ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.131(b)(1)

Contaminant	Methodology	EPA method	ASTM [4]	SM 21st edition [1]
*	* * *	*	*	
HAA5	LLE (diazomethane)/GC/ECD			6251 B
	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	557 [14]		
Bromate	Two-Dimensional Ion Chromatography (IC)	302.0 [18]		
	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	557 [14]		
	Chemically Suppressed Ion Chromatography		D 6581–08 A	
	Electrolytically Suppressed Ion Chromatography		D 6581–08 B	
Chlorite	Chemically Suppressed Ion Chromatography		D 6581–08 A	
	Electrolytically Suppressed Ion Chromatography		D 6581–08 B	

3. On page 57917, the fourth table heading, Alternative Testing Methods With MRL > 0.0010 mg/L for Monitoring Listed at 40 CFR 141.132(b)(3)(ii)(B) should read Alternative Testing Methods With MRL ≤ 0.0010 mg/L for Monitoring Listed at 40 CFR 141.132(b)(3)(ii)(B).

4. On page 57918, the table should appear as follows:

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 143.4(b)

Contaminant	Methodology	EPA Method	ASTM [4]	SM 21st edition [1]	SM Online [3]
*	* * *	*	*	*	*
Sulfate	Ion Chromatography			4110 B	
	Gravimetric with ignition of residue			4500–SO_4^{-2} C	4500–SO_4^{-2} C–97
	Gravimetric with drying of residue			4500–SO_4^{-2} D	4500–SO_4^{-2} D–97
	Turbidimetric method		D 516–07	4500–SO_4^{-2} E	4500–SO_4^{-2} E–97
	Automated methylthymol blue method			4500–SO_4^{-2} F	4500–SO_4^{-2} F–97
*	* * *	*	*	*	*

[FR Doc. Z9–27044 Filed 12–1–09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0330; FRL–8799–9]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of hexythiazox in or on potato. The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 2, 2009. Objections and requests for hearings must be received on or before February 1, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0330. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

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 cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0330 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 1, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0330, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26375) (FRL–8128–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7182) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.448 be amended by establishing tolerances for combined residues of the insecticide/miticide 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 potato at 0.02 parts per million (ppm). That notice referenced a summary of the petition prepared by Gowan, the registrant, on behalf of IR-4, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of hexythiazox in or on potato at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hexythiazox has a low order of 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.

The target organs of hexythiazox are the liver and adrenal glands in dogs, rats and mice, with the dog being the most sensitive species. Effects seen in the chronic dog study include increased liver and adrenal weights, along with associated histopathology of the liver (hypertrophy) and adrenal glands (adrenal cortex hypertrophy). Increased liver weights, along with decreased body weight and weight gain were also observed in the rat and the mouse studies. In the subchronic study in the rat, increased liver weights in both sexes were observed, in addition to increased ovarian and kidney weights, and adrenal histopathology (fatty degeneration of the adrenal zona fasciculata) in the females.

Previously, an acute endpoint was selected for the acute dietary risk assessment for females ages 13 and above, based on delayed ossification observed in the rat developmental toxicity study. However, delayed ossification is not considered an appropriate endpoint attributable to a single exposure. No other endpoint attributable to a single exposure was identified from the available oral toxicity database.

There was no qualitative or quantitative evidence of increased susceptibility of fetuses from *in utero* exposure in studies in rats and rabbits. Although the rat developmental study showed delayed ossification in the offspring, this occurred at the same or higher dose than the maternal LOAEL of 720 milligrams/kilograms/day (mg/kg/day), at which decreased body weight gain and food consumption were observed. No adverse effects were observed in the developmental rabbit study at the highest dose tested (HDT) of 1,080 mg/kg/day. There was no evidence of increased susceptibility through postnatal exposure of offspring to hexythiazox.

Previously, carcinogenic risk for hexythiazox was assessed quantitatively

assuming the cancer response is linear at low doses. However, in June 2009, the Agency re-evaluated the carcinogenic potential of hexythiazox following release of EPA's Final Guidelines for Carcinogen Risk Assessment in March, 2005. After considering the updated guidelines, EPA has classified hexythiazox as ''likely to be carcinogenic to humans'' based upon increased incidences of benign and malignant liver tumors in high-dose female mice, and benign mammary gland tumors, observed in high dose male rats. There was no evidence of carcinogenicity in male mice and female rats. However, EPA determined that a non-quantitative risk assessment approach (i.e., nonlinear, reference dose (RfD) approach) was appropriate for hexythiazox. This change in position was based on a re-evaluation of the weight of the evidence taking into account the updated 2005 cancer risk assessment guidelines. EPA concluded that the evidence as a whole was not strong enough to warrant quantitative estimation of carcinogenic risk to humans, based on the following considerations:

i. The liver tumors in mice are a very common tumor in that species were only observed in high dose females.

ii. The mammary tumors in rats were benign and were only observed in high dose male rats.

iii. Hexythiazox was shown to be non-mutagenic in mammalian somatic cells and germ cells. Additionally, the chronic NOAEL used for establishing the chronic RfD (2.5 mg/kg/day, from the 1–year toxicity feeding study in the dog), is approximately 65-fold lower than the lowest dose that induced tumors (in female mice at 163 mg/kg/day). Therefore, the chronic RfD of 0.025 mg/kg/day is judged to be protective of all chronic effects including potential carcinogenicity of hexythiazox.

There is no evidence of neurotoxicity or potential immunotoxicity for hexythiazox in the toxicology database.

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 New Use on Potatoes Grown in Oregon, Washington and Idaho Only,'' page 10 in docket ID number EPA–HQ–OPP–2007–0330.

B. Toxicological Endpoints

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

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

A summary of the toxicological endpoints for hexythiazox used for human risk assessment can be found at *http://www.regulations.gov* in the document ''Hexythiazox. Human Health Risk Assessment to Support New Use on Potatoes Grown in Oregon, Washington and Idaho Only,'' page 10 in docket ID number EPA–HQ–OPP–2009– EPA–HQ–OPP–2007–0330.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerance 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 United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues, assumed 100 percent crop treated (PCT), and incorporated default processing factors.

iii. *Cancer.* EPA has determined that the chronic reference dose is sufficient to evaluate all chronic risks for this chemical, including carcinogenic potential. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for hexythiazox. Tolerance level residues and 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*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of hexythiazox for chronic exposures, including cancer and non-cancer assessments are estimated to be 2.26 parts per billion (ppb) for surface water and 0.00503 ppb for ground water.

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

chronic dietary, including cancer, risk assessment, the highest modeled water concentration value of 2.26 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Hexythiazox is not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that hexythiazox does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for hexythiazox includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. As discussed in Unit III.A., there was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring following exposure to hexythiazox in these studies.

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 incomplete under the new 40 CFR part 158 data requirements for conventional pesticides, which requires certain generic testing, including acute and subchronic neurotoxicity studies and an immunotoxicity study. However, the toxicology database does not show any evidence of treatment-related effects on the nervous system or the immune system. The overall weight of evidence suggests that this chemical does not directly target either system. Although acute and subchronic neurotoxicity studies and an immunotoxicity study are required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registrations, the Agency does not believe that conducting these studies will result in a lower POD than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UFDB) is not needed to account for the lack of these studies.

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 of *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 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. There are no uses which would result in postapplication exposure of children or 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate UFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 45% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for hexythiazox.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Hexythiazox is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to hexythiazox through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Hexythiazox is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to hexythiazox through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., the Agency has determined that the chronic reference dose is sufficient to evaluate all chronic risks for this chemical, including carcinogenic

potential. 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

The existing enforcement method (high performance liquid chromatography using ultraviolet detection (HPLC/UV)) published in the *Pesticide Analytical Manual (PAM) II* is adequate to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian or Mexican MRLs (maximum residue levels) for residues of hexythiazox on potatoes.

V. Conclusion

Therefore, a tolerance is established for combined residues of hexythiazox, (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on potato at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 20, 2009.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.448 is amended by alphabetically adding potato to the table in paragraph (c) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

* * * * *

(c) * * *

Commodity	Parts per million
* * * * *	
Potato	0.02
* * * * *	

[FR Doc. E9–28673 Filed 12–01–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0556; FRL–8799–2]

Fenpyroximate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of fenpyroximate and its Z-isomer in or on berry, low growing, subgroup 13–07G, at 1.0 part per million (ppm). Nichino America, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 2, 2009. Objections and requests for hearings must be received on or before February 1, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).