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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0412; FRL-9391-1]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes new tolerances and revises existing tolerances for residues of hexythiazox in or on multiple commodities which are identified and discussed later in this document. Gowan Company and the Interregional Research Project Number 4 (IR-4) requested the 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 docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0412, is 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), EPA West 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: 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; email 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. 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-2013-0412 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-2013-0412, 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.htm*.

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 September 28, 2012 (77 FR 59578) (FRL-9364-6), January 16, 2013 (78 FR 3377) (FRL-9375-4), and August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued notices pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F8054 and PP 2F8073 by Gowan Company, P.O. Box 556, Yuma, AZ 85336; and PP 2E8016 by the Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.448 be amended by establishing tolerances for 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 grain, sorghum, grain at 3.0 parts per million (ppm); grain, sorghum, forage at 5 ppm; grain, sorghum, stover at 6 ppm; egg at 0.05 ppm; poultry, meat at 0.05 ppm; poultry, meat byproducts at 0.05 ppm; by increasing the established tolerance for milk from 0.02 ppm to 0.05 ppm and the established tolerances for ruminant meat byproducts from 0.05 ppm to 0.5 ppm (PP 2F8054); and by amending the regional restriction of the tolerances for cotton, gin byproducts; and cotton, undelinted seed by including Arizona (PP 2F8073). Petition 2E8016 requested that 40 CFR 180.448 be amended by establishing tolerances for

residues of hexythiazox in or on pepper/eggplant subgroup 8–10B at 1.5 ppm; fruit, pome, group 11–10 at 0.25 ppm; caneberry subgroup 13–07A at 1.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1.0 ppm; and berry, low growing, subgroup 13–07G at 3.0 ppm. The documents referenced summaries of the petitions, which are available in the docket, *http://www.regulations.gov* by docket ID numbers EPA-HQ-OPP-2012-0624 (PP 2F8054), EPA-HQ-OPP-2012-0923 (PP 2F8073), and EPA-HQ-OPP-2012-0357 (PP 2E8016). There were no comments received in response to the notices of filing.

Based on EPA's review of the data supporting the petitions, Gowan Company revised their petition PP 2F8054 by adding a request for an increase in the established tolerance for grain, aspirated fractions; deleting the proposed tolerance for poultry, meat; and by deleting the proposed changes to the established tolerances for milk; and for poultry, meat byproducts.

The IR-4 revised their petition PP 2E8016 by increasing the proposed tolerances for fruit, pome, group 11-10; and for berry, low growing, subgroup13-07G. 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 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 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. The toxicity database for hexythiazox is complete. Hexythiazox has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It produces mild eye irritation, is not a dermal irritant, and is negative for dermal sensitization. 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* and/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 evidence as a whole is not strong enough to warrant a quantitative estimation of human risk. Since the effects seen in the study that serves as the basis for the chronic reference dose (RfD) occurred at doses substantially below the lowest dose that induced tumors, the Agency concluded that quantification of risk using a non-linear approach; i.e., RfD, for hexythiazox will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to hexythiazox.

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 document "Hexythiazox. Human Health Risk Assessment to Support New Uses on Grain Sorghum, Pepper/Eggplant Subgroup 8-10B, Pome Fruit Group 11-10, Caneberry Subgroup 13-07A, Small Vine Climbing, Except Fuzzy Kiwifruit Subgroup 13-07F, and Low Growing Berry Subgroup 13-07G" in docket ID number EPA-HQ-OPP-2013-0412.

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 discussed in Unit III.B. of the final rule published in the **Federal Register** of February 8, 2013 (78 FR 9322) (FRL-9376-9).

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 USDA 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*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A. of the **Federal Register** of March 17, 2010 (75 FR 12691) (FRL–8813-7), 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 Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS), the estimated drinking water concentrations (EDWCs) of hexythiazox for chronic exposures for non-cancer and cancer assessments is estimated to be 4.31 parts per billion (ppb) for surface water. Since surface water residues value greatly exceed groundwater EDWCs, 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, 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. Since a quantitative dermal risk assessment is not needed for hexythiazox; MOEs 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. Adult postapplication 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. Post application hand-to-mouth and object-to-mouth exposures are expected to be short-term (1 to 30 days) in duration due to the intermittent nature of applications in residential environments. Given the long half-life of hexythiazox in soil, intermediate-term (1 to 6 months) exposure is also possible 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 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 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. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. The dietary risk assessment is highly conservative and not expected to underestimate risk. 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 postapplication 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 82% of the cPAD for children 1-2 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 9,100 for adults and 1,300 for children. 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 9,300 for adults and 1,500 for children. 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 UV detection (HPLC/UV)) is available for the enforcement of tolerances for residues of hexythiazox and its metabolites containing the PT-1-3 moiety in crop and livestock commodities. 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 FFDCA 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.

Codex MRLs for plant commodities are established for eggplant at 0.1 ppm, pome fruit at 0.4 ppm, grapes at 1.0 ppm, and strawberry at 6 ppm (proposed) for residues of hexythiazox and its metabolites containing the PT-1-3-moiety, expressed as hexythiazox. The U.S. is currently harmonized with Codex with respect to residue definition in plants, and is recommending tolerances for CG 11-10 (pome fruit), CSG 13-07F (small, vine climbing fruit, except kiwifruit), and CSG 13-07G (low growing berry) that are harmonized with the current Codex MRLs for pome fruit, grapes (representative commodity of CSG 13-07F), and strawberry (representative commodity of CSG 13-07G). The current Codex MRL of 0.1 ppm for eggplant is based on a use in the Netherlands at a significantly lower application rate than the use currently proposed in the U.S. The Codex MRL would not cover residues seen in the U.S. field trial data; therefore harmonization with codex with respect to eggplants is not possible at this time.

The Agency is currently harmonized with Codex with respect to the residue definition in livestock commodities. The current milk tolerance of 0.05 ppm is harmonized with the Codex MRL for milk. The Agency is recommending an increase in the ruminant meat byproduct tolerances to 0.5 ppm and an increase in the current egg tolerance to 0.05 ppm to harmonize with Codex.

The Agency classified the use on poultry meat at § 180.6(a)(3), no reasonable expectation of finite residues; therefore the U.S. will not need to set a tolerance for this commodity. The relevant Codex MRL has been set at 0.05 ppm with a footnote that states “absent at the limit of quantitation”. Effectively, the Codex MRL acknowledges

the absence of residues and the U.S. determination that no tolerance is required results in a harmonized approach to residues in poultry meat. There are no Canadian or Mexican MRLs currently established for hexythiazox.

C. Revisions to Petitioned-For Tolerances

Based on EPA's review of the data supporting the petitions, Gowan Company revised their petition PP 2F8054 as follows:

- By adding a request for an increase in the established tolerance for grain, aspirated fractions from 0.5 ppm to 5 ppm. The submitted residue chemistry data show that sorghum residues concentrate in aspirated grain fractions (AGF), and that an increased tolerance of 5 ppm is needed to cover residues in sorghum AGF.
- By deleting the proposed tolerance for poultry, meat; and the proposed changes to the established tolerances for milk; and poultry, meat byproducts. Poultry metabolism and feeding studies demonstrate that there are not likely to be residues in poultry meat; therefore a tolerance on poultry meat is not required. The data also shows that the current tolerances for milk; and poultry, meat byproducts; are adequate and no changes are required at this time.

The IR-4 revised their petition PP 2E8016 as follows:

- By increasing the proposed tolerances for fruit, pome, group,11-10 from 0.25 ppm to 0.4 ppm; and for berry, low growing, subgroup13-07G from 3 ppm to 6 ppm. The Agency is recommending these changes to harmonize with Codex MRLs.

The Agency is also removing the established tolerances for fruit, pome, group 11; caneberry subgroup 13A; grape; and strawberry from 40 CFR. These tolerances are being replaced by the fruit, pome, group 11-10; caneberry subgroup 13-07A; fruit, small,

vine climbing, subgroup 13-07F, except fuzzy kiwifruit; and berry, low growing, subgroup 13-07G, respectively. The Agency concluded that based on the residue data, these changes are required to support the new uses.

V. Conclusion

Therefore, tolerances are established for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, as requested in the petitions.

VI. Statutory and Executive Order Reviews

This final rule establishes 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 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 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 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 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 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) (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 of 1995 (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: July 2, 2013.

Lois Rossi,

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:

a. Remove the following commodities in the table in paragraph (a) “Caneberry subgroup 13A;” “Fruit, pome, group 11;” “Grape;” and “Strawberry.”

b. Revise the following commodities in the table in paragraph (a) “Cattle, meat byproducts;” “Egg;” “Goat, meat byproducts;” “Grain, aspirated fractions;” “Horse, meat byproducts;” and “Sheep, meat byproducts.”

c. Add alphabetically the commodities to the table in paragraph (a).

d. Revise the following commodities in the table in paragraph (c) “Cotton, gin byproducts, CA only;” and “Cotton, undelinted seed, CA only.”

e. Add alphabetically the commodities to the table in paragraph (c).

The revisions and additions read as follows:

§ 180.448 Hexythiazox; tolerance for residues.

(a) *General.* * * *

Commodity	**Parts per million**
* * *	* *
Berry, low growing, subgroup 13-07G	6
Caneberry subgroup 13-07A	1
* * *	* *
Cattle, meat byproducts	0.5
* * *	* *
Egg	0.05
Fruit, pome, group 11-10	0.4
Fruit, small, vine climbing, subgroup 13-07F,	1

except fuzzy kiwifruit	
* * *	* *
Goat, meat byproducts	0.5
Grain, aspirated fractions	5
* * *	* *
Horse, meat byproducts	0.5
* * *	* *
Pepper/eggplant subgroup 8-10B	1.5
* * *	* *
Sheep, meat byproducts	0.5
* * *	* *

* * * * *

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

Commodity	**Parts per million**
* * *	* *
Cotton, gin byproducts, CA and AZ only	3.0
Cotton, undelinted seed, CA and AZ only	0.20
* * *	* *
Sorghum, grain, forage (EPA Regions 6-8 only)	5
Sorghum, grain, grain (EPA Regions 6-8 only)	3
Sorghum, grain, stover (EPA Regions 6-8 only)	6
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