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) (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: September 26, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.626 is amended by revising the table in paragraph (a)(1) to read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Alfalfa, forage	0.02
Alfalfa, hay	0.02
Beet, sugar, roots	0.25
Corn, sweet kernel plus cob with husks removed	0.04
Grain, aspirated grain fractions	11
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; forage	8.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; hay	7.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; stover	10
Grain, cereal, forage, fodder and straw, group 16, except sorghum, straw	5.0
Grain, cereal, group 15, except sweet corn and sorghum	0.35
Pea and bean, dried shelled, except soybean, subgroup 6C	0.9
Peanut	0.02
Potato	0.02
Rapeseed, seed	0.15
Rice, hulls	0.90
Soybean, forage	4.5
Soybean, hay	17
Soybean, seed	0.15

* * * * *

[FR Doc. 2011–25704 Filed 10–4–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0906; FRL–8874–6]

Isopyrazam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of isopyrazam in or on banana. Syngenta Crop Protection, Inc., requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 5, 2011. Objections and requests for hearings must be received on or before December 5, 2011, 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–2009–0906. 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: Shaunta Hill, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8961; *e-mail address: hill.shaunta@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://www.gpoaccess.gov/ecfr.*

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–2009–0906 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 December 5, 2011. 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–2009–0906, 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 February 4, 2010 (75 FR 5790) (FRL–8807–5), 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 9E7606) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide isopyrazam, in or on banana at 0.05 ppm parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available 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 isopyrazam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isopyrazam 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. Isopyrazam is of low acute toxicity by the oral, dermal and inhalation routes, and is not a skin or eye irritant. The primary target organ for isopyrazam toxicity is the liver based on subchronic and chronic oral studies in the rat, mouse rabbit and dog. The principal effects observed in these studies are increased organ weight and centrilobular hepatocyte hypertrophy. Liver toxicity is usually accompanied by reductions in body weight and food consumption. Isopyrazam does not cause reproductive toxicity. Developmental effects (eye abnormalities) were observed in the absence of maternal toxicity in two range finding developmental toxicity studies in rabbits providing some evidence of sensitivity/susceptibility following pre- and/or postnatal exposure. Developmental studies in rats produced developmental effects but only at doses that were also maternally toxic. Acute and subchronic oral neurotoxicity studies in rats show no evidence of neurotoxicity. Effects characteristic of neurotoxicity (side-to-side head wobble, ataxia, reduced stability) were observed on day 2 in one subchronic oral study in dogs and at week 4 in a second subchronic dog study. These effects were not observed in the chronic dog study. However, EPA concluded for the following reasons that it is unlikely that there was a neurotoxic basis for these effects. First, the effects were seen only in a study not specifically conducted to identify neurotoxic potential and where detailed clinical and histopathological analyses for neurotoxic effects were not performed whereas isopyrazam showed no evidence of neurotoxicity in the available acute and subchronic neurotoxicity studies. Second, isopyrazam is not structurally similar to known neurotoxicants or neurotoxic classes of chemicals. Finally, its pesticidal mode of action does not demonstrate potential for neurotoxicity. Based on these findings, a developmental neurotoxicity study for isopyrazam is not required.

There is no evidence of immunotoxicity based on a 28-day dietary immunotoxicity study in rats. The lowest observed adverse effect level

(LOAEL) for immunotoxicity was not identified and the no observed adverse effect level (NOAEL) for immunotoxicity is 1,356 milligrams/kilograms (mg/kg). The study NOAEL was 127 mg/kg/day, based on transient body weight loss and high liver weights at both 608 and 1,356 mg/kg/day. The toxicology database for isopyrazam does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system.

Isopyrazam is classified as ''Likely to be Carcinogenic to Humans'' based on tumors in male and female rats. Specific information on the studies received and the nature of the adverse effects caused by isopyrazam as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Isopyrazam Human Health Risk Assessment for the Establishment of a Tolerance for isopyrazam (SYN52043) Fungicide in/on Imported Banana,'' on pp. 8–12 in docket ID number EPA–HQ–OPP–2009–0906.

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 (LOC) 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.*

PODs for incidental oral, dermal and inhalation exposure are not needed to assess risk for the requested tolerance on bananas because use of isopyrazam will only lead to dietary exposure, and have therefore not been selected for this risk assessment.

The acute POD of 30 mg/kg/day (NOAEL) was selected based on the NOAEL from a subchronic toxicity study in dogs. In that study, clinical signs of toxicity (side-to-side head wobble) were observed beginning on day 2 and continuing throughout the study in 1 of 4 male dogs at the LOAEL of 100 mg/kg/day. Transient clinical signs (side-to-side head wobble, ataxia, reduced stability) were also observed at 300 mg/kg/day in 3 of 4 male dogs on days 2 and 3 only. An uncertainty factor of 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation) was applied to the NOAEL to obtain an aRfD of 0.30 mg/kg/day. This endpoint is considered to occur following a single dose and is applicable to the population of concern (general population, including infants and children). It is considered to be a very conservative endpoint since it is based on observations in 1/4 dogs and these acute clinical signs were not reproduced in a second 90-day study in dogs or in the chronic dog study. This endpoint is also protective of the effects seen at the limit dose (2,000 mg/kg/day) in the acute neurotoxicity study in rats (decreased rearing and locomotor activity) and the developmental effect (bilateral microphthalmia) in the developmental rabbit studies (at doses ≥400 mg/kg/day). Therefore, a separate acute dietary endpoint for females of reproductive age is not necessary. As discussed in this unit, EPA has reduced the Food Quality Protection Act (FQPA) Safety Factor (SF) to 1x, and thus the acute Population Adjusted Dose (aPAD) is equivalent to the acute Reference Dose (aRfD).

The chronic POD of 5.5 mg/kg/day was selected based on the NOAEL in a chronic toxicity/carcinogenicity feeding study in rats. The LOAEL in that study was 27.6 mg/kg/day based on decreased body weight and body weight gain in females; increased incidences of hepatocellular hypertrophy, pigment in centrilobular hepatocytes, eosinophilic foci of altered hepatocytes, vacuolation of centrilobular hepatocytes, bile duct hyperplasia, and bile duct fibrosis in both sexes; and brown pigment in the kidney in females. An uncertainty factor of 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation) was applied to the dose to obtain the chronic reference dose (cRfD) of 0.055 mg/kg/day. As discussed in this unit, EPA has reduced the FQPA SF to 1x, and thus, the chronic population adjusted dose (cPAD) is equivalent to the cRfD.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isopyrazam, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from isopyrazam 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.

A conservative acute dietary (food only) exposure analysis was performed for the general U.S. population and various population subgroups. Tolerance level residues and 100 percent crop treated (PCT) assumptions were used. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for processed commodities, since separate tolerances are not considered necessary for processed banana commodities.

ii. Chronic *exposure.* Conservative chronic and cancer dietary (food only) exposure analyses were performed for the general U.S. population and various population subgroups. Tolerance level residues and 100 PCT assumptions were used. DEEM default and empirical processing factors were used for banana processed commodities, since separate tolerances for these commodities were not considered necessary.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that isopyrazam should be classified as ''Likely to be Carcinogenic to Humans''.

A linear quantification of carcinogenic potential was required for isopyrazam based on rat tumors. A cancer slope factor or Q1* of 0.00629 $(mg/kg/day)^{-1}$ was calculated based on

an increase in liver adenomas and/or carcinomas in female rats. The resulting cancer aggregate (food) exposure estimate was less than the level of concern. Cancer risk was 1.3×10^{-7} for the general U.S. population. Cancer risk was quantified using the same estimates as discussed in Unit III.C.1.ii.

2. *Dietary exposure from drinking water.* An assessment of residues in drinking water is not needed because there is no drinking water exposure associated with the establishment of a tolerance on imported crops.

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). Isopyrazam 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 isopyrazam to share a common mechanism of toxicity with any other substances, and isopyrazam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isopyrazam 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 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 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.* There is some evidence for increased susceptibility following pre- and or postnatal exposures based on effects seen in range finding developmental toxicity studies in rabbits. Developmental effects (eye abnormalities) were observed in two preliminary developmental studies in Himalayan rabbits in the absence of maternal toxicity. These effects occurred at relatively high doses (200–400 mg/kg/day). There was no evidence of increased susceptibility in the main study in New Zealand white rabbits. In range finding and definitive developmental toxicity studies in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to isopyrazam was observed. There was no evidence of increased susceptibility in a 2-generation reproduction study following pre- or postnatal exposure to isopyrazam. There is no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with isopyrazam. Clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproduction study and a dose-response relationship for the effects of concern is well characterized. The dose used for the acute dietary risk assessment (30 mg/kg/day), based on effects seen in the subchronic dog study, is protective of the developmental and offspring effects seen in rabbits at 200–400 mg/kg/day. Based on these considerations, there are no residual uncertainties for pre-and/or postnatal susceptibility.

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 isopyrazam is complete and adequate for assessing increased susceptibility under FQPA;

ii. There is no indication of increased susceptibility of fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies in rats;

There is some evidence for increased susceptibility following pre- and or postnatal exposures based on effects seen in range finding developmental toxicity studies in rabbits. However, based on the discussion above, EPA has concluded that there are no residual uncertainties for pre-and/or postnatal susceptibility.

iii. The dietary risk assessment is based on parent plus metabolite residues in/on banana, and will not underestimate dietary exposure to isopyrazam. For the acute, chronic and cancer dietary analyses, tolerance level residues of parent plus metabolite and 100 PCT assumptions were used for all treated commodities. There are no residual uncertainties identified in the exposure databases.

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 margin of exposure (MOE) exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to isopyrazam will occupy less than 1% of the aPAD for all populations.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isopyrazam from food will utilize less than 1% of the cPAD for all populations receiving the greatest exposure. There are no residential uses for isopyrazam.

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). Isopyrazam is not registered in the U.S. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for isopyrazam.

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). Isopyrazam is not registered in the U.S. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for isopyrazam.

5. *Aggregate cancer risk for U.S. population.* The Cancer Assessment Review Committee (CARC) classified isopyrazam as Likely to be Carcinogenic to Humans. This classification was based on the presence of thyroid follicular cell tumors in male rats, and liver and uterine tumors in female rats at doses that were adequate to evaluate the carcinogenic potential of isopyrazam. No treatment-related tumors were seen in mice. There is no mutagenic concern for isopyrazam.

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 isopyrazam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM006.01B) is available 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

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

The Codex has not established a MRL for isopyrazam on banana.

V. Conclusion

Therefore, a tolerance is established for residues of isopyrazam, in or on banana at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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) (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: September 27, 2011.

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 180.654 is added to read as follows:

§ 180.654 Isopyrazam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide isopyrazam, including its metabolites and degradates, in or on the commodity

listed below. Compliance with the tolerance levels specified below is to be determined by measuring only isopyrazam, 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid (9-isopropyl-1,2,3,4-tetrahydro-1,4-methano-naphthalen-5-yl)-amide, in or on the following commodity.

Commodity	Parts per million
Banana[1]	0.05

[1] There is no U.S. registration for use of isopyrazam on banana.

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

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

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

[FR Doc. 2011–25707 Filed 10–4–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Parts 18 and 19

RIN 2105–AD60

Grants and Cooperative Agreements to State and Local Governments: DOT Amendments on Regulations on Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations

AGENCY: Department of Transportation (DOT), Office of the Secretary (OST).

ACTION: Final rule.

SUMMARY: The Department of Transportation (DOT) is adopting a public proposal on Grants and Cooperative Agreements to State and Local Governments; Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations. The rule amends Department of Transportation regulations on uniform administrative requirements for grants and agreements with Institutions of Higher Education, Hospitals and other Non-profit Organizations. Specifically, the DOT is making requirements for these grants and agreements consistent with the uniform administrative requirements for grants and cooperative agreements to State and Local governments. In addition, this rule updates references to applicable cost principles for grants and cooperative agreements with State and Local Governments that appear in current Department of Transportation regulations.

DATES: This rule is effective November 4, 2011.

FOR FURTHER INFORMATION CONTACT: Ellen Shields, Office of the Senior Procurement Executive, Office of Administration (M–61), (202) 366–4268, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday, except Federal holidays.

Background

Regulations governing two types of U.S. Department of Transportation grant and cooperative agreements recipients are found in Parts 18 and 19 of Title 49 of the Code of Federal Regulations:

1. *49 CFR part 18:* Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

2. *49 CFR part 19:* Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

Both of these parts contain a provision that governs allowable costs. However, 49 CFR 18.22 imposes specific limitations on the use of grant funds while 49 CFR 19.27 merely lists cost principles applicable to each kind of grant and agreement recipient. Specifically, under 49 CFR 18.22(a), grant funds may only be used for:

(1) The allowable costs of the grantees, subgrantees and cost-type contractors, including allowable costs in the form of payments to fixed-price contractors; and

(2) Reasonable fees or profit to cost-type contractors but not any fee or profit (or other increment above allowable costs) to the grantee or subgrantee.

Public comments on this matter were solicited in a **Federal Register** notice dated May 2, 2008. Only one comment was received, from Robert Taylor, regarding the Office of Management and Budget (OMB) cost principle circulars as well as revisions prohibiting the payment of profit or fee to grantees and subgrantee covered by 49 CFR part 19. This comment did not pertain to the content of the proposed rule. Therefore, we are adopting the proposed rule without change.

This rule imposes the same limitation on the use of funds used for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations as there are on the use of funds used for Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

In addition, this rule updates references to applicable cost principles for grants and cooperative agreements with State and Local Governments that appear in 49 CFR 18.22(b) and include comparable updates references in 49 CFR 19.27(b). These updated references are necessary in light of the establishment of title 2 of the Code of Federal Regulations in 2004. Subtitle A of title 2 of the Code of Federal Regulations consists of government-wide guidance from the Office of Management and Budget (OMB) to Federal agencies for grants and other financial assistance and nonprocurement agreements that previously had been contained in seven separate OMB circulars and other OMB policy documents. Currently, 49 CFR 18.22(b) references three specific OMB circulars that are now codified in several Parts in chapter II, subtitle A of title 2 of the Code of Federal Regulations. This rule amends 49 CFR 18.22(b) by replacing the citations to these former OMB circulars with the appropriate references in title 2 of the Code of Federal Regulations and would reflect these same changes in 49 CFR 19.27(b).

The rule also makes minor referencing revisions to the Office of Management and Budget (OMB) cost principle circulars and, consistent with OMB materials, revises prohibitions on payment of profit or fee to grantees and subgrantees covered by 49 CFR part 19. The revised referencing is needed as the OMB cost circulars have been published in Title II of the Code of Federal Regulations since August 2005. However, these OMB circulars are only published as guidance (see 2 CFR 1.105(a)). Also, the OMB circular number has been retained in the title of each circular, for example, 2 CFR part 225, Cost Principles for State and Local Governments (OMB Circular A–87).

The title for the CFR part 19, which includes the OMB Circular number in the title, is included in the reference for all three cost principles. In addition, this makes the formatting of all titles in 49 CFR sections 18.22 and 18.27 consistent.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The DOT has determined that this document does not constitute a significant rule within the meaning of Executive Order 12866 or within the meaning of Department of Transportation regulatory policies and procedures. DOT anticipates that the