requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

• Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
• does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
• is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
• does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
• does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
• does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 14, 2014. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 27, 2014.

Shaun L. McGrath,

Regional Administrator, Region 8.

40 CFR part 52 is amended to read as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

Subpart G—Colorado

■ 2. Section 52.332 is amended by adding paragraph (s) to read as follows:

§ 52.332 Control strategy: Particulate Matter.

* * * * *

(s) Revisions to the Colorado State Implementation Plan, PM_{10} Revised Maintenance Plan for Telluride, as adopted by the Colorado Air Quality Control Commission on November 19, 2009, State effective on December 30, 2009, and submitted by the Governor's designee on March 31, 2010. The revised maintenance plan satisfies all applicable requirements of the Clean Air Act.

[FR Doc. 2014–02841 Filed 2–10–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0454; FRL–9904–31]

Fenpropidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropidin in or on banana. Syngenta, Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 11, 2014. Objections and requests for hearings must be received on or before April 14, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0454, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0454 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 April 14, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0454, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL–9372–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7980) by Syngenta, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that EPA establish import tolerances for residues of the fungicide fenpropidin, in or on banana, unbagged fruit at 9.0 parts per million (ppm) and banana, pulp from unbagged fruit at 0.40 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received in response to the notice of filing.

Based upon review of the data supporting the petition, tolerances for banana, unbagged fruit have been revised from 9.0 to 10 ppm. The reason for this change is explained in Unit IV.D.

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 fenpropidin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpropidin 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 nervous system, eye, stomach, esophagus, and skin are the major target organs for fenpropidin. The principal toxic effects in laboratory animals following oral exposure to fenpropidin are irritant effects on the esophagus, stomach, and skin, with peripheral parts of the body (tail and ears) affected as well. The skin lesions in the mouse following oral exposure include dry and/or flaky skin on tail, paws, and ears, loss of tail tip; hyperkeratosis of tail, ear, esophagus, subcutis, stomach, dermatitis of ear and tail, and hyperplasia of the nose. Skin lesions in the rat following chronic oral exposure include dry and flaky skin around mouth, tail tip missing, pustules on tail, and damaged or shortened tails. The skin lesions in the dog following oral exposure *via* capsules included indurated and inelastic pads; scale formation on external ear; reddening of skin of thoracic, inguinal, and axillary regions; hardened foot pads; microscopic findings of acanthosis of the epidermis and ear; hyperkeratosis of footpad and ear; and skin inflammation following chronic oral exposure. An acute lethality study shows that fenpropidin is not acutely toxic by the oral route of exposure.

Clinical signs of neurotoxicity and neuropathology are the other major toxic effects observed following oral exposure in the rat and dog, and the dog is the most sensitive species for the neurotoxic effects. In the rat 90-day neurotoxicity study, hindpaw grip strength was decreased in both sexes and forepaw grip strength was decreased in males during the functional observational battery (FOB) evaluations. Bilateral hindlimb paralysis/paresis, which correlated with the histopathological finding of demyelination of the spinal cord, cranial and spinal nerve roots, and proximal peripheral nerve, was observed in one female rat at the highest dose tested. In dogs, paresis was observed in one male dog that was sacrificed on week 38, and demyelination of the spinal cord was observed in three of four male dogs at the high dose.

In the chronic toxicity/carcinogenicity study in rats, benign pancreatic cell adenomas were seen in high-dose male rats. Tumors were not increased in the mouse carcinogenicity study in either sex or in the female rat. Mutagenicity is not of concern. Although the rat study showed that fenpropidin was associated with benign pancreatic islet cell adenomas in the male, the Agency determined that quantification of risk using a non-linear approach; i.e., the chronic reference dose (RfD), for fenpropidin will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fenpropidin. The conclusion is based on the following considerations: (i) The tumors found were benign; (ii) the tumors are common age-related tumors; (iii) the tumors occurred in only one sex in one species; (iv) fenpropidin is not mutagenic; and (v) no carcinogenic response was seen in either sex in the mouse.

Specific information on the studies received and the nature of the adverse effects caused by fenpropidin 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 ''Fenpropidin: Human Health Risk Assessment to Support the Proposed Tolerance for Imported Bananas'' at page 10 in docket ID number EPA–HQ–OPP–2012–0454.

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 fenpropidin used for human risk assessment is shown in the following table.

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENPROPIDIN 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 (Females 13–49 years of age).	NOAEL = 10 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.10 mg/kg/day. aPAD = 0.10 mg/kg/day.	Developmental toxicity study (rabbit). LOAEL = 20 mg/kg/day based on [on increased fetal (litter) incidence of malformations (persistent truncus arteriosus, severely malaligned sternebrae) and decreased male fetal body weight in the absence of maternal effects. (does dosed on GD 7–28).
Acute dietary (Infants and children)	NOAEL = 7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.07 mg/kg/day. aPAD = 0.07 mg/kg/day.	Developmental neurotoxicity study (rat). LOAEL = 27 mg/kg/day based on [decreased brain weight, decreased radial thickness of the cortex at level 3, and decreased vertical height of the dentate hilus at level 3 in females on PND 72.
Chronic dietary (All populations)	NOAEL= 2.3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.023 mg/kg/day. cPAD = 0.023 mg/kg/day.	Rat chronic/carcinogenicity. LOAEL = 11.8 mg/kg/day based on [decreased body weight and body weight gains in females, clinical signs in males and females (pustules on tail, missing tail tip, and dry, flaky skin around mouth), and microscopic liver lesions (centrilobular fat) in females.
Cancer (Oral, dermal, inhalation)	Quantification of risk using a non-linear approach; *i.e.,* RfD, for fenpropidin will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fenpropidin.		

Point of Departure (POD) = A data point or an estimated point derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animals to humans (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. cPAD = chronic population adjusted dose. RfD = reference dose. N/A = not applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpropidin, EPA assessed dietary exposures from fenpropidin 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. Such effects were identified for fenpropidin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, EPA made the following assumptions for the acute exposure assessment: Residues will be present in bananas at the highest field trial value from banana pulp (the edible portion of the fruit), 100 percent crop treated (PCT), and Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA conducted from 2003–2008 as well. As to residue levels in food, EPA made the following assumptions for the chronic exposure assessment: Residues will be present in bananas at the average field trial values from banana pulp, 100 PCT, and DEEM–FCID Version 3.16.

iii. *Cancer.* Based on the data summarized in Unit III.A., the Agency has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fenpropidin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA used anticipated residues in the dietary assessment for fenpropidin. One hundred PCT and field trial residues were assumed for all food commodities. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The proposed tolerance in or on imported banana will not impact residues in the U.S. drinking water. Therefore, a drinking water assessment was not needed.

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). Fenpropidin 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 fenpropidin to share a common mechanism of toxicity with any other substances, and fenpropidin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenpropidin 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 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 potential impact of *in utero* fenpropidin exposure was investigated in two developmental toxicity studies (one in the rat and one in the rabbit), a rat developmental neurotoxicity study (DNT) and a two multi-generation reproduction toxicity study in rats. In the rat developmental toxicity study, a quantitative susceptibility was observed; asymmetrically shaped sternebrae #5 occurred at the high dose in the absence of maternal toxicity. In the rabbit developmental study, a quantitative susceptibility was noted with an increase in fetal (litter) incidence of malformations (persistent truncus arteriosus and severely malaligned sternebrae) in the absence of maternal toxicity. A qualitative susceptibility was noted in the rat developmental neurotoxicity study (DNT). In that study, the pup effects were: Increased number of dead pups/cannibalized pups; decreased brain weight; decreased radial thickness of the cortex (level 3); decreased male pup body weight during the preweaning period; and decreased vertical height of the dentate hilus (level 3) in PND 72 females. At the same dose in the maternal animals, the only adverse effect observed was skin irritation (scabbing and hair loss around the mouth and forelimbs). Qualitative susceptibility in the 2-generation reproduction study was based on the decrease in pup body weights and delayed onset of sexual maturation observed at the same dose that resulted in decreased maternal body weight and increased incidence/severity of cortical fatty changes in adrenals. The apparent enhanced sensitivity may be due to the limited number of evaluations conducted in dams in these studies rather than a true sensitivity of the young. Clear NOAELs were established for the endpoints of concern, and these are the basis for the acute dietary endpoints for females 13+ and for infants and children.

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 fenpropidin is complete.

ii. The level of concern for neurotoxicity is low because there is a developmental neurotoxicity study in rats, the effects are well characterized, the dose-response curve for these effects are well characterized, and clear NOAELs have been identified.

iii. Though there is evidence of quantitative susceptibility in the rat and rabbit developmental toxicity studies and qualitative susceptibility in the 2-generation reproduction study in rats and the DNT in rats, the endpoints and doses selected for risk assessment are protective for these effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on conservative high-end assumptions in the dietary exposure assessment, including the use of 100 PCT assumptions and field trial residues. This is an import tolerance; therefore, there is no drinking water, no residential, and no occupational exposure.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Partially refined acute dietary exposure assessments were performed using individual points of departure (PODs) for the two population subgroups all infants and children, and females 13–49 years old. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure to fenpropidin from food will occupy 3% of the aPAD for infants <1 year old and <1% of the aPAD for females 13–49 years old, for the populations at the 95th percentile of exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenpropidin from food 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 fenpropidin.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since the petitioner is proposing a tolerance in/on imported banana and since fenpropidin is not registered for any use patterns that would result in short-term and intermediate-term residential exposure, selection of incidental oral, dermal, and inhalation point of departures for assessment of residential exposure is not required.

4. *Aggregate cancer risk for U.S. population.* In the chronic toxicity/carcinogenicity study in rats, benign pancreatic cell adenomas were seen in high-dose male rats. Tumors were not increased in the mouse carcinogenicity study in either sex or in the female rat. Mutagenicity is not of concern. Although the rat study showed that fenpropidin was associated with benign pancreatic islet cell adenomas in the male, the Agency determined that quantification of risk using a non-linear approach; i.e., the chronic reference dose (RfD), for fenpropidin will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fenpropidin. The conclusion is based on the following considerations: (i) The tumors found were benign; (ii) the tumors are common age-related tumors; (iii) the tumors occurred in only one sex in one species; (iv) fenpropidin is not mutagenic; and (v) no carcinogenic response was seen in either sex in the mouse.

5. *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 fenpropidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (independent laboratory validation trial (ILV) and liquid chromatography with mass spectrometric (LC–MS/MS) detection method (Method No. REM 164.09)) are 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; 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.

The Codex has not established MRLs for fenpropidin.

C. Response to Comments

One comment was received from an anonymous commenter objecting to increasing the tolerances. The comment contained no scientific data or evidence to rebut the Agency's conclusions that no harm will result to infants and children from aggregate exposure to fenpropidin residues.

D. Revisions to Petitioned-for Tolerances

Based on the analysis of the residue field trial data and Organization for Economic Cooperation and Development (OECD) tolerance calculator procedure, a banana tolerance of 10 ppm for residues of fenpropidin is appropriate. The Agency excluded residue values from one of the field trials. The study author reported that samples from that field trial may have been mislabeled as residues were higher in the control samples; therefore, results from this test were not used in the tolerance calculations. A tolerance for banana pulp is not required; tolerances are to be established on the whole banana fruit.

V. Conclusion

Therefore, tolerances are established for residues of fenpropidin, (1-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]piperidine), including its metabolites and degradates, in or on banana at 10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 31, 2014.

Steven P. Bradbury,

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. Add § 180.676 to subpart C, to read as follows:

§ 180.676 Fenpropidin; tolerances for residues.

(a) *General.* Tolerances are established for the residues of fenpropidin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fenpropidin (1-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]piperidine).

Commodity	Parts per million
Banana [1]	10

[1] There are no U.S. registrations as of December 13, 2013.

(b) *Section 18 tolerance.* [Reserved]

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

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

[FR Doc. 2014–02936 Filed 2–10–14; 8:45 am]

BILLING CODE 6560–50–P