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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0338 and EPA-HQ-OPP-2015-0339; FRL-9942-32]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of hexythiazox in or on citrus and cotton. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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: The dockets for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0338 and EPA-HQ-OPP-2015-0339, are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCa section 408(g), 21 U.S.C. 346a, 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-2015-0338 and EPA-HQ-OPP-2015-0339 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0338 and EPA-HQ-OPP-2015-0339, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 17, 2015 (80 FR 42462) (FRL-9929-13), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5F8346 and PP 5F8356) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569. The petitions requested that tolerances currently listed in 40 CFR 180.448 be amended for residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on citrus, dried pulp at 0.6 parts per million (ppm); citrus, oil at 26 ppm; fruit, citrus, group 10 at 0.6 ppm; cotton gin byproducts at 15 ppm; and cotton, undelinted seed at 0.5 ppm. That document referenced a summary of the petitions prepared by Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revoked citrus, dried pulp tolerance as it is covered by the recommended fruit, citrus, group 10-10 tolerance. For citrus oil, EPA revised the tolerance to 25 ppm and for cotton undelinted seed to 0.4 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDC section 408(b)(2)(A)(i) of FFDC 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 FFDC 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 for hexythiazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with hexythiazox 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 low acute toxicity by oral, dermal and inhalation routes of exposure. It is not a dermal irritant, is negative for dermal sensitization and produces only mild eye irritation. Hexythiazox is associated with toxicity of the liver and adrenals following subchronic and chronic exposure to dogs, rats and mice, with the dog being the most sensitive species. The prenatal developmental studies in rabbits and rats and the two-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* or postnatal exposure to hexythiazox. Reproductive toxicity was not observed. There is no concern for immunotoxicity or neurotoxicity following exposure to hexythiazox. The toxicology database for hexythiazox does not show any evidence of treatment-related effects on the immune system. Hexythiazox is classified as “likely to be

carcinogenic to humans;” however, the weight of evidence indicates that assessing chronic risk using the chronic population adjusted dose will be protective for any potential carcinogenic effects. Since the effects seen in the study that serves as the basis for the chronic PAD occurred at doses substantially below the lowest dose that induced tumors, the chronic PAD is considered protective of all chronic effects including potential carcinogenicity.

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 can be found at <http://www.regulations.gov> in the document: Hexythiazox. Human Health Risk Assessment to Support Amended Uses on Cotton and Citrus in docket ID number EPA-HQ-OPP-2015-0338 or EPA-HQ-OPP-2015-0339.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). 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 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 is shown in Table 1 of this unit.

Table 1. --Summary of Toxicological Doses and Endpoints for Hexythiazox for use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	No risk is expected from this exposure scenario as no hazard was identified in any toxicity study for this duration of exposure.		
Chronic dietary (All populations)	NOAEL= 2.5 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.025 mg/kg/day cPAD = 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.

<p>Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)</p>	<p>NOAEL= 30 mg/kg/day $UF_A = 10 \times$ $UF_H = 10 \times$ FQPA SF = 1x</p>	<p>LOC for MOE = 100</p>	<p>2-generation reproduction study – Rat LOAEL = 180 mg/kg/day based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights.</p> <p>Co-critical</p> <p>13-Week Oral Toxicity Study – Rat</p> <p>NOAEL = 5.5 mg/kg/day</p> <p>LOAEL = 38 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 zona fasciculata. @ 397.5/257.6 mg/kg/day, decreased body-weight gain in females, slight swelling of hepatocytes in central zone (both sexes), increased incidence of glomerulonephrosis in males, increased adrenal weights.</p>
<p>Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)</p>	<p>Oral study NOAEL= 30 mg/kg/day (inhalation absorption rate = 100%) $UF_A = 10 \times$ $UF_H = 10 \times$</p>	<p>LOC for MOE = 100</p>	<p>2-generation reproduction study – Rat LOAEL = 180 mg/kg/day based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights.</p>

			<p>Co-Critical</p> <p>13-Week Feeding Study – Rat</p> <p>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 zona fasciculata.</p>
Cancer (Oral, dermal, inhalation)	<p>Classification: “Likely to be Carcinogenic to Humans”. Insufficient evidence to warrant a quantitative estimation of human risk using a cancer slope factor based on the common liver tumors (benign and malignant) observed only in high dose female mice, and benign mammary gland tumors of no biological significance, observed only in high dose male rats in the absence of mutagenic concerns. The chronic RfD is protective of all chronic effects including potential carcinogenicity of hexythiazox.</p>		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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. No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's 2003 – 2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues, assumed 100 percent crop treated (PCT), and incorporated DEEM default processing factors when processing data were not available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to hexythiazox. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

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 Surface Water Concentration Calculator, the estimated drinking water concentrations (EDWCs) of hexythiazox for chronic exposures for non-cancer assessments are estimated to be 4.3 parts per billion (ppb) for surface water. Since groundwater residues are not

expected to exceed surface water residues, surface water residues were used in the dietary risk assessment. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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 currently registered for the following uses that could result in residential exposures: ornamental plantings, lawns, recreational sites such as campgrounds and golf courses, turf, and fruit and nut trees in residential settings. EPA assessed residential exposure using the following assumptions:

Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Intermediate-term exposures are not likely because of the intermittent nature of applications by residential applicators. Since hexythiazox does not pose a significant dermal risk, a quantitative dermal risk assessment was not performed and handler margins of exposure (MOE) were calculated for the inhalation route of exposure only.

Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated residential plants. Post-application exposures are expected to be short-term (1 to 30 days) in duration for most exposure scenarios, and intermediate-term (1 to 6 months) in duration for soil ingestion only due to the aerobic soil metabolism half-life for hexythiazox. Adult post-application exposures were not assessed since no quantitative dermal risk assessment is needed for hexythiazox and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure

resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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. 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 development studies in rabbits and rats and the two-generation reproduction study in rats showed no indication of increased susceptibility 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 complete.
- ii. There is no indication 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. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer 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 appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect, resulting from a single oral exposure, was identified and no acute dietary endpoint was selected.

Therefore, hexythiazox is not expected to pose an acute risk.

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 81% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

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 currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,300 for children and 9,900 for adults. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

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 currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1,500 for children and 9,900 for adults. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

5. Aggregate cancer risk for U.S. population. As discussed in Unit III.C.1.iii., EPA concluded that regulation based on the chronic reference dose will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern.

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 (high performance liquid chromatography method with ultraviolet detection (HPLC/UV)) is available to enforce the tolerance expression. This method is listed in the U.S. EPA Index of Residue Analytical methods under hexythiazox as method AMR-985-87.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FDCA section

408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for residues of hexythiazox on citrus, fruits but not for cotton. The Codex plant residue definition is for hexythiazox as opposed to the U.S. definition which includes hexythiazox plus metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety. The differences in U.S. and Codex residue definitions prohibits harmonization.

C. Revisions to Petitioned-For Tolerances

Although the petitioner requested an amended tolerance for citrus, dried pulp at 0.6, the Agency has determined that no such tolerance is necessary because that commodity is covered by the established citrus group 10-10 tolerance. The Agency is revising the tolerance for citrus oil to 25 ppm based on the following: By multiplying the citrus oil processing factor (104X) from the 2006 processing study (D334889, 07/03/2006, T. Bloem) by the highest average field trial (HAFT) residue for lemons (0.243 ppm) from the submitted citrus study since lemons are the citrus crop that produced the highest residues.

As noted in its most recent crop group rulemaking in the **Federal Register** of August 22, 2012 (77 FR 50617) (FRL-9354-3), EPA generally does not establish new tolerances under pre-existing crop groups that have been updated. EPA updated crop group 10 in 2010, making the new group 10-10. Therefore, EPA is establishing citrus fruit group tolerances for group 10-10, rather than crop group 10 as requested.

The Agency is amending the tolerance for cotton, undelinted seed at 0.4 ppm based on the available cotton data that reflect a national use at the label specified 35 day pre-harvest interval (PHI) to calculate the 0.4 ppm tolerance.

V. Conclusion

Therefore, tolerances are amended for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on citrus, oil at 25 ppm; fruit, citrus, group 10-10 at 0.6 ppm; cotton, gin byproducts at 15 ppm; cotton, undelinted seed at 0.4 ppm. The current citrus, dried pulp tolerance is revoked because it is unnecessary due to the establishment of the fruit, citrus, group 10-10 tolerance.

VI. Statutory and Executive Order Reviews

This action amends tolerances 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). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "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 action 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 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.

This action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: March 22, 2016.

Susan Lewis,
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 § 180.448:

i. Add alphabetically the entries for “Cotton, gin byproducts” and “Cotton, undelinted seed” to the table in paragraph (a).

ii. Remove the entry for “Citrus, dried pulp” from the table in paragraph (a).

iii. Revise the entry for “Citrus, oil” in the table in paragraph (a).

iv. Remove the entries for “Cotton, gin byproducts, CA and AZ only”, and “Cotton, undelinted seed, CA and AZ only” from the table in paragraph (c).

v. Revise the entry for “Fruit, citrus group 10 (CA, AZ, TX only)” in the table in paragraph (c).

The additions and revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * *	* * *
Citrus, oil	25
* * *	* * *
Cotton, gin byproducts	15
Cotton, undelinted seed	0.4
* * *	* * *

* * *

(c) *Tolerances with regional registrations.* * * *

Commodity	Parts per million
* * *	* * *
Fruit, citrus group 10-10 (CA, AZ, TX only)	0.6
* * *	* * *

* * *