explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

VII. Legal Authority

Statutory authority for the rules proposed today can be found in 42 U.S.C. 7401–7671q.

List of Subjects in 40 CFR Part 80

Environmental protection, Fuel additives, Gasoline, Imports, Reporting and recordkeeping requirements.

Dated: December 22, 2005.

Stephen L. Johnson,

Administrator.

For the reasons set forth in the preamble, we propose to amend part 80 of title 40 of the Code of Federal Regulations to read as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7545, and 7601(a).

2. Subpart K is added to read as follows:

Subpart K—Renewable Fuel Standard

§ 80.1100 How is the statutory default requirement for 2006 implemented?

(a) *Definitions.* (1) *Renewable fuel.* (i) Renewable fuel means motor vehicle fuel that is used to replace or reduce the quantity of fossil fuel present in a fuel mixture used to operate a motor vehicle, and which

(A) Is produced from grain, starch, oil seeds, vegetable, animal, or fish materials including fats, greases, and oils, sugarcane, sugar beets, sugar components, tobacco, potatoes, or other biomass, or

(B) Is natural gas produced from a biogas source, including a landfill, sewage waste treatment plant, feedlot, or other place where decaying organic material is found.

(ii) The term ''renewable fuel'' includes cellulosic biomass ethanol, waste derived ethanol, biodiesel, and any blending components derived from renewable fuel.

(2) *Cellulosic biomass ethanol* means ethanol derived from any lignocellulosic or hemicellulosic matter that is available on a renewable or recurring basis, including dedicated energy crops and trees, wood and wood residues, plants, grasses, agricultural residues, fibers, animal wastes and other waste materials, and municipal solid waste. The term also includes any ethanol produced in facilities where animal wastes or other waste materials are digested or otherwise used to displace 90 percent or more of the fossil fuel normally used in the production of ethanol.

(3) *Waste derived ethanol* means ethanol derived from animal wastes, including poultry fats and poultry wastes, and other waste materials, or municipal solid waste.

(4) *Small refinery* means a refinery for which the average aggregate daily crude oil throughput for a calendar year (as determined by dividing the aggregate throughput for the calendar year by the number of days in the calendar year) does not exceed 75,000 barrels.

(5) *Biodiesel* means a diesel fuel substitute produced from nonpetroleum renewable resources that meets the registration requirements for fuels and fuel additives established by the Environmental Protection Agency under section 211 of the Clean Air Act. It includes biodiesel derived from animal wastes (including poultry fats and poultry wastes) and other waste materials, or biodiesel derived from municipal solid waste and sludges and oils derived from wastewater and the treatment of wastewater.

(b) *Renewable Fuel Standard for 2006.* The percentage of renewable fuel in the total volume of gasoline sold or dispensed to consumers in 2006 in the United States shall be a minimum of 2.78 percent on an annual average volume basis.

(c) *Responsible parties.* Parties collectively responsible for attainment of the standard in paragraph (b) of this section are refiners (including blenders) and importers of gasoline. However, a party that is a refiner only because he owns or operates a small refinery is exempt from this responsibility.

(d) *EPA determination of attainment.* EPA will determine after the close of 2006 whether or not the requirement in paragraph (b) of this section has been met. EPA will base this determination on information routinely published by the Energy Information Administration on the annual domestic volume of gasoline sold or dispensed to U.S. consumers and of ethanol produced for use in such gasoline, supplemented by readily available information concerning the use in motor fuel of other renewable fuels such as cellulosic biomass ethanol, waste derived ethanol, biodiesel, and other non-ethanol renewable fuels.

(1) The renewable fuel volume will equal the sum of all renewable fuel volumes used in motor fuel, provided that:

(i) One gallon of cellulosic biomass ethanol or waste derived ethanol shall be considered to be the equivalent of 2.5 gallons of renewable fuel; and

(ii) Only the renewable fuel portion of blending components derived from renewable fuel shall be counted towards the renewable fuel volume.

(2) If the nationwide average volume percent of renewable fuel in gasoline in 2006 is equal to or greater than the standard in paragraph (b) of this section, the standard has been met.

(e) *Consequence of nonattainment in 2006.* In the event that EPA determines that the requirement in paragraph (b) of this section has not been attained in 2006, a deficit carryover volume shall be added to the renewable fuel volume obligation for 2007 for use in calculating the standard applicable to gasoline in 2007.

(1) The deficit carryover volume shall be calculated as follows:

$$DC = V_{gas} \cdot (R_s - R_a)$$

Where:

DC = Deficit carryover in gallons of renewable fuel

V_{gas} = Volume of gasoline sold or dispensed to U.S. consumers in 2006, in gallons

R_s = 0.0278

R_a = Ratio of renewable fuel volume divided by total gasoline volume determined in accordance with paragraph (d)(2) of this section.

(2) There shall be no other consequence of failure to attain the standard in paragraph (b) of this section in 2006 for any of the parties in paragraph (c) of this section.

[FR Doc. 05–24610 Filed 12–29–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0518; FRL–7752–1]

Hexythiazox; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish tolerances for combined residues of 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 grape; citrus fruit, crop group 10 (CA, AZ, TX only); citrus, oil; citrus, dried pulp; fruit, pome, group 11; apple, wet pomace; and cattle, sheep, goat, and horse meat byproducts under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: Comments must be received on or before January 30, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0518, by one of the following methods:

- *Federal eRulemaking Portal http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*: EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.
- *E-mail*: Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number EPA–HQ–OPP–2005–0518.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number EPA–HQ–OPP–2005–0518.
- *Hand delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number EPA–HQ–OPP–2005–0518. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2005–0518. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/docket*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through the EDOCKET and or regulations.gov; your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Olga Odiott, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; e-mail address: *odiott.olga@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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

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

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI). In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a

Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background and Statutory Findings

In the **Federal Register** of June 1, 2005 (70 FR 31455) (FRL–7711–8), EPA issued a notice under section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6569) by Gowan Company, 370 S. Main St., Yuma, AZ 85365. The petition requested that 40 CFR 180.448 be amended by establishing a tolerance for combined residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent), in or on grapes at 1.0 part per million (ppm), raisins at 4.0 ppm, citrus at 0.5 ppm, and citrus oil at 2.0 ppm. 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.

EPA is issuing this action as a proposed rule (rather than a final rule) because after review of the initial petition and the Notice of Filing the Agency has determined that:

- The existing tolerance for apple, wet pomace must be revised to 2.5 ppm.
- The existing tolerances for cattle, goat, sheep, and horse meat byproducts must be revised to 0.12 ppm.

EPA has also determined that:

- The existing tolerances for apple and pear can be deleted since a tolerance is being proposed for the entire pome fruit group.
- The proposed tolerances for grapes at 1.0 ppm; citrus fruit, crop group 10 at 0.5 ppm; and citrus oil at 2.0 ppm should be revised to 0.75 ppm, 0.35 ppm, and 0.90 ppm, respectively.
- Tolerances for citrus, dried pulp at 1.5 ppm; and fruit, pome, group 11 at 1.7 ppm are necessary.
- The proposed tolerance for raisins is not necessary.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances of November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of hexythiazox on grape at 0.75 ppm; citrus fruit, crop group 10 (CA, AZ, TX only) at 0.35 ppm; citrus, oil at 0.90 ppm; citrus, dried pulp at 1.5 ppm; fruit, pome, group 11 at 1.7 ppm; apple, wet pomace at 2.5 ppm; and cattle, sheep, goat, and horse meat byproducts at 0.12 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 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of April 18, 2001 (66 FR 19879) (FRL–6778–8). Since that time a micronucleus assay study has been submitted and reviewed. Based on the submitted studies hexythiazox has been classified as nonmutagenic.

B. Toxicological Endpoints

The dose at which 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 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 inter-species 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 (aRfD or cRfD) 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 (SF).

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 inter-species differences and 10X for intra-species 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 Table 1 of this unit:

TABLE 1.—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 Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary - females (13-50 years) of age	NOAEL = 240 mg/kg/day UF = 100 aRfD = 2.4 mg/kg/day	FQPA SF = 1x aPAD = 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)	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.		
Chronic dietary (all populations)	NOAEL= 2.5 mg/kg/day UF = 100 cRfD = 0.025 mg/kg/day	FQPA SF = 1x cPAD = 0.025 mg/kg/day	One–year toxicity 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*= $2.22x10^{-2}$mg/kg/day^{-1}	Increases in incidence of malignant and combined benign/malignant liver tumors in female mice
Short-term dermal (1-30 days) (occupational)	Oral maternal NOAEL = 240 mg/kg/day (dermal absorption rate = 2%)	LOC for MOE = 100 (occupational)	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
Short-term inhalation (1-30 days)(occupational)	Oral maternal NOAEL= 240 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational)	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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.448) for the combined residues of hexythiazox, in or on a variety of raw agricultural commodities ranging from 0.10–10 ppm. Tolerances have also been established for these same compounds in/on milk (0.02 ppm), ruminant fat (0.02 ppm), and ruminant meat byproducts (0.02 ppm) as a result of secondary residues. 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 1–day or single exposure. The Lifeline™ (ver. 3.00) and Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 2.03) models were used for the assessments. Both of these models use food consumption data from the U. S. Department of Agriculture (USDA's) 1994–1996, and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues, 100% crop treated, and DEEM™ (ver 7.81) default processing factors for all plant and livestock residues.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Lifeline™ (ver. 3.00), and DEEM-FCID™, (ver. 2.03) models evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Average percent crop treated (PCT) estimates for several registered commodities, projected PCT estimates for proposed commodities, average field trial residues, FDA monitoring data for stone fruit (excluding cherry) and pome fruit,

experimentally determined processing factors when available, and anticipated livestock residues (dietary burden calculated using average field trial and PCT estimates).

iii. *Cancer*. The cancer dietary analyses were also conducted using the Lifeline™ (ver. 3.00), and DEEM-FCID™, (ver. 2.03) models. The cancer dietary analyses assumed the same plant and livestock residues as that of the chronic analyses.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA 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 PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows. Average values for PCT data were used in the chronic and cancer analyses for the following commodities with established tolerances: <1% for almonds, apples, apricots, cherries, prunes, plums, and walnuts; 5% for nectarines, peaches, and pears; 10% for dates; and 20% for strawberries. Projected average PCT values were used for proposed commodities as follows: 23% for grapes and 21% for oranges.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, PCT estimates are derived from available federal, state, and private market survey data. For existing crop sites on pesticide registrations (''existing use''), EPA uses an average PCT for chronic dietary exposure estimates. The average PCT figure is derived by combining available federal, state, and private market survey data on the existing use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary exposure estimates. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation.

The Agency projects PCT for a new pesticide use by assuming that the PCT for the pesticide's initial five years will not exceed the average PCT of the dominant pesticide (the one with the largest PCT) within its chemical type over three latest available years. For grapes hexythiazox was compared with imidacloprid. For oranges, hexythiazox was compared with abamectin and S-methoprene. The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is non-proprietary and directly available without computation. This method of projecting PCT for a new pesticide, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant pesticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant pesticide could be exceeded are whether the new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide within its similar type, whether it is more cost-effective than the dominant pesticide, and whether it is likely to be readily accepted by growers and experts.

As to Conditions 2 and Condition 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 ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

The acute, chronic, and cancer analyses incorporated modeled surface water and/or ground water estimates generated using PRZM/EXAMS and SCI-GROW, respectively. The SCI-GROW model evaluated the highest registered/proposed application rate. The PRZM/EXAMS model evaluated all registered/proposed application scenarios. The PRZM/EXAMS evaluation considered potential spatial variation by using model scenarios which represent a combination of specific agronomic, soil, and climatological parameters which are geographically specific.

Based on the PRZM/EXAMS and SCI-GROW models the estimated drinking water concentrations (EDWCs) of hexythiazox for acute exposures are estimated to be 4.23 parts per billion (ppb) for surface water and 0.00503 ppb for ground water. The EDWCs for chronic exposures are estimated to be 2.26 ppb for surface water and 0.00503 ppb for ground water. The EDWCs for cancer are estimated to be 1.72 ppb for surface water and 0.00503 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).

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to hexythiazox and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for 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 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 prenatal and postnatal toxicology data base indicates no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

3. *Conclusion*. EPA determined that the special FQPA SF to protect infants and children should be removed. The recommendation is based on the following:

- The toxicology data base for hexythiazox is considered complete for selecting toxicity endpoints for risk assessment. The toxicity profile of hexythiazox can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects.
- Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.
- There is no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

E. Aggregate Risks and Determination of Safety

Acute, chronic, and cancer modeled drinking water estimates were incorporated directly into the aggregate dietary analysis, rather than using back-calculated drinking water levels of comparison (DWLOCs). EPA is no longer comparing EDWCs generated by water quality models with DWLOCs. Instead, EPA is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentrations into our aggregate assessments relies on actual CSFII-reported drinking water consumption and more appropriately reflects the full distribution of drinking water concentrations.

The acute analysis assumed the PRZM/EXAMS 1 in 10–year annual peak drinking water concentration. The chronic analysis assumed the PRZM/EXAMS 1 in 10–year annual mean concentration. These estimates were higher than the SCI-GROW estimates.

The DEEM-FCID™ cancer analysis assumed the PRZM/EXAMS 30–year annual mean concentration (which was higher than the SCI-GROW estimate). Since Lifeline™ allows for the assignment of different drinking water concentrations for those individuals in households with private wells, the Lifeline™ analysis incorporated both the PRZM/EXAMS 30–year annual mean concentration and the SCI-GROW concentration. The Lifeline™ analysis assumed the SCI-GROW concentration for individuals obtaining drinking water from individual wells and the PRZM/EXAMS 30–year annual mean concentration for individuals in households receiving drinking water from public water systems and other sources.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the resulting Lifeline™ and DEEM-FCID™ exposure estimates were <1% of the aPAD for females 13-49 years old. An acute endpoint for the remaining population subgroups was not identified. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HEXYTHIAZOX (FOOD + DRINKING WATER)

Population Subgroup	aPAD (mg/kg/day)	%aPAD		Exposure (mg/kg/day)	
		DEEM-FCID	Lifeline	DEEM-FCID	Lifeline
Females (13-49 years old)	2.4	<1	<1	0.010176	0.0120

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, the resulting Lifeline™ and DEEM-FCID™ exposure estimates were <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants and 1% of the cPAD for children 1-2 years old, the children subpopulation at greatest exposure]. There are no residential uses for hexythiazox that result in chronic residential exposure to hexythiazox. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO HEXYTHIAZOX (FOOD + DRINKING WATER)

Population Subgroup	cPAD (mg/kg/day)	%cPAD		Exposure (mg/kg/day)	
		DEEM-FCID	Lifeline	DEEM-FCID	Lifeline
General U.S. population	0.025	<1	<1	0.000110	0.000094
All Infants <(1 year old)	0.025	<1	<1	0.000217	0.000185
Children (1-2 years old)	0.025	1	1	0.000267	0.000251

3. *Aggregate cancer risk for U.S. population*. Based on the exposure assumptions described in this unit the resulting cancer DEEM-FCID™ and Lifeline™ dietary exposure estimates for the U.S. population yielded a cancer risk of 2.30 in 1 million and 2.03 in 1 million, respectively. DEEM-FCID™ resulted in a higher cancer risk estimate due to differing drinking water assumptions described in this unit (Lifeline™ permits incorporation of the entire PRZM-EXAMS distribution when conducting a cancer analysis while DEEM-FCID™ permits only a point estimate). Based on a the DEEM-FCID™ analysis, the major contributors to the cancer risk were water (35% of total exposure), strawberry (15% of total exposure), grape (14% of total exposure), field corn (13% of total exposure), citrus (9% of total exposure), caneberry (5% of total exposure), and hop (5% of total exposure). The remaining commodities combined for 4% of the total exposure.

Under the reasonable certainty of no harm standard in FFDCA section 408(b)(2)(A)(ii), cancer risks must be no greater than negligible. EPA has consistently interpreted negligible cancer risks to be risks within the range of an increased cancer risk of 1 in 1 million. Risks as high as 3 in 1 million have been considered to be within this risk range. EPA concludes that the estimated cancer risk for hexythiazox is within the negligible risk range. The Agency notes that hexythiazox has been classified as a possible human carcinogen based on increased incidence of liver tumors in female mice. No chemical-related oncogenic effects were reported in male mice or in male and female rats, and hexythiazox has been classified as nonmutagenic. A summary of the cancer dietary exposure estimates for hexythiazox are shown in Table 4 of this unit:

TABLE 4.—AGGREGATE CANCER DIETARY EXPOSURE AND RISK FOR HEXYTHIAZOX (FOOD + DRINKING WATER)

Population Subgroup	Q_1*1	Exposure (mg/kg/day)		Risk	
		DEEM-FCID	Lifeline	DEEM-FCID	Lifeline
General U.S. population	0.022	0.000104	0.00091	2.30×10^{-6}	2.03×10^{-6}

4. *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. Analytical Enforcement Methodology

The Pesticide Analytical Manual Volume II (PAM II) of the Food and Drug Administration (FDA) includes suitable analytical methods for the determination of hexythiazox and metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (AMR-985–87) in pome fruit, grape, and citrus, livestock tissue, and milk.

B. International Residue Limits

The Codex and EPA tolerance expression differ; therefore, harmonization is not possible

C. Conditions

As a condition of registration the registrant must submit the following data:

- Apple and pear field trial data for the emulsifiable concentrate (EC) formulation. The recommended tolerance may overestimate actual expected residues following application of hexythiazox as labeled since is based on an exaggerated rate from the wettable powder residue trial and the maximum factor by which the EC formulation

exceeded the WP formulation in the apple side-by-side field trials.

- An orange processing study.

V. Conclusion

Tolerances are proposed for combined residues of 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 grape at 0.75 ppm; citrus fruit, crop group 10 (CA, AZ, TX only) at 0.35 ppm; citrus, oil at 0.90 ppm; citrus, dried pulp at 1.5 ppm; fruit, pome, group 11 at 1.7 ppm; apple, wet pomace at 2.5 ppm; and cattle, sheep, goat, and horse meat byproducts at 0.12 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed 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). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishing a tolerance, in effect, removes the statutory bar on the use of a pesticide on the specified crops and thus has no negative economic impact. 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 proposed rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: December 22, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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 removing the commodities ''apple'' and ''pear'' and alphabetically adding new commodities to the table in paragraphs (a) and (c) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Citrus, dried pulp	1.5
Citrus, oil	0.90
* * *	* *
Fruit, pome, group 11	1.7
* * *	* *
Grape	0.75
* * *	* *

* * * * *

(c) * * *

Commodity	Parts per million
* * *	* *
Fruit, citrus group 10 (CA, AZ, TX only)	0.35

* * * * *

3. Section 180.448 is amended by revising the following commodities in the table in paragraph (a) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Apple, wet pomace	2.5

Commodity	Parts per million
* * *	* *
Cattle, meat byproducts	0.12
* * *	* *
Goat, meat byproducts ...	0.12
* * *	* *
Horse, meat byproducts	0.12

Commodity	Parts per million
* * *	* *
Sheep, meat byproducts	0.12

* * * * *

[FR Doc. E5–8037 Filed 12–29–05; 8:45 am]
BILLING CODE 6560–50–S