

*Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCa, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions

of section 408(n)(4) of FFDCa. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: May 14, 2008.

**Donald Stubbs,**

*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. Section 180.627 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.627 Fluopicolide; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Brassica, head and stem, subgroup 5A .....	5.0
Vegetable, bulb, crop group 3–07 .....	7.0
Vegetable, leaves of root and tuber, group 2 .....	15.0
Vegetable, root, subgroup 1A, except sugar beet and carrot .....	0.15

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2005–0309; FRL–8365–2]

**Hexythiazox; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of hexythiazox in or on corn, field, grain;

corn, field, stover; and corn, field, forage. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 28, 2008. Objections and requests for hearings must be received on or before July 28, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0309. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced

Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Olga Odiott, Registration Division (7505P), 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](mailto: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 those engaged in the following activities:

- 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 to provide 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?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot

e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0309 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 as required by 40 CFR part 178 on or before July 28, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2005-0309, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### **II. Petition for Tolerance**

In the **Federal Register** of March 1, 2006 (71 FR 10506) (FRL-7756-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6953) by Gowan Company, 370 South Main Street, Yuma, AZ 85364. The petition requested that 40 CFR 180.448 be amended by establishing tolerances for combined residues of the insecticide 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, in or on corn, field, grain at 0.05 parts per million (ppm); corn, field, stover at 2.0 ppm; and corn, field, forage at 2.0 ppm. That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerance levels to 0.02 ppm for corn, field, grain; 2.5 ppm for corn, field, stover; and 6.5 ppm for corn, field, forage. The reasons for these changes are explained in Unit IV.D.

##### **III. Aggregate Risk Assessment and Determination of Safety**

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...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of hexythiazox on corn, field, grain at 0.02 ppm; corn, field, stover at 2.5 ppm; and corn, field, forage at 6.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Hexythiazox has a low order of acute toxicity for the oral, dermal and inhalation routes of exposure. It produces mild eye irritation, is not a dermal irritant, and is negative for dermal sensitization. The target organs of hexythiazox are the liver and adrenal glands, with the dog being the most sensitive species. In a subchronic toxicity study in rats, increased liver and adrenal weights as well as adrenal histopathology (fatty degeneration of the adrenal zone fasciculata) were seen. In a 4-week range-finding study in dogs, effects included increased liver and adrenal weights (reported in the chronic dog study). Chronic studies in dogs, rats, and mice support the liver and adrenal effects seen in the subchronic studies. In the chronic dog study, increased liver and adrenal weights were observed, along with associated histopathology of the liver (hypertrophy) and adrenal glands (adrenal cortex hypertrophy). In the chronic feeding/carcinogenicity studies in rats and mice, effects included decreased body weight gain and increased liver weights. The effects of hexythiazox on the adrenal glands could be an indication of endocrine disruption. However, in all studies in which these effects were seen, a NOAEL was determined. The data provided no indication of increased susceptibility in rats or rabbits from *in utero* and post-natal exposure to hexythiazox. There was no evidence of carcinogenicity in male and female rats; however, there were increased incidences of malignant and combined benign/malignant liver tumors in female B6C3FT mice. Hexythiazox was not mutagenic in bacteria or Chinese hamster ovary (CHO) cells. It was negative for chromosomal aberrations in CHO and did not cause unscheduled DNA synthesis (UDS) in primary rat hepatocytes. In an acceptable micronucleus assay, there was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow of treated mice after any dose or treatment time. Hexythiazox has been found classified as nonmutagenic.

Specific information on the studies received and the nature of the adverse 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 are discussed in the final rule published in the **Federal Register** of December 30, 2005 (70 FR 77363) (FRL-7752-1).

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for hexythiazox used for human risk assessment can be found at <http://www.regulations.gov> in document *Hexythiazox- Human Health Risk Assessment for the Section 3*

*Registration for Application to Field Corn; 14- February-2008*, page 11 in docket ID number EPA-HQ-OPP-2005-0309.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in (40 CFR 180.448). EPA assessed dietary exposures from hexythiazox in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA tolerance-level residues, 100% crop treated (PCT), and DEEM-FCID (ver 7.81) default processing factors for all plant and livestock residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA used PCT estimates, average field trial residues, experimentally determined processing factors when available, and anticipated livestock residues (dietary burden calculated using average field trial residues).

iii. *Cancer.* Cancer risk was assessed using the same estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and 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 residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

*Condition a.* 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 the pesticide residue.

*Condition b.* The exposure estimate does not underestimate exposure for any significant subpopulation group.

*Condition c.* 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

1% for apples, cherries, and prunes; 5% for almonds, apricots, mint, peaches, pears, plums, and walnuts; 10% for dates, caneberries, and nectarines; 25% for strawberries; and 50% for hops.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency used projected percent crop treated (PPCT) information as follows:

15% for grapes and 18% for oranges.

EPA estimates PPCT for a new pesticide use by assuming that the PCT during the pesticide's initial five years of use on a specific site will not exceed the average PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that site over the most recent

surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with a new insecticide). 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 publicly available and does not have to be calculated from other available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factor that bears on whether the estimated PPCT could be exceeded is whether there are concerns with pest pressures as indicated in emergency exemption requests or other readily available information. All information currently available has been considered for hexythiazox, and it is the opinion of EPA that it is unlikely that the actual PCT for hexythiazox will exceed the estimated PPCT during the next five years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable 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 used screening level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of hexythiazox

1. The EDWCs for acute exposures are estimated to be 4.23 parts per billion (ppb) for surface water and 0.00503 ppb for ground water.

2. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 2.26 ppb for surface water and 0.00503 ppb for ground water.

3. The EDWCs for chronic exposures for cancer assessments are estimated to be 1.72 ppb for surface water and 0.00503 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

1. For acute dietary risk assessment, the water concentration value of 4.23 ppb was used to assess the contribution to drinking water.

2. For chronic dietary risk assessment, the water concentration of value 2.26 ppb was used to assess the contribution to drinking water.

3. For cancer dietary risk assessment, the water concentration of value 1.72 ppb was used to assess the contribution to drinking 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 any specific use patterns that would result in residential exposure.

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

substances that have a common mechanism of toxicity.”

EPA has not found hexythiazox to share a common mechanism of toxicity with 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 assumed that hexythiazox does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

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 has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for hexythiazox is adequate 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.

ii. There is no evidence that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or

in young rats in the 2-generation reproduction study.

iv. The concern for endocrine related effects (increase in ovarian weight and adrenal weights and/or adrenal pathology) seen in various species is low because there is a well established NOAEL protecting from the effects, no reproductive parameters were affected in the 2-generation reproduction study at the highest dose tested (180 mg/kg/day), there is no evidence of increased susceptibility of infants and children in the database and the doses selected for the cRfD and intermediate and long-term dermal and inhalation exposure assessments are based on the NOAELs protecting from the endocrine related effects. EPA concluded that the selected endpoints adequately account for these potential effects and no additional data are required.

v. There are no residual uncertainties identified in the exposure databases. Although the chronic food exposure assessment is refined, EPA believes that the assessment is based on reliable data and will not underestimate exposure/risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. These assessments will not underestimate the exposure and risks posed by hexythiazox.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to hexythiazox will occupy <1% of the aPAD for (females 13-49 years old) the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox

from food and water will utilize 1% of the cPAD for (children 1-2 years old) the population group receiving the greatest exposure. There are no residential uses for hexythiazox.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to hexythiazox through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to hexythiazox through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for chronic exposure, EPA has estimated increased cancer risk from exposure to hexythiazox at 2 in 1 million ( $2 \times 10^{-6}$ ). Based on a critical commodity analysis, the major contributors to the cancer risk were water (38% of total exposure), strawberry (20% of total exposure), and field corn syrup (16% of 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 interprets 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.

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 or to infants and children from aggregate exposure to hexythiazox residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (Method AMR-985-87.) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

*B. International Residue Limits*

There are no currently established CODEX, Canadian, or Mexican MRLs for residues of hexythiazox in/on the subject commodities.

*C. Response to Comments*

There was one comment received on the notice of filing. The commenter, B. Sachua, requested that a zero tolerance be set for hexythiazox based on the commenter's generalized criticisms of EPA's risk assessment process. EPA has responded to B. Sachua's generalized comments for hexythiazox and other chemicals on several occasions. (See the **Federal Register** of March 22, 2006 (71 FR 14409) (FRL-7768-3); and the **Federal Register** January 7, 2005 (70 FR 1349) (FRL-7691-4).

*D. Revisions to Petitioned-For Tolerances*

EPA revised the proposed tolerance levels (from 0.05 to 0.02 ppm for corn, field, grain; 2.0 to 2.5 ppm for corn, field, stover; and 2.0 to 6.5 ppm for corn, field, forage) based on the field trial data and the maximum residue limit (MRL) tolerance calculator.

**V. Conclusion**

Therefore, tolerances are established 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 corn, field, grain at 0.02 ppm; corn, field, stover at 2.5 ppm; and corn, field, forage at 6.0 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: May 16, 2008.

**Daniel J. Rosenblatt,**

*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. Section 180.448 is amended by alphabetically adding the following commodities to the table in paragraph (c) to read as follows:

**§ 180.448 Hexythiazox, tolerances for residues.**

\* \* \* \* \*  
(c) \* \* \*

Commodity	Parts per million
Corn, field, grain .....	0.02
Corn, field, stover .....	2.5
Corn, field, forage .....	6.0
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