E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks; Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use; and Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

As indicated previously, this action is not a ''regulatory action'' as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) and Executive Order 13211 (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

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). The Congressional Review Act, 5 U.S.C. 801 *et seq.* does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2012–5383 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0659; FRL–9336–6]

Pyriofenone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, including its metabolites and degradates, in or on grape and grape, raisin. ISK BioSciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 7, 2012. Objections and requests for hearings must be received on or before May 7, 2012, 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–2010–0659. 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: Heather Garvie, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0034; email address: *garvie.heather@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 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://ecfr.gpoaccess.gov/cgi/t/text/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–2010–0659 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 May 7, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0659, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54629) (FRL–8843–3), 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 0E7731) by ISK BioSciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide pyriofenone (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on grape at 0.2 parts per million (ppm).

That notice referenced a summary of the petition prepared by ISK BioSciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.*

There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has modified the petitioned for tolerance for pyriofenone by increasing the tolerance level for grape and establishing a separate tolerance for grape, raisin. The reasons for these changes are explained in Unit IV.D.

These are the first tolerances established for pyriofenone. There are no registered uses for pyriofenone in the United States. The tolerances were requested in connection with use of pyriofenone on grapes grown overseas. These tolerances will allow grapes and processed grape commodities containing pyriofenone residues to be imported to the United States.

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 pyriofenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriofenone 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 liver and kidney were affected by treatment with pyriofenone, and although more effects were noted with increasing duration of exposure, effects were generally not severe. These effects included increased liver weight, microscopic changes, and clinical chemistry changes in rats, mice, and/or dogs. Kidney effects included increased organ weight, microscopic changes, and clinical chemistry changes in rats and mice and an increased incidence of chronic nephropathy in rats. Clinical signs included vomiting and loose stools in dogs and peri-genital staining in mice. Also noted were skin changes in the 2-year rat study (atrophy of hair follicles or perifolliculitis) and increased cecal weight or distended cecum in rat studies. Mutagenicity and carcinogenicity testing was negative and the cancer classification for pyriofenone is ''not likely to be carcinogenic to humans'' and therefore there is no cancer risk associated with exposure to pyriofenone.

No developmental or reproductive toxicity occurred in the rat studies. Abortions were noted in the rabbit developmental study and were associated with decreased maternal body weight gain and food consumption. There was no evidence of neurotoxicity and a developmental neurotoxicity study is not needed for pyriofenone. Immunotoxicity testing in rats and mice was negative. Pyriofenone has a low acute toxicity by the oral exposure route. Dermal toxicity, inhalation toxicity, and ocular irritation studies are not available because these exposure routes are not applicable to non-domestic uses. Specific information on the studies received and the nature of the adverse effects caused by pyriofenone 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 ''Pyriofenone. Human-Health Risk Assessment for the Establishment of Tolerances for Pyriofenone Fungicide in/on Imported Grapes,'' dated November 1, 2011 at pp. 16–30 in docket ID number EPA–HQ–OPP–2010–0659.

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 used for human risk assessment is shown in the Table of this unit.

In risk assessments for import commodities, endpoints are typically selected for dietary exposure only. Endpoints for incidental oral, dermal, and inhalation exposures are not

selected for import tolerances due to lack of potential occupational or residential exposure. No adverse effects attributable to a single exposure were identified for pyriofenone; therefore, an acute dietary endpoint was not selected for pyriofenone.

Consideration was given to selecting abortions/premature delivery from the rabbit developmental study as an endpoint for assessing acute dietary risk. Typically, abortions observed early in the pregnancy in a developmental toxicity study are assumed to be attributable to a single exposure and thus appropriate for acute dietary risk assessment.

In the rabbit developmental toxicity study, abortions occurred in 2 does on gestation day 18 at the highest dose tested (300 milligram/kilogram/day (mg/kg/day). In this case the abortions were determined not to be attributable to a single exposure since the abortions occurred late in gestation (GD 18) and prior to which both does had significantly lower-food consumption resulting in lower body weight or body weight gain. In the range-finding study, abortions and premature delivery seen in 2 does also showed an association to the lower body weight and food consumption. Thus, the potential nutrient deficiency and maternal toxicity resulting from loss in body weight and lower food consumption were assumed to result in the abortions/premature delivery rather than the test compound.

For the chronic dietary risk assessment, a NOAEL of 9 mg/kg/day was selected based on the increased incidence of chronic nephropathy seen in female rats at 46 mg/kg/day (LOAEL) in the 2-year carcinogenicity study. Typically, chronic nephropathy occurs as spontaneous lesions in geriatric rats and in some cases, exposure to a chemical may exacerbate this kidney lesion. In this case, however, chronic nephropathy was considered to be adverse because the incidences of this lesion was significantly increased in females at 46 mg/kg/day (30/35) and also at the next higher dose of 254 mg/kg/day (36/45, $p<0.005$). In the chronic study with dogs, the effects (e.g., clinical signs, alterations in clinical pathology, organ weights, or histopathology) were determined to be not adverse since the findings were isolated, highly variable, and/or there was a lack of dose-response or a clear target organ for toxicity.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRIOFENONE 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	An acute dietary endpoint was not selected because toxicity from a single dose was not identified in the hazard database.		
Chronic dietary (All populations).	NOAEL= 9 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.09 mg/kg/day cPAD = 0.09 mg/kg/day	Chronic toxicity/carcinogenicity study—rat NOAEL = 9 mg/kg/day based on increased nephropathy seen in female rats at LOAEL = 46 mg/kg/day.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans''.		

FQPA SF = FQPA Safety Factor. LOAEL = lowest observed adverse effect level.
LOC = Level of Concern. mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies).

Specific information on the toxicological endpoints for pyriofenone can be found at *http://www.regulations.gov* in document ''Pyriofenone. Human-Health Risk Assessment for the Establishment of Tolerances for Pyriofenone Fungicide in/on Imported Grapes,'' dated November 1, 2011 at pp.16–30 in docket ID number EPA–HQ–OPP–2010–0659.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyriofenone, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pyriofenone 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 pyriofenone; 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 Intakes by Individuals (CSFII). As to residue levels in food, EPA conducted an unrefined, screening-level chronic dietary risk assessment assuming tolerance level residues for grapes, raisins, and all other processed grape commodities; and 100% of all grapes are treated with pyriofenone.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyriofenone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* Pyriofenone is not registered for use in the United States; therefore, exposure to pyriofenone in drinking water is not expected.

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). Pyriofenone 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 pyriofenone to share a common mechanism of toxicity with any other substances, and pyriofenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance assessment action, therefore, EPA has not assumed that pyriofenone has 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 the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site 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 toxicological database for pyriofenone is complete with regard to pre- and postnatal toxicity, and there are no residual uncertainties. As the data summarized in Unit III.A. showed, pyriofenone exposure did not result in quantitative or qualitative increased sensitivity in the young.

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 pyriofenone is complete.

ii. There is no indication that pyriofenone is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that pyriofenone 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 assessment was performed based on the assumptions of 100 PCT and tolerance-level residues. This assessment will not underestimate the exposure and risks posed by pyriofenone.

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. For this action there is potential exposure to pyriofenone from food only.

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, pyriofenone 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 pyriofenone from food only will utilize 1% of the cPAD for children (1–2 years old), the population group receiving the greatest exposure. There are no residential uses for pyriofenone. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyriofenone is not expected.

3. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyriofenone is classified as ''not likely to be carcinogenic to humans.'' EPA does not expect pyriofenone to pose a cancer risk.

4. *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 pyriofenone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method based on the proposed enforcement method (Method ISK 0341/074208, Revision #4) was used to determine residues of pyriofenone in or on grapes (Raw Agricultural Commodity (RAC)) and its processed fractions for the crop field trial and grape processing studies associated with this petition. The validated limit of quantitation (LOQ) is 0.01 ppm. This method was adequately validated for data collection purposes and a successful independent laboratory validation study was conducted. Therefore, the LC/MS/MS method is acceptable for use as an enforcement method.

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; email address: *residuemethods@epa.gov.*

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 MRL.

The Codex has not established a MRL for pyriofenone. However, review of this tolerance on imported grapes is being conducted with Canada, and the U.S. and Canada are harmonized on the residue definition and recommended tolerances.

C. Revisions to Petitioned-For Tolerances

The tolerance level for grape being established by EPA differs from that

proposed in the tolerance petition submitted by the ISK Biosciences Corporation. The Agency used the Organization for Economic Cooperation and Development tolerance calculation procedures to determine that the tolerance level of 0.30 ppm is needed. The petitioner did not propose a separate tolerance for grape, raisin, but processing studies showed that residues could concentrate, necessitating a higher tolerance of 0.50 ppm. Finally, EPA has revised the tolerance expression to clarify that:

1. As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyriofenone not specifically mentioned.

2. Compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established (without U.S. registrations) for residues of the fungicide, pyriofenone, including its metabolites and degradates, in or on grape at 0.30 ppm and grape, raisin at 0.50 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA 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 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) (Pub. L. 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: February 17, 2012.

Steven Bradbury,

Director, 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 180.660 is added to subpart C to read as follows:

§ 180.660 Pyriofenone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide pyriofenone, including its metabolites and degradates, in or on the following commodities listed in the table. Compliance with the tolerance levels specified in the table is to be determined by measuring only pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on the following commodities:

Commodity	Parts per million
Grape [1]	0.30
Grape, raisin [1]	0.50

[1] There are no U.S. registrations for grape and grape, raisin.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012–5271 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2011–0108; FRL–9339–8]

RIN 2070–AB27

Modification of Significant New Uses of Tris Carbamoyl Triazine; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of February 8, 2012 concerning the modification of significant new uses of the chemical substance identified generically as tris carbamoyl triazine, which was the subject of premanufacture notice (PMN)