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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0155; FRL-9968-12]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing tolerance for residues of the ovicide/miticide hexythiazox in/on hop, dried cones, by increasing the current tolerance from 2.0 parts per million (ppm) to 20 ppm. Gowan Company requested modification of this tolerance 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-2017-0155, 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), 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: Michael L. Goodis, P.E., Director, 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-2017-0155 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-2017-0155, 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 June 8, 2017 (82 FR 26641) (FRL-9961-14), EPA issued a document pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP #6F8489) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569. This petition requested that 40 CFR 180.448 be amended by establishing a tolerance for residues of hexythiazox in or on hop, dried cones at 20 ppm. This document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov*. No comments were received in response to the referenced notice of filing.

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.

Hexythiazox has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It produces mild eye irritation and is not a skin irritant or skin sensitizer. 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" based on a treatment-related increase in benign and malignant liver tumors in female mice and the presence of mammary gland tumors (fibroadenomas) in male rats; however, the evidence as a whole was not strong enough to warrant the use of a linear low dose extrapolation model applied to the animal data (Q_1*) for a quantitative estimation of human risk because the common liver tumors (benign and malignant) were only observed in high-dose female mice, and benign mammary gland tumors were only observed in high-dose male rats. Since the effects seen in the study that serves as the basis for the chronic reference dose (cRfD) occurred at doses substantially below the lowest dose that induced tumors (and there is no mutagenic concern for hexythiazox), the cRfD 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* within the document entitled "Hexythiazox. Human Health Risk Assessment for Amended Use on Hops," dated September 5, 2017, which can be found in docket ID number EPA-HQ-OPP-2017-0155.

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 the Table of this unit.

Table --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	One-Year Feeding Toxicity Study - Dogs LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights, and associated adrenal histopathology.
Incidental Oral Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months)	NOAEL= 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	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.
Dermal Short- and Intermediate-term	A quantitative dermal risk assessment is not necessary since no dermal hazard is anticipated. There is no evidence of increased quantitative or qualitative susceptibility of the young following *in utero* and pre-and post-natal exposure to hexythiazox.		
Inhalation Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months)	Oral NOAEL= 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	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.

Cancer (oral, dermal, and inhalation)	Classification: "Likely to be Carcinogenic to Humans." A 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.

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 toxic effects attributable to a single dose of hexythiazox were observed in the toxicology database; therefore, a quantitative acute dietary exposure and risk assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary (food and drinking water) exposure assessment, EPA used the Dietary Exposure Evaluation Model (DEEM-FCID), Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003-2008. As to residue levels in food, EPA used tolerance-level residues, assumed 100 percent

crop treated (PCT), and incorporated DEEM 7.81 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., *Chronic exposure*.

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 PCT 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*.

Surface water and groundwater estimated drinking water concentrations (EDWCs) do not result in any change to the existing EDWCs determined from a recent drinking water assessment derived on hops. Specifically, since hops is already a registered use that was recently assessed during registration review, no new drinking water scenarios were identified with this proposed increase in application rates that would require a new drinking water assessment to be conducted. In fact, the highest EDWCs associated with all uses of hexythiazox continue to be from use on sorghum in the Western U.S., using the Pesticide Root Zone Model (PRZM) surface

water modeling scenario. Furthermore, based on the Agency's previous assessment, the EDWCs of hexythiazox for chronic exposures are estimated to be 4.3 parts per billion (ppb) for surface water and 2.4 ppb for ground water (DP 433290, 5/9/2016; DP 404023, 1/17/2012), and the higher of these values was used in the dietary exposure model to assess chronic dietary risk.

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 residential uses, including ornamental landscape plantings, turf, and fruit and nut trees in residential sites.

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, handler MOEs were calculated for the inhalation route of exposure only. EPA uses the term "post-application" to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. There is potential for post-application for individuals exposed as a result of being in an environment that has been previously treated with hexythiazox. Adult residential post-application dermal exposures were not assessed since no dermal hazard was identified for hexythiazox. The residential post-application exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hand-to-mouth, object to- 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/science/residential-exposure-sop.html*.

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 Food Quality Protection Act Safety Factor (FQPA 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. 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 toxic effects attributable to a single dose of hexythiazox were observed in the toxicology database; therefore, a quantitative acute aggregate risk assessment for hexythiazox is not required.

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 93% 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, drinking water, and residential inhalation exposures result in an aggregate MOE for adults (7,500) that greatly exceeds the LOC of 100, and is 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 the combined intermediate-term food, drinking water, and residential oral exposures result in an aggregate MOE for children (1,150) that greatly exceeds the LOC of 100, and is 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 cRfD will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern; therefore, the Agency concludes that aggregate exposure to hexythiazox will not pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology.

An adequate High performance liquid chromatography using ultra-violet detection (HPLC/UV) analytical method 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. The limit of quantification (LOQ) for hexythiazox residues is 0.02 ppm.

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 Federal Food, Drug and Cosmetic Act (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 has established an MRL for residues of hexythiazox on hops at 3 ppm. The U.S. tolerance for residues of hexythiazox on hops cannot be harmonized based on approved label instructions. Based on available residue data, compliance with label instructions would result in exceedances of a tolerance harmonized with the Codex MRL.

V. Conclusion

Therefore, the existing tolerance for residues of the ovicide/miticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in/on hop, dried cones is increased from 2.0 ppm to 20 ppm.

VI. Statutory and Executive Order Reviews

This action amends an existing tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). 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: October 6, 2017_____

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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 revising the entry “Hop, dried cones” in the table in paragraph (a) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Hop, dried cones	20
****	***

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[FR Doc. 2017-23439 Filed: 10/27/2017 8:45 am; Publication Date: 10/30/2017]