of radioactivity 72 hours after dosing was as follows: (1) 30% (male and female) was excreted in the urine, (2) 60% (female) to 67% (male) was excreted in the feces, and (3) about 4% (male) to 10% (female) of the administered radioactivity remained in the tissues, with the highest concentration in the fat (2.3 ppm, males; 5.4 ppm, females). Significant sex differences existed for the pharmacokinetics of NA-73 in these rats, with females exhibiting slower elimination rats and higher tissue residues (about double) than males. NA-73 was metabolized to a large number of metabolites that were excreted both in the urine and feces. Seven metabolites were structurally identified in addition to the parent compound in both excreta of both sexes, with the major fecal metabolite, PT-1-8 (cis) accounting for 10% of the dosed radioactivity. The others were all minor metabolites accounting for less than 1.4%. About 20% of the dose was excreted as unchanged NA-73 (97% of which was in the feces). No significant sex difference was apparent with respect to metabolite formation.
870.7600	Dermal penetration	The total percent of dose absorbed averaged 2%, 1%, and 1.1% for cannulated rats (10-hour sacrifice) and 0.8%, 0.2%, and 0.2% for non-cannulated rats (1-hour sacrifice) at the low, medium, and high dose levels, respectively. The amount of radioactivity in the blood, carcass, urine and other organs totaled <2% of the applied dose. The results of this study (2% dermal absorption) can be used for risk assessment purposes.

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.

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 hexythiazox used for human risk assessment is shown in the following Table 2:

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF and LOC for risk assessment	Study and toxicological effects
Acute Dietary (females 13–50 years of age)	Developmental NOAEL = 240 mg/kg/day UF = 100 Acute RfD = 2.4 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 2.4 mg/kg/day	Developmental Toxicity Study—Rat Developmental LOAEL = 720 mg/kg/day based on delayed ossification
Acute Dietary (general population including infants and children)[2]			
Chronic Dietary (all populations)	NOAEL = 2.5 mg/kg/day UF = 100 Chronic RfD = 0.025 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.025 mg/kg/day	1–Year Toxicity Feeding Study—Dog LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology
Short-Term Dermal (1–7 days) (Occupational/Residential)	Oral maternal NOAEL = 240 mg/kg/day (dermal absorption rate = 2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Developmental Toxicity Study—Rat LOAEL = 720 mg/kg/day based on decreased maternal body weight gain during gestation days 7–17 and decreased food consumption on gestation days 9–12
Intermediate-Term Dermal (1 week–several months) (Occupational/Residential)	Oral NOAEL = 5.4 mg/kg/day (dermal absorption rate = 2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	13–Week Feeding Study—Rat LOAEL = 38.1 mg/kg/day based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zone fasciculata
Long-Term Dermal (several months—lifetime) (Occupational/Residential)	Oral NOAEL = 2.5 mg/kg/day (dermal absorption rate = 2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	1–Year Feeding Study—Dog LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology
Short-Term Inhalation (1–7 days) (Occupational/Residential)	Oral NOAEL = 240 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational)	Developmental Toxicity Study—Rat

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF and LOC for risk assessment	Study and toxicological effects
		LOC for MOE = 100 (Residential, includes the FQPA SF)	LOAEL = 720 mg/kg/day based on decreased maternal body weight gain during gestation days 7–17 and decreased food consumption on gestation days 9–12
Intermediate-Term Inhalation (1 week–several months) (Occupational/Residential)	Oral NOAEL = 5.4 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	13–Week Feeding Study—Rat LOAEL = 38.1 mg/kg/day based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zone fasciculata
Long-Term Inhalation (several months—lifetime) (Occupational/Residential)	Oral NOAEL = 2.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	1–Year Feeding Study—Dog LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology
Cancer (oral, dermal, inhalation)	Category C (possible human carcinogen)	Q_1* = 2.22 x 10^{-2}	Increases in incidence of malignant and combined benign/malignant liver tumors in mice

[1] UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern

[2] A dose and endpoint attributable to a single exposure were not identified from the available oral toxicity studies, including maternal toxicity in the developmental toxicity 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.* Tolerances have been established (40 CFR 180.448) for the residues of hexythiazox, in or on a variety of raw agricultural commodities. Tolerances are established on plant commodities ranging from 0.02 ppm on apples to 2.0 ppm on hops. Hexythiazox is the common name for the active ingredient in Savey Ovicide/Miticide. When formulated as the product Savey 50 WP, the product is registered for agricultural use on outdoor terrestrial food crops. When sold under an alternate brand name, Hexygon, the product is also registered for commercial non-food use on outdoor ornamental and nursery stock. Savey 50 WP contains 50% hexythiazox by weight. For these petitions, Savey® will be applied to hops, stone fruit, pome fruit, strawberry, and cotton crops at a maximum of 0.1875 pounds of active ingredient per acre (ai/Acre) (1.6 lbs ai/Acre for cotton). Savey® is formulated as a wettable powder (packaged in open bags or water soluble paks) and is applied once per season or crop. Savey provides control against tetranychid mite species by direct or indirect contact with treated plant surfaces. According to label specifications the use of this product may include alternation of active classes of insecticides on succeeding generations and targeting the most susceptible life stage. Risk assessments were conducted by EPA to assess dietary exposures from hexythiazox 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 acute dietary risk assessments, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg. A conservative analysis was performed using existing and recommended tolerance level residues and 100% crop treated (CT) information for all commodities. For acute dietary risk, EPA's level of concern is >100% aPAD. The acute dietary exposure estimate for the females 13-50 years old subgroup is presented in Table 3 at the 95th percentile. The results of the acute analysis indicate that the estimated acute dietary risk associated with the existing and recommended uses of hexythiazox is below EPA's current level of concern for the females 13-50 years old subgroup, as shown in the following Table 3:

TABLE 3.—ACUTE RESULT AT 95TH PERCENTILE FROM DEEM® ANALYSIS

Subgroup	Exposure (mg/kg/day)	% aPAD
Females 13-50 years old	0.002617	<1

For the acute dietary analysis, existing and recommended tolerance level residues and 100% CT information were used for all commodities (conservative, Tier 1 analysis). DEEM® default processing factors were used.

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 Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For chronic dietary risk assessments, the 3–day average of consumption for each sub-population was combined with residues in commodities to determine average exposure in mg/kg/day. A refined, deterministic analysis was performed using AR levels for most crops and % CT or anticipated market share information for all crops. For chronic dietary risk, EPA's level of concern is >100% cPAD. Dietary exposure estimates for the U.S. population and other representative subgroups are presented in Table 4. The results of the chronic analysis indicate that the estimated chronic dietary risk associated with the existing and recommended uses of hexythiazox is below EPA's current level of concern for the U.S. population and all population subgroups, as shown in the following Table 4:

TABLE 4.—SUMMARY OF RESULTS FROM CHRONIC DEEM® ANALYSIS

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000011	<1
All infants (<1 year old)	0.000027	<1
Children (1-6 years old)	0.000028	<1
Children (7-12 years old)	0.000015	<1
Females (13-50 years old)	0.000008	<1
Males (13-19 years old)	0.000004	<1
Males (20 + years old)	0.000008	<1
Seniors (55 + years old)	0.000010	<1

For the chronic and cancer analyses, ARs from field trial data, the weighted average of %CT Quantitative Usage Analyses (QUA), and processing factors (where applicable) were used (see Table 5). DEEM® default processing factors were used unless otherwise noted in the following Table 5:

TABLE 5.—SUMMARY OF HEXYTHIAZOX ARS FOR CHRONIC AND CANCER DIETARY RISK ASSESSMENT BASED ON FIELD-TRIAL DATA

Commodity	Recommended Tolerance (ppm)	Processing Factor	AR (ppm)	CT/Anticipated Market Share (%)
Almond nutmeat	0.30	NA	0.046	2
Almond hulls	10	NA	2.7	2
Cherries	1.0	NA	0.20	<1
Peaches	1.0	NA	0.14	1
Nectarines	1.0	NA	0.054	2
Undelinted cottonseed	0.20	NA	0.059	1
Cottonseed meal	0.20	0.01 x	0.059	1
Refined cottonseed oil	0.20	0.13 x	0.059	1
Apples	0.50	NA	0.12	2

TABLE 5.—SUMMARY OF HEXYTHIAZOX ARS FOR CHRONIC AND CANCER DIETARY RISK ASSESSMENT BASED ON FIELD-TRIAL DATA—Continued

Commodity	Recommended Tolerance (ppm)	Processing Factor	AR (ppm)	CT/Anticipated Market Share (%)
Apple juice	0.50	0.5 x[c]	0.12	2
Wet apple pomace	0.80	2.4 x	0.12	2
Pears[b]	0.30	NA	0.30*	3
Hops[b]	2.0	NA	2.0*	45
Dates[b]	0.10	NA	0.10*	45
Strawberries	3.0	NA	0.75	14
Milk	0.02	NA	0.00019	
Liver[a]	0.02	NA	0.0016	
Meat by-products (except liver)[a]	0.02	NA	0.00066	
Fat[a]	0.02	NA	0.00021	
Hog Meat	0.02	NA	1.0×10^{-9}[d]	
Hog Liver	0.02	NA	4.8×10^{-8}[d]	
Hog Meat by-products (except liver)	0.02	NA	2.0×10^{-8}[d]	
Hog Fat	0.02	NA	6.3×10^{-9}[d]	

*Ars were not calculated for these crops
[a]These ARs were used for meat, fat and meat by-products of cattle, horses, goats and sheep in the chronic and cancer analyses.
[b]ARs were not calculated for commodities not included in the subject petitions.
[c]DEEM® default ratio kept constant for ''apple-juice/cider'' and ''apple-juice-concentrate''.
[d]These ARs were rounded up to 0.000001 ppm because DEEM® can not accomidate more than 6 place holders.

iii. *Cancer*. A refined, deterministic carcinogenic risk estimate analysis was performed using AR levels for most crops and % CT or anticipated market share information for all crops. The dietary exposure estimate for the U.S. population is presented in Table 6. The result of the carcinogenicity analysis indicates that the estimated dietary risk associated with the existing and recommended uses is below the level the Agency generally considers negligible for excess lifetime cancer risk (1×10^{-6}), as shown in the following Table 6:

TABLE 6.—SUMMARY OF RESULTS FROM CARCINOGENIC DEEM® ANALYSIS

Subgroup	Exposure (mg/kg/day)	Lifetime Risk
U.S. Population	0.000011	2.4×10^{-7}

For the cancer analyses, ARs from field trial data, the weighted average of %CT (QUA) and processing factors (where applicable) were used (see Table 5 above). DEEM® default processing factors were used unless otherwise noted in Table 5.

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information specified above. The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting

for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which hexythiazox may be applied in a particular area.

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

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 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 hexythiazox they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of hexythiazox in surface water and ground water for acute exposures are estimated to be 910.32 ng/L for surface water and 1.47 ng/L for ground water. The EECs for chronic exposures are estimated to be 280.88 ng/L for surface water and 1.47 ng/L 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). Hexythiazox 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 hexythiazox 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, hexythiazox 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 hexythiazox 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. *Safety factor for infants and children*—i. *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.

ii. *Prenatal and postnatal sensitivity*. EPA has evaluated the toxicology data base of hexythiazox and re-assessed the cRfD, as well as the toxicological endpoints recommended for acute dietary and occupational/residential exposure risk assessments. The Agency also addressed the potential enhanced sensitivity of infants and children from exposure to hexythiazox as required by FQPA and concluded that the pre- and post-natal toxicology data base for hexythiazox is complete with respect to FQPA considerations. The results of these studies indicated no increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to hexythiazox. In the developmental toxicity study in rabbits, no

developmental effects were seen at doses up to the limit dose. In the developmental toxicity study in rats, the developmental effects (delayed ossification) occurred at the same dose level (720 mg/kg/day) as the maternal effects (decreased maternal body weight gain and decreased food consumption). In the two generation reproduction study, the effects in the offspring (decreased pup body weight during lactation and delayed hair growth and/or eye opening) were observed only at treatment levels which resulted in evidence of parental toxicity (decreased body weight gain and increased absolute and relative liver, kidney, and adrenal weights).

A developmental neurotoxicity (DNT) study is not required at this time. However, EPA has requested an evaluation to determine the relationship between the adrenal effects (increased adrenal weights and/or adrenal pathology) seen in four studies (90-day feeding study in rats, chronic/carcinogenicity rat, chronic dog, and 2-generation reproduction study in rats) and the need for a DNT. It appears that the effects are more endocrine-related (not developmental) and will be addressed once the endocrine policy is in place. The possibility of the effects being endocrine related is also supported by reports of ovarian weight increases in several studies in rats. In addition, the results of the developmental toxicity studies in rats and rabbits and the 2-generation reproduction study do not support a DNT. No neuropathology or CNS malformations were seen in the developmental toxicity studies. In the 2-generation reproduction study in rats, there were no findings in pups that were suggestive of changes in neurological development, although no functional assessment was performed. Additionally, there was no evidence of neurotoxicity in other studies.

iii. *Conclusion*. There is a complete toxicity data base for hexythiazox and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed and reduced to 1x. The FQPA factor is removed because an additional safety factor is not needed to protect the safety of infants and children.

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*. Acute aggregate risk estimates are below EPA's level of concern. A Tier 1 acute dietary exposure analysis for hexythiazox was performed using tolerance level residues and assuming 100% crop treated for all commodities. The acute analysis applied to the population subgroup Females 13-50 yrs old. The acute dietary exposure estimates (food only) for this population subgroup was <1% of the aPAD. Thus, the acute dietary risk associated with the proposed uses of hexythiazox does not exceed EPA's level of concern (>100% aPAD). The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. For the acute scenario, the DWLOCs are 72,000 ppb for females 13-50 years old. For ground and surface water, the EECs for hexythiazox are less than EPA's DWLOCs for hexythiazox in drinking water as a contribution to acute aggregate exposure as shown in Table 7 below. Therefore, EPA concludes with reasonable certainty that residues of hexythiazox in drinking water do not contribute significantly to the acute aggregate human health risk at the present time, as shown in the following Table 7:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HEXYTHIAZOX

Scenario/Population Subgroup	aPAD, mg/kg/day	Dietary Exposure, mg/kg/day	Allowable Drinking Water Exposure[1], mg/kg/day	DWLOC, ppb	Surface Water, ppb	Ground Water, ppb
Females 13-50 yrs old	2.4	0.002617	2.4	72,000	0.910	0.0015

[1]Allowable Drinking Water Exposure (mg/kg/day) = aPAD (mg/kg/day) - Dietary Exposure from DEEM (mg/kg/day)

2. *Chronic risk*. Chronic (non-cancer) aggregate risk estimates are below EPA's level of concern. A refined analysis was performed using AR levels for most crops and % CT or anticipated market share information for all crops. The chronic analysis applied to the U.S. population and all population subgroups. The chronic (non-cancer) dietary exposure estimates (food only) for the general U.S. population and all population subgroups were <1% of the

cPAD. Thus, the chronic (non-cancer) dietary risk associated with the proposed uses of hexythiazox does not exceed EPA's level of concern (>100% cPAD). The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. For the chronic (non-cancer) scenario, the DWLOCs are 870 ppb for the U.S. population, 870 ppb for females 13-50 years old, and 250 ppb for all infants (<1 year old). For ground and surface water, the EECs for hexythiazox are less than EPA's DWLOCs for hexythiazox in drinking water as a contribution to chronic (non-cancer) aggregate exposure (Table 8). Therefore, EPA concludes with reasonable certainty that residues of hexythiazox in drinking water do not contribute significantly to the chronic (non-cancer) aggregate human health risk at the present time, as shown in the following Table 8:

TABLE 8.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO HEXYTHIAZOX

Scenario/Population Subgroup	cPAD, mg/kg/day	Dietary Exposure, mg/kg/day	Allowable Drinking Water Exposure[1], mg/kg/day	DWLOC, ppb	Surface Water EEC, ppb	Ground Water EEC, ppb
U.S. Population	0.025	0.000011	0.025	870	0.094	0.0015
All infants (<1 year old)	0.025	0.000027	0.025	250	0.094	0.0015
Children (1-6 years old)	0.025	0.000028	0.025	250	0.094	0.0015
Children (7-12 years old)	0.025	0.000015	0.025	250	0.094	0.0015
Females (13-50 years old)	0.025	0.000008	0.025	870	0.094	0.0015
Males (13-19 years old)	0.025	0.000004	0.025	870	0.094	0.0015
Males (20+ years old)	0.025	0.000008	0.025	870	0.094	0.0015
Seniors (55+ years old)	0.025	0.000010	0.025	870	0.094	0.0015

[1] Allowable Drinking Water Exposure (mg/kg/day) = cPAD (mg/kg/day) - Chronic Dietary Exposure from DEEM® (mg/kg/day)

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

5. *Aggregate cancer risk for U.S. population*. Chronic (cancer) aggregate risk estimates are below EPA's level of concern. A refined analysis was performed using AR levels for most crops and % CT or anticipated market share information for all crops. The chronic analysis applied to the U.S. population and all population subgroups. The carcinogenic risk estimate (food only) for the general U.S. was $<1 \times 10^{-6}$. Thus, the carcinogenic dietary risk associated with the proposed uses of hexythiazox does not exceed the level of concern that the Agency generally considers negligible for excess lifetime cancer risk (1×10^{-6}). The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. For the carcinogenic risk scenario, the DWLOCs are 1.2 ppb for the U.S. population. For ground and surface water, the EECs for hexythiazox are less than EPA's DWLOCs for hexythiazox in drinking water as a contribution to carcinogenic aggregate exposure (Table 9). Therefore, EPA concludes with reasonable certainty that residues of hexythiazox in drinking water do not contribute significantly to the carcinogenic aggregate human health risk at the present time, as shown in the following Table 9:

TABLE 9.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (CANCER) EXPOSURE TO HEXYTHIAZOX

Scenario/Population Subgroup	Q_1*	Dietary Exposure, mg/kg/day	Allowable Drinking Water Exposure[1], mg/kg/day	DWLOC, ppb[2]	Surface Water EEC, ppb	Ground Water EEC, ppb
U.S. Population	2.22×10^{-2}	0.000011	0.000034	1.2	0.094	0.0015

[1] Allowable Drinking Water Exposure (mg/kg/day) = negligible risk($1 \times 10^{-6}/Q_1$* - (average food + residential exposure (ADD) (mg/kg/day)
[2] $DWLOC_{cancer}$ = chronic water exposure (mg/kg/day) $\times$ body weight (kg)/water consumption (L) $\times 10^{-3}$(mg/µg)

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

IV. Other Considerations

A. Metabolism in Plants and Animals

Plants. Metabolism studies have been submitted and reviewed in conjunction with petitions for hexythiazox tolerances in/on apples, pears, grapes and citrus. The residues of concern in these crops are hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety.

No further plant metabolism data are necessary to support the proposed uses on apples, almonds, stone fruits and strawberries. However, as metabolism

data are only available for fruit, the nature of the residue is not understood in cotton. Given the limited metabolism of hexythiazox observed in apple, pear, grape and citrus leaves and that the use on cotton will be limited to California, EPA concludes that the nature of the residue is understood in cotton for the purposes of this petition only. For a national registration on cotton, additional plant metabolism data will be required.

Livestock. The Agency has previously concluded that the nature of the residues of hexythiazox in cattle and goats is adequately understood. The residues of concern in ruminants are hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety.

A poultry metabolism study was reviewed in conjunction with the original tolerance petition for apples and was deemed inadequate due to incomplete characterization of 14C-residues in liver, fat and eggs. However, as the available data indicate that the metabolism of hexythiazox in poultry is similar to that in plants and ruminants, EPA can recommend in favor of permanent tolerances for cotton RACs provided that the registration is conditional upon submission of an adequate poultry metabolism study.

B. Analytical Enforcement Methodology

The HPLC/UV analytical methods (EN-CAS Method Nos. ENC–4/96, –5/96, and –4/97, respectively) used for determining the combined residues of hexythiazox and its metabolites in apples, cotton, and rotational crops are adequate for data collection purposes. The submitted HPLC/UV analytical method (EN-CAS Method No. ENC-8/96) used for determining the combined residues of hexythiazox and its metabolites in/on almond and stone fruit commodities is also adequate for data collection purposes. Adequate method validation data were submitted. These methods are based on Method AMR–985–87, which has been deemed acceptable as a tolerance enforcement method in conjunction with a petition for use on apples. The method has been validated for use on various crop commodities, and has been forwarded to FDA for inclusion in PAM II. This earlier method is considered sufficient to enforce the proposed permanent tolerances for residues in/on apples, cotton, stone fruit, almonds, and strawberries. The PAM-II analytical enforcement method for residues of hexythiazox and its metabolites (AMR–985–87) is available to measure residues in meat, milk and eggs.

The petitioner has submitted data describing the testing of hexythiazox through FDA Multiresidue protocols C through E. This information has been forwarded to the FDA. In addition, hexythiazox and its metabolites have been tested according to the FDA Multiresidue protocols C through E by BASF Corporation in conjunction with a petition for use on hops. The information pertaining to the testing of hexythiazox *per se*, which indicated that hexythiazox was not recovered from hops, has been forwarded to the FDA. Multiresidue method testing data for the major metabolites of hexythiazox have been submitted to EPA and will be forwarded to FDA.

C. Magnitude of Residues

An adequate number of residue field trials reflecting the proposed use rules were submitted to EPA to demonstrate that tolerances for apples at 0.5 ppm; wet apple pomace at 0.80 ppm; stone fruits (except plums) at 1 ppm; almond at 0.3 ppm and almond hulls at 10 ppm; milk at 0.02 ppm; fat of cattle, goats, horses, swine and sheep at 0.02 ppm; meat by-products of cattle, goats, horses, swine and sheep at 0.02 ppm; cotton, undelinted seed (CA only), at 0.20 ppm; and cotton gin byproducts (CA only) at 3.0 ppm will not be exceeded when hexythiazox products labeled for these uses are used as directed. For strawberries, EPA is requiring submission of additional crop field studies from three other strawberry growing areas of the United States as confirmatory data in support of the proposed tolerances.

D. Rotational Crop Restrictions

A limited confined rotational crop study was submitted and needs to be repeated as a condition of registration. Although the study was limited in nature, the data indicated that residues of hexythiazox and its metabolites would not be present in crops planted 4 months after application of hexythiazox. The proposed label specifies a 120-day rotational crop restriction. Therefore, tolerances for residues in rotational crops will not be required.

E. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for residues of hexythiazox per se in/on cherries and peaches at 1 mg/kg, plums (including prunes) at 0.2 mg/kg, apples at 0.5 mg/kg and strawberries at 0.5 mg/kg; no codex MRLs are established for residues in/on cotton commodities. The Codex MRLs and U.S. tolerances are not compatible because the U.S. tolerance expression currently includes parent hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety. Neither Canadian nor Mexican MRLs have been established for residues of hexythiazox in the subject crops.

F. Endocrine Disruption

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect.... EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the **Federal Register** of December 28, 1998, 63 FR 71541 (FRL–XXXX–X). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of hexythiazox and its end-use products for endocrine effects may be required.

V. Conclusion

Therefore, the tolerances are established 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 almond at 0.3 ppm and almond hulls at 10 ppm; apple at 0.50 ppm; apple, wet pomace at 0.80 ppm; cotton, undelinted seed (CA only), at 0.20 ppm; and cotton gin byproducts (CA only) at 3.0 ppm; milk at 0.02 ppm; fruit, stone (except plums) at 1.0 ppm; strawberry at 3.0 ppm; fat of cattle, goats, horses, swine, and sheep at 0.02 ppm; and meat byproducts of cattle, goats, horses, swine, and sheep at 0.02 ppm.

Conditional registration for use of hexythiazox on these crops are being proposed to allow development and review of a 21-day dermal toxicity study (data gap); an acceptable *in vivo* mouse micronucleus assay; an acceptable poultry metabolism study; and three additional strawberry residue trials.

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–301061 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 28, 2000.

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–301061, 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 file format 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required 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 require 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 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).

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: September 21, 2000.

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), (346a) and 371.

2. Section 180.448 is amended by revising the table in paragraph (a), by removing from the table in paragraph (b) the entries for ''cotton seed, undelinted''; ''cotton gin byproducts''; ''hops''; and ''strawberries'', and by adding text to paragraph (c) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond	0.30
Almond, hulls	10
Apple	0.50
Apple, wet pomace	0.80
Cattle, fat	0.02
Cattle, mbyp	0.02
Fruit, stone, group (except plums)	1.0
Goat, fat	0.02
Goat, mbyp	0.02
Hops	2.0
Horse, fat	0.02
Horse, mbyp	0.02
Milk	0.02
Pears	0.30
Sheep, fat	0.02
Sheep, mbyp	0.02
Strawberry	3.0
Swine, fat	0.02
Swine, mbyp	0.02

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations as defined 40 CFR 180.1(n), are established for the combined 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 the following commodities:

Commodity	Parts per million
Cotton, gin byproducts (CA only)	3.0
Cotton, undelinted seed (CA only)	0.20

* * * * *

[FR Doc. 00–24945 Filed 9–28–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301059; FRL–6745–2]

RIN 2070–AB78

Methacrylic Acid-Methyl Methacrylate-Polyethylene Glycol Methyl Ether Methacrylate Copolymer; and Maleic Anhydride-α-Methylstyrene Copolymer Sodium Salt; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of two polymers methacrylic acid-methyl methacrylate-polyethylene glycol methyl ether methacrylate copolymer; and maleic anhydride-α-methylstyrene copolymer sodium salt when used as an inert ingredient surfactant in or on growing crops or when applied to raw agricultural commodities after harvest. Huntsman Petrochemical Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of methacrylic acid-methyl methacrylate-polyethylene glycol methyl ether methacrylate copolymer; and maleic anhydride-α-methylstyrene copolymer sodium salt.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301059, must be received by EPA on or before November 28, 2000.

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 XI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301059 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373 and e-mail address: alston.treva@epa.gov.