stoichiometric equivalent of zoxamide in or on the raw agricultural commodity ginseng at 0.30 ppm and vegetable, tuberous and corm, subgroup 1C at 0.06 ppm. In addition, tolerances are established for residues, determined by measuring only zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxypropyl)-4-methylbenzamide, in or on raw agricultural commodity tomato subgroup 8–10A at 2.0 ppm and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 5.0 ppm. Lastly, upon the establishment of the aforementioned tolerances, the established tolerances for grape at 3.0 ppm; tomato at 2.0 ppm; and potato at 0.060 ppm are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 25, 2016.

Susan Lewis,

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. In § 180.567:

■ a. In the table in paragraph (a)(1):

■ i. Add alphabetically entries for ''Fruit, small vine climbing'' and ''Tomato subgroup 8–10A''; and

■ ii. Remove the entries for ''Grape'' and ''Tomato''; and

■ b. In the table in paragraph (a)(2):

■ i. Add alphabetically entries for ''Ginseng'' and ''Vegetable, tuberous and corm''; and

■ ii. Remove the entry ''Potato''.

The additions read as follows:

§ 180.567 Zoxamide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	5.0
* * * * *	
Tomato subgroup 8–10A	2.0
* * * * *	

(2) * * *

Commodity	Parts per million
Ginseng	0.30
* * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.06

* * * * *

[FR Doc. 2016–04740 Filed 3–7–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0443; FRL–9943–21]

Fluopyram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, amends, and deletes tolerances for residues of fluopyram in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 8, 2016. Objections and requests for hearings must be received on or before May 9, 2016, 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–2015–0443, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0443 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 9, 2016. 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–2015–0443, 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*.

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 August 26, 2015 (80 FR 51759) (FRL–9931–74), 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 4F8284) by Bayer CropScience, 2 T. W. Alexander Drive, Research Triangle Park, North Carolina 27709. The petition requested that 40 CFR 180.661 be amended by establishing tolerances for residues of the fungicide fluopyram in or on the raw agricultural commodities artichoke, globe at 4.0 parts per million; aspirated grain fractions at 50.0 ppm; peanut hay at 40.0 ppm; hops at 60.0 ppm; root vegetables, except beet, sugar, root, crop subgroup 1B at 0.30 ppm; tuberous and corm vegetables, crop subgroup 1C at 0.10 ppm; potato wet peel at 0.30 ppm; vegetables, leaves of root and tuber, crop group 2 at 30.0 ppm; bulb vegetables, bulb onion (crop subgroup 3–07A) at 0.30 ppm; bulb vegetables, green onions (crop subgroup 3–07B) at 15.0 ppm; leafy greens (crop subgroup 4A), without spinach at 20.0 ppm; leafy greens (crop subgroup 4A) spinach at 40.0 ppm; leafy petioles subgroup, celery (crop subgroup 4B) at 20.0 ppm; brassica leafy vegetables: Head and stem (crop subgroup 5A) at 4.0 ppm; brassica leafy vegetables: Leafy greens (crop subgroup 5B) at 50.0 ppm; soybean forage at 9.0 ppm; soybean hay at 30.0 ppm; legume vegetables: Edible podded (crop subgroup 6A) at 4.0 ppm; legume vegetables: Succulent shelled peas and beans (crop subgroup 6B) at 0.20 ppm; legume vegetables: Dried shelled peas and beans (crop subgroup 6C) at 0.70 ppm; vegetable, foliage of legume vegetables, forage, hay and vines, forage (crop group 7) at 90.0 ppm; fruiting vegetables, tomato subgroup (crop subgroup 8–10A) at 1.00 ppm; fruiting vegetables, pepper/eggplant subgroup (crop subgroup 8–10B) at 3.00 ppm; cucurbit vegetables (crop group 9A), melon subgroup at 0.90 ppm; cucurbit vegetables (crop group 9B), cucumber/squash subgroup at 0.30 ppm; citrus fruits (crop group 10–10) at 0.90 ppm; citrus oil at 8.0 ppm; pome fruit (crop group 11–10) at 2.0 ppm; stone fruit (crop group 12–12A), cherry subgroup at 2.00 ppm; stone fruit (crop group 12–12B), peach subgroup at 1.00 ppm; stone fruit (crop group 12–12C), plum subgroup at 0.50 ppm; berries and small fruit: Caneberry (crop subgroup 13–07A) at 5.0 ppm; berries and small fruit: Bushberry (crop subgroup 13–07B) at 7.0 ppm; raisins at 4.0 ppm; berries and small fruit, small fruit vine climbing, except fuzzy kiwi (crop subgroup 13–07F) at 1.5 ppm; berries and small fruit: Low growing berry (crop subgroup 13–07G) at 2.0 ppm; sorghum, grain at 1.5 ppm; wheat milled by-products at 2.0 ppm; grass forage, fodder and hay: Forage (crop group 17) at 80.0 ppm; herb crop (crop subgroup 19A) at 70.0 ppm; dill seed at 70.00 ppm; herbs, dried at 400 ppm; oilseeds, rapeseed, canola (crop subgroup 20A) at 0.70 ppm; oilseeds, sunflower, seed (crop subgroup 20B) at 0.70 ppm; and oilseeds: Cottonseed (crop subgroup 20C) at 0.80 ppm and in or on the animal commodities chicken, meat byproducts at 0.40 ppm; chicken, fat at 0.15 ppm; chicken, meat at 0.10 ppm; goat, fat at 4.00 ppm; and goat, meat at 4.00 ppm. Bayer CropScience also requests to establish a tolerance in 40 CFR 180.661 for indirect or inadvertent

residues of the fungicide fluopyram in or on the raw agricultural commodity sugarcane, cane at 0.08 ppm. The petition also requested to amend tolerances in 40 CFR 180.661 for residues of the fungicide fluopyram in or on the raw agricultural commodities peanut at 0.20 ppm; sugar beet, roots at 0.09 ppm; soybean, seed at 0.30 ppm; soybean forage at 9.0 ppm; soybean hay at 30.0 ppm; tree nuts (crop group 14) at 0.04 ppm; almond hulls at 10.00 ppm; grain, cereal, except rice and sorghum (crop group 15) at 0.90 ppm; cereal grain, except rice, forage, fodder and straw (crop group 16) at 20.0 ppm; and cotton gin by-product at 30.00 ppm and in or on the animal commodities cattle, meat byproducts at 40.00 ppm; cattle, fat at 4.00 ppm; cattle, meat at 4.00 ppm; milk, cattle at 2.00 ppm; eggs, chicken at 0.20 ppm; hog, meat byproducts at 0.40 ppm; hog, fat at 0.04 ppm; hog, meat at 0.04 ppm; horse, meat byproducts at 40.00 ppm; horse, fat at 4.00 ppm; horse, meat at 4.00 ppm; goat, meat byproducts at 40.00 ppm; sheep, meat byproducts at 40.00 ppm; sheep, fat at 4.00 ppm; and sheep, meat at 4.00 ppm. Bayer CropScience also requests to delete tolerances in 40 CFR 180.661 for residues of the fungicide fluopyram in or on the raw agricultural commodities apple at 0.30 ppm; bean, dry at 0.09 ppm; beet, sugar, roots at 0.04 ppm; apple wet pomace at 0.60 ppm; cherry at 0.60 ppm; grape, wine at 2.0 ppm; potato at 0.02 ppm; strawberry at 1.5 ppm; and watermelon at 1.0 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, 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 is issuing some tolerances that vary from the fluopyram tolerances as requested. The reasons for these changes are explained in Unit IV.C.

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 fluopyram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopyram 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.

Decreased body weight and liver effects were the common and frequent findings in the fluopyram subchronic and chronic oral toxicity studies in rats, mice, and dogs, and they appeared to be the most sensitive effects. Liver effects were characterized by increased liver weight, hepatocellular hypertrophy, hepatocellular vacuolation, increased mitosis and hepatocellular necrosis. Thyroid effects were found at dose levels similar to those that produced liver effects in rats and mice; these effects consisted of follicular cell hypertrophy, increased thyroid weight, and hyperplasia at dose levels greater than or equal to 100 milligrams/kilogram/day (mg/kg/day). Changes in thyroid hormone levels were also seen in a subchronic toxicity study. In male mice, there was an increased incidence of thyroid adenomas.

Although increased liver tumors were observed in female rats in the carcinogenicity study, EPA has concluded that fluopyram is ''Not Likely to be Carcinogenic to Humans'' at doses that do not induce cellular proliferation in the liver or thyroid glands. This classification was based on convincing evidence that non-genotoxic modes of action for liver tumors in rats and thyroid tumors in mice have been established and that the carcinogenic effects have been demonstrated as a result of a mode of action dependent on activation of the CAR/PXR receptors. The Agency is using a point of departure for regulating fluopyram (NOAEL of 1.2 mg/kg/day) that is below the doses that cause cell proliferation in the liver (11 mg/kg/day) and subsequent liver tumor formation (89 mg/kg/day); therefore, the Agency concludes that exposure to fluopyram will not be carcinogenic. Moreover, fluopyram is not genotoxic or mutagenic.

Fluopyram is not a developmental toxicant, nor did it adversely affect reproductive parameters. No evidence of qualitative or quantitative susceptibility was observed in developmental studies in rats and rabbits or in a multigeneration study in rats.

In an acute neurotoxicity study, transient decreased motor activity was seen only on the day of treatment, but no other findings demonstrating neurotoxicity were observed. In addition, no neurotoxicity was observed in the subchronic neurotoxicity study in the presence of other systemic adverse effects. Fluopyram did not produce treatment-related effects on the immune system.

Fluopyram has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Fluopyram is not a skin or eye irritant or sensitizer under the conditions of the murine lymph node assay. Specific information on the studies received and the nature of the adverse effects caused by fluopyram 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 entitled: ''Fluopyram: Human Health Risk Assessment for Proposed New Uses on Crop Subgroup 1B, Subgroup 1C, Crop Group 2, Subgroup 3–07A, Subgroup 3–07B, Subgroup 4A, Subgroup 4B, Subgroup 5A, Subgroup 5B, Subgroup 6A, Subgroup 6B, Dried Beans, Soybean, Subgroup 8–10A, Subgroup 8–10B, Subgroup 9A, Subgroup 9B, Subgroup 10–10, Group 11–10, Subgroup 12–12A, Subgroup 12–12B, Subgroup 12–12C, Subgroup 13–07A, Subgroup 13–07B, Subgroup 13–07F, Subgroup 13–07G, Crop Group 15 (except corn and Rice), Crop Group 16, Subgroup 19A, Dill Seed, Subgroup 20A, Subgroup 20B, Subgroup 20C, Artichoke (Globe), Hops, and Sugarcane (Rotated). Amended Tolerance Requests for the Registered Uses due to Crop Group/Subgroup Expansion Requests. Proposed New Uses on Turf Grass, Ornamentals, and Christmas trees, and as a seed treatment to Peanuts'' in

docket ID number EPA–HQ–OPP–2015–0443.

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://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1*.

A summary of the toxicological endpoints for fluopyram used for human risk assessment is shown in Table 1.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOPYRAM 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 (General population including infants and children).	NOAEL = 50 mg/kg/day. UF_A = 10x UF_H =10x FQPA SF = 1x	Acute RfD = 0.50 mg/kg/day. aPAD = 0.50 mg/kg/day.	Acute Neurotoxicity Study in Rats LOAEL = 100 mg/kg/day based on decreased motor and locomotor activity in females. The LOAEL in males was 125 mg/kg/day.
Acute dietary (Females 13–50 years of age).	An endpoint attributable to a single dose exposure has not been identified for this subpopulation.		
Chronic dietary (All populations)	NOAEL = 1.2 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.012 mg/kg/day. cPAD = 0.012 mg/kg/day.	Combined Chronic/Carcinogenicity in Rats LOAEL = 6.0 mg/kg/day based on follicular cell hypertrophy in the thyroid, and increased liver weight with gross pathological and histopathological findings.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 14.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction study in rats LOAEL = 82.8 mg/kg/day based on clinical pathology changes, decreased spleen and thymus weights, increased liver weight and centrilobular hypertrophy in parents, and decreased body weight and body weight gain with decreases in spleen and thymus weights and slight delay in preputial separation in offspring.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	28-day dermal study in rats LOAEL = 1000 mg/kg/day based on increased cholesterol (F), increased prothrombin time (M).
Inhalation short-term (1 to 30 days) and intermediate-term (1–6 months).	NOAEL = 14.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	Reproduction study in rats LOAEL = 82.8 mg/kg/day based on clinical chemistry changes and increased kidney weight in parents, and decreased body weight and body weight gain with decreases in spleen and thymus weights in offspring.
Cancer (Oral, dermal, inhalation).	"Not Likely to be Carcinogenic to Humans" at doses that do not induce cellular proliferation in the liver or thyroid glands.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. Mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopyram, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopyram tolerances in 40 CFR 180.661. EPA assessed dietary exposures from fluopyram 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 fluopyram. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA included tolerance residue levels, the assumption

of 100% crop treated, and processing factors (empirical and default).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA included average residue levels, % crop treated, and processing factors (empirical and default).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopyram does not pose a cancer risk to humans at doses that do not induce cellular proliferation in the liver or thyroid glands. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* 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.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for the chronic dietary exposure assessment for existing uses as follows:

Almonds 33%; apples 40%; blackberries 55%; blueberries 54%; broccoli 24%; cantaloupes 22%; celery 60%; corn field 9%; corn, sweet 15%; cucumbers 41%; dry beans/peas 7%; fresh tomatoes 64%; grape wine 79% (used for grape, wine and sherry); head lettuce 67%; leaf lettuce 62%; oranges 39%; peaches 56%; pears 43%; peanuts 67%; potatoes 64%; processed tomatoes 57%; pumpkins 45%; snap beans 44%; soybeans 17%; spinach 43%; squash 47%; strawberries 75%; sugar beets 48%; watermelons 54%; and wheat 17% (from spring wheat at 17% and winter wheat at 6%).

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluopyram may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fluopyram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopyram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model Ground Water (PRZM GW) and the surface water concentration calculator (SWCC), the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are estimated to be 50.6 parts per billion (ppb) for surface water and 97.6 ppb for ground water. The chronic exposures for non-cancer assessments are estimated to be 17.3 ppb for surface water and 90.5 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 97.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 90.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluopyram is proposed for use that could result in residential exposures: golf course turf, residential lawns, fruit trees, nut trees, ornamentals and gardens. EPA assessed residential exposure using the following assumptions: short-term dermal, oral (derived from incidental oral hand to mouth post-application exposures to treated lawn in children), and inhalation exposures derived from treating lawns by hose-end sprayers (adults); residential post-application exposures: adults and children (1 to <2 years old) dermal exposure to treated turf during high contact lawn activities; children (1 to <2 years old) incidental oral exposure as a result of contacting treated turf; adults and youths (11 to <16 yr old) dermal exposure to treated turf during mowing and golfing activities; children (6 to <11 years old) dermal exposure to treated turf during golfing activities; and adults and

children (6 to <11 years old) dermal exposure to treated gardens. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 fluopyram to share a common mechanism of toxicity with any other substances, and fluopyram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluopyram 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 available developmental toxicity studies in rats and rabbits and the multi-generation reproduction in rats demonstrate no evidence of increased susceptibility in the developing or young animals which were exposed during pre- or post-natal periods.

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 fluopyram is complete.

ii. There is no indication that fluopyram is a neurotoxic chemical. Although transient decreases in motor and locomotor activities in the acute neurotoxicity study were seen on the day of treatment and limited use of hind-limbs and reduced motor activity was seen in the rat chronic/carcinogenicity study, there were no other associated neurobehavioral or histopathology changes found in other studies in the fluopyram toxicity database. The effects seen in the chronic/carcinogenicity study were in the presence of increased mortality and morbidity such as general pallor and emaciated appearance. Therefore, the reduced motor activity and limited use of hind-limbs seen in these two studies were judged to be the consequence of the systemic effects and not direct neurotoxicity. Additionally there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluopyram 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 acute dietary exposure assessment was performed using conservative exposure inputs, including tolerance-level residues for all crops, whereas the chronic dietary assessment included average field-trial residue levels for all crops. The acute dietary assessment assumed 100 PCT, whereas the chronic dietary assessment utilized average percent crop treated numbers for several crops. Both acute and chronic dietary assessments incorporated empirical or default processing factors. The dietary exposure assessment also assumed that all drinking water will contain fluopyram at the highest EDWC levels modeled by the Agency for ground or surface water. Therefore, it can be concluded that the dietary exposure analysis does not underestimate risk from acute and chronic dietary exposure to fluopyram. While there is the potential for handler and post-application residential exposure, the best data and approaches currently available were used in the fluopyram residential assessment. The Agency used the current conservative approaches for residential assessment, many of which include recent upgrades to the SOPs. The Agency believes that the calculated risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the calculations are based. Therefore, residential exposures are unlikely to be underestimated.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluopyram will occupy 35% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopyram from food and water will utilize 81% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopyram is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluopyram is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluopyram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs from handler inhalation exposure (the most conservative risk estimate) of 1,500 for adults. For children 1–2 years old, post-application incidental oral exposures aggregated with food and drinking water resulted in an MOE of 1,500. Because EPA's level of concern for fluopyram is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure

takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term residential exposure is not expected given the intermittent nature of applications in residential settings.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A, because the Agency is regulating exposure to fluopyram at doses lower than those that may induce cellular proliferation in the liver or thyroid glands, fluopyram is not expected to pose a cancer risk to humans.

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 fluopyram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The German multiresidue method DFG Method S 19, a gas chromatography with mass selective detection (GC/MSD) method, is the method for the enforcement of tolerances for fluopyram residues in/on crop commodities and a high performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS), Method 01079, has been accepted for the enforcement of tolerances for residues of fluopyram and its metabolite, AE C656948-benzamide, in livestock commodities. The validated limit of quantitation (LOQ) is 0.01 ppm and the calculated limit of detection (LOD) is 0.003 ppm for each analyte in each matrix. The method was adequately validated using cattle milk, fat, muscle, liver, and kidney, and hen whole egg fortified with fluopyram and AE C656948-benzamide, each at 0.01 and 0.10 ppm. The method was subjected to ILV using samples of beef muscle, beef liver, eggs, and milk fortified with fluopyram and AE C656948-benzamide, each at 0.01 and 0.10 ppm.

Adequate enforcement methodology DFG Method S 19 and Method 01079 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.

There are Codex maximum residue levels MRLs established on berries (blackberry and raspberry 3 ppm), broccoli and Brussels sprouts (0.3 ppm), dry beans (0.07 ppm), head cabbage (0.15 ppm), carrot (0.4 ppm), cauliflower (0.09 ppm), cherry (0.7 ppm), cucumber (0.5 ppm), dried grapes (currants, raisins and sultanas 5 ppm), grapes (2 ppm), leek (0.15 ppm), lettuce (head and leaf 15 ppm), onion bulb (0.07 ppm), peach subgroup (1 ppm), peanut (0.03 ppm), plums (0.5 ppm), pome fruits (0.5 ppm), potato (0.03 ppm), rapeseed (1 ppm), strawberry (0.4 ppm), sugar beet (0.04 ppm), tomato (0.4 ppm), and tree nuts (0.04 ppm).

The tolerance definitions are harmonized among the US, Canada, and Codex for all plant and livestock commodities. In addition, the U.S. tolerances for grape (within the fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F), peach (within the fruit, stone, peach subgroup 12–12B), and plum (within the fruit, stone, plum subgroup 12–12C) are harmonized with the Codex MRLs for grape, peach, and plum.

Harmonization with Codex MRLs for berries (blackberry and raspberry 3 ppm), broccoli and Brussels sprouts (0.3 ppm), dry beans (0.70 ppm), head cabbage (0.15 ppm), cauliflower (0.09 ppm), cherry (0.7 ppm), cucumber (0.5 ppm), leek (0.15 ppm), lettuce (head and leaf 15 ppm), onion bulb (0.07 ppm), peanut (0.03 ppm), pome fruits (0.5 ppm), potato (0.03 ppm), rapeseed (1 ppm), strawberry (0.4 ppm), sugar beet (0.04 ppm), tomato (0.4 ppm), and tree nuts (0.04 ppm) is not possible because the Codex MRLs are lower than the recommended U.S. tolerances. The U.S. tolerances cannot be harmonized because following the approved label directions could result in residues above the recommended tolerances. The U.S. tolerances for carrot and raisin are higher than the Codex MRLs. EPA is not harmonized with Codex in order to remain harmonized with Canada.

The U.S. and Codex livestock MRLs are not harmonized due to different livestock dietary burdens. Fluopyram is approved for use on more livestock feed stuffs in the United States and thus contributes to a greater portion of the assessment of the livestock dietary burden in the United States than in the assessment of livestock dietary burden supporting the Codex MRLs. Harmonization could lead to tolerance exceedances when the pesticide is used legally in the United States.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerances differ from the tolerances that EPA is establishing for sugar beet roots, onion bulbs, leafy greens subgroup 4A, crop subgroup 6C, fruiting vegetables (8–10B), melon subgroup 9A, citrus, subgroup 13–07F, raisin, tree nuts, crop group 15, herb subgroup 19A, dill seed, and subgroup 20A.

For citrus, crop group 15, fruiting vegetables (8–10B), onion bulbs, rapeseed subgroup 20A, and tree nuts, the Organization for Economic Cooperation and Development (OECD) statistical calculation procedures applied to the field trial residue data provided a different value than the petitioned-for tolerances. Also, for crop group 15 and subgroup 20A, the values petitioner requested were based on a data set that excluded a field trial (on sorghum and canola, respectively) as an outlier based on statistical tests. However, the trials could not be excluded by the Agency since there were no abnormal field conditions.

While the petitioner requested a tolerance for crop group 15, except rice and sorghum, the Agency has determined that a crop group 15 tolerance, except corn and rice is appropriate. This is due to the wide variation in residue levels from the available data. The minimum residues on sweet corn at 0.01 ppm and the maximum residues on sorghum 3.2 ppm differ by more than 5x; therefore, the tolerance level (1.5 ppm) is not appropriate to establish a crop group tolerance with all the representative crops. Rather, based on the available data, EPA is establishing tolerances on grain, cereal, except rice and corn, group 15 at 4.0 ppm; and individual tolerance on corn, field, grain at 0.02 ppm; corn, pop, grain at 0.02 ppm; and corn, sweet, kernal plus cob with husks removed at 0.01 ppm.

Although the petitioner requested two separate tolerances for commodities of subgroup 4A, the available data support a tolerance of 40 ppm for residues of fluopyram in/on leafy greens subgroup 4A and at 20 ppm on leaf petioles subgroup 4B.

The petitioner requested two separate tolerances for herb subgroup 19A, fresh and herbs, dried. Because subgroup 19A covers both dried and fresh herbs, the Agency is establishing a tolerance on herb subgroup 19A at 40 ppm, based on available data.

The petitioner has requested to establish tolerances on vegetables, legume; dried beans and peas, except soybeans (subgroup 6C) at 0.70 ppm. Because only data on dried beans is available, there is not sufficient data to support establishing a subgroup tolerance. Therefore, based on the available residue data for dried beans, the Agency is establishing an individual tolerance of 0.70 ppm on dried beans only. EPA is establishing dry bean tolerance at 0.70 ppm to harmonize with Canada.

The petitioner had requested to establish tolerances on vegetables, cucurbit, cucumber/squash subgroup at 0.30 ppm and fruit, pome at 1.0 ppm. Based on available data that reflect the proposed use pattern, EPA is establishing a tolerance on squash/cucumber subgroup 9B at 0.60 ppm and fruit, pome, group 11–10 at 0.80 ppm.

For harmonization purposes with Canada, tolerances being established for sugar beet, melon subgroup 9A, tree nuts, and subgroup 13–07F are slightly increased above the tolerance levels requested for those commodities.

The requested grape, raisin tolerance of 4.0 ppm is being reduced to 3.0 ppm based on the highest average field trial (HAFT) (0.948 ppm) for grape and processing factor of 2.4.

Because use of fluopyram is limited to Region 3 (Florida), the Agency is establishing a tolerance with a regional registration for inadvertent or indirect residues of fluopyram on sugarcane, cane (0.08 ppm) when sugarcane is used as a rotational crop.

The requested tolerances for livestock commodities were based on some livestock feed stuffs that have been withdrawn from the list of crops to be treated with fluopyram. Based on a recalculation of the livestock dietary burden, the Agency is establishing tolerances for livestock commodities that are lower than requested.

In addition, the Agency has revised several commodity terms to reflect the current commodity definitions used by the Agency and revised several tolerance level values to be consistent with EPA's practice of extending tolerance values out to two significant figures.

Although the petition requested a tolerance for nut tree group 14, the Agency is establishing a tolerance for nut, tree 14–12 consistent with its stated policy of not establishing tolerances for pre-existing crop groups. *See* 77 FR 50617, 50619 (Aug. 22, 2012).

Finally, the requests for tolerances were withdrawn for the following commodities: Crop group 7 at 90.0 ppm; crop group 17 at 80.0 ppm; peanut hay at 40.0 ppm, soybean forage at 9.0 ppm; and soybean hay at 30.0 ppm. A separate tolerance for wheat, milled byproducts is not needed as it is covered by the crop group 15 tolerance.

V. Conclusion

Therefore, tolerances are established for residues of fluopyram in or on almond, hulls at 10 ppm; artichoke, globe at 4.0 ppm, bean, dry at 0.70 ppm; beet, sugar at 0.10 ppm; berry, low growing, except cranberry, subgroup 13–07G at 2.0 ppm; brassica, head and stem, subgroup 5A at 4.0 ppm; brassica, leafy greens, subgroup 5B at 50 ppm; bushberry subgroup 13–07B at 7.0 ppm; grain, aspirated grain fractions at 50 ppm; caneberry subgroup 13–07A at 5.0 ppm; cereal, forage, fodder and straw, group 16 at 20 ppm; cherry subgroup 12–12A at 2.0 ppm; citrus, oil at 8.0 ppm; corn, field, grain at 0.02 ppm; corn, pop, grain at 0.02 ppm; corn, sweet, kernel plus cob with husks removed 0.01 ppm; cotton, gin byproducts at 30 ppm; cottonseed subgroup 20C at 0.80 ppm; dill, seed at 70 ppm; rapeseed subgroup 20A at 5.0 ppm; fruit, citrus, group 10–10 at 1.0 ppm; fruit, pome, group 11–10 at 0.80 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm; grape, raisin at 3.0 ppm; grain, cereal, group 15, except corn and rice at 4.0 ppm; grain, herb subgroup 19A at 40 ppm; hop, dried cones at 60 ppm; leaf petioles subgroup 4B at 20 ppm; leafy greens subgroup 4A at 40 ppm; melon subgroup 9A at 1.0 ppm; nut, tree, group 14–12 at 0.05 ppm; onion, bulb, subgroup 3–07A at 0.40 ppm; onion, green, subgroup 3–07B at 15 ppm; pea and bean, succulent shelled, subgroup 6B at 0.20 ppm; peach subgroup 12–12B at 1.0 ppm; peanut at 0.20 ppm; potato, wet peel at 0.30 ppm; pepper/eggplant subgroup 8–10B at 4.0 ppm; plum subgroup 12–12C at 0.50 ppm; soybean, seed at 0.30 ppm; squash/cucumber subgroup 9B at 0.60 ppm; sunflower subgroup 20B at 0.70 ppm; tomato subgroup 8–10A at 1.0 ppm; vegetable, leaves of root and tuber, group 2 at 30 ppm; vegetable, legume, edible podded, subgroup 6A at 4.0 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.30 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.10 ppm.

Tolerances are also established for residues of fluopyram and its metabolite 2-(trifluoromethyl)benzamide, expressed in parent equivalents for cattle, fat at 0.70 ppm; cattle, meat at 0.80 ppm; cattle, meat byproducts at 7.5 ppm; egg at 0.08 ppm; goat, fat at 0.70 ppm; goat, meat at 0.80 ppm; goat, meat byproducts at 7.5 ppm; hog, meat byproducts at 0.20 ppm; horse, fat at 0.70 ppm; horse, meat at 0.80 ppm; horse, meat byproducts at 7.5 ppm; milk at 0.40 ppm; poultry, fat at 0.04 ppm; poultry, meat at 0.04 ppm; poultry, meat byproducts at 0.16 ppm; sheep, fat at 0.70 ppm; sheep, meat at 0.80 ppm; and sheep, meat byproducts at 7.5 ppm.

In addition, the Agency is removing tolerances for almond, hull; apple, wet pomace; bean, dry; beet, sugar, root; canola seed; cotton, gin byproducts; cotton, undelinted seed; cherry; grape, wine; grain, cereal, except rice, group 15; grain, cereal, forage, fodder, and straw, group 16; nut, tree, group 14; peanut; pistachio; potato; soybean forage; soybean hay; soybean, seed; strawberry; and watermelon because they are superseded by other tolerances being established in this action.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 1, 2016.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.661 is revised to read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide Fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only fluopyram in or on the commodity.

Commodity	Parts per million
Almond, hulls	10
Artichoke, globe	4.0
Banana [1]	1.0
Bean, dry	0.70
Beet, sugar	0.10
Berry, low growing, except cranberry, subgroup 13–07G	2.0
Brassica, head and stem, subgroup 5A	4.0
Brassica, leafy greens, subgroup 5B	50
Bushberry subgroup 13–07B	7.0
Caneberry subgroup 13–07A	5.0
Cherry subgroup 12–12A	2.0
Citrus, oil	8.0
Corn, field, grain	0.02
Corn, pop, grain	0.02
Corn, sweet, kernel plus cob with husks removed	0.01
Cotton, gin byproducts	30
Cottonseed subgroup 20C	0.80
Dill, seed	70
Fruit, citrus, group 10–10	1.0
Fruit, pome, group 11–10	0.80
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2.0
Grain, aspirated grain fractions	50
Grain, cereal, forage, fodder and straw, group 16	20
Grain, cereal, group 15, except corn and rice	4.0
Grape, raisin	3.0
Herb subgroup 19A	40
Hop, dried cones	60
Leafy greens subgroup 4A	40
Leafy petioles subgroup 4B	20
Melon subgroup 9A	1.0
Nut, tree, group 14–12	0.05
Onion, bulb, subgroup 3–07A	0.40
Onion, green, subgroup 3–07B	15
Pea and bean, succulent shelled, subgroup 6B	0.20
Peach subgroup 12–12B	1.0
Peanut	0.20
Pepper/eggplant subgroup 8–10B	4.0
Plum subgroup 12–12C	0.50
Potato, wet peel	0.30
Rapeseed subgroup 20A	5.0
Soybean, seed	0.30
Squash/cucumber subgroup 9B	0.60
Sunflower subgroup 20B	0.70
Tomato subgroup 8–10A	1.0
Vegetable, leaves of root and tuber, group 2	30
Vegetable, legume, edible podded, subgroup 6A	4.0
Vegetable, root, except sugar beet, subgroup 1B	0.30
Vegetable, tuberous and corm, subgroup 1C	0.10

[1] There are no U.S. registrations.

(2) Tolerances are established for residues of the fungicide fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including its metabolites and degradates. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluopyram and its metabolite, 2-(trifluoromethyl)benzamide, calculated as the stoichiometric equivalent of fluopyram, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.70
Cattle, meat	0.80
Cattle, meat byproducts	7.5
Egg	0.08
Goat, fat	0.70
Goat, meat	0.80
Goat, meat byproducts	7.5
Hog, fat	0.20
Hog, meat	0.02
Hog, meat byproducts	0.20
Horse, fat	0.70
Horse, meat	0.80
Horse, meat byproducts	7.5
Milk	0.40
Poultry, fat	0.04
Poultry, meat	0.04
Poultry, meat byproducts	0.20
Sheep, fat	0.70
Sheep, meat	0.80
Sheep, meat byproducts	7.5

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(1), are established for indirect or inadvertent residues of fungicide fluopyram, N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including

its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only fluopyram in or on the commodity.

Commodity	Parts per million
Sugarcane, cane	0.08

(d) *Indirect or inadvertent residues.* It is recommended that tolerances be established for indirect or inadvertent residues of fungicide fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only fluopyram in or on the commodity.

Commodity	Parts per million
Alfalfa, forage	0.45
Alfalfa, hay	1.1
Soybean, seed	0.10

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BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, and 495

[CMS–1631–F2]

RIN 0938–AS40

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule with comment period published in the November 16, 2015 **Federal Register** (80 FR 70886 through 71386) entitled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016.''

DATES: *Effective date:* This correcting document is effective March 7, 2016.

Applicability date: The corrections indicated in this document are applicable beginning January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Lisa Ohrin Wilson (410) 786–8852, or Matthew Edgar (410) 786–0698, for issues related to physician self-referral updates. Jessica Bruton, (410) 786–5991 for all other issues.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2015–28005 (80 FR 70886 through 71386), the final rule entitled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016'' (hereinafter referred to as the CY 2016 PFS final rule with comment period), there were a number of technical and typographical errors that are identified and corrected in section IV., the Correction of Errors. The effective date for the rule was January 1, 2016, except for the definition of ''ownership or investment interest'' in § 411.362(a), which has an effective date of January 1, 2017. These corrections are applicable as of January 1, 2016. We note that Addenda B and C to the CY 2016 PFS final rule with comment period as corrected by this correcting amendment are available on the CMS Web site at *http://www.cms.gov//PhysicianFeeSched/*.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 70894, we inadvertently omitted a sentence from the first comment summary regarding applying the same overrides used for the MP RVU calculations to the PE calculations.

On page 70894, we inadvertently omitted a clause from the response summary regarding the overrides that also apply to the MP RVU calculation in the development of PE RVUs.

On page 70898, due to data errors made in the ratesetting process, many of the values contained in Table 4: Calculation of PE RVUs under Methodology for Selected Codes, are incorrect.

On page 70953, we inadvertently included language regarding the application of the equipment utilization assumption.

On page 70971,

a. Due to a typographical error, the work RVU for CPT code 76945 was listed incorrectly. As a result, the work RVU for CPT code 76948 was also inadvertently listed incorrectly.

b. Due to a typographical error, we inadvertently referred to CPT code 76948 rather than CPT code 76945.

On page 70992, due to a typographical error in Table 13—CY 2016 Actions on Codes with CY 2015 Interim Final RVUs, the CY 2016 work RVU for CPT code 76948 was incorrectly displayed.

On page 71317, we inadvertently included language in our comment discussion on the issue regarding compensation arrangements.

On page 71357,

a. Due to data errors, we incorrectly stated the estimated CY 2016 net reduction in expenditures.

b. Due to data errors, we incorrectly stated the reduction to the conversion factor.

c. Due to data errors, we incorrectly stated the CY 2016 PFS conversion factors. As a result, many of the values in Table 60—Calculation of the CY 2016 PFS Conversion Factor, are incorrect.

d. Due to data errors, we incorrectly stated the CY 2016 PFS anesthesia conversion factors. As a result, many of the values in Table 61—Calculation of the CY 2016 PFS Anesthesia Conversion Factor, are incorrect.

On pages 71358 through 71359, due to data errors, many of the values in Table 62—CY 2016 PFS Estimated Impact On Total Allowed Charges By Specialty, are incorrect.

On pages 71359 through 71360, due to data errors, many of the values in Table 63— Impact on CY 2016 Payment for Selected Procedures, are incorrect.

On page 71369,

a. Due to data errors, we incorrectly stated the CY 2016 national payment amount in the nonfacility setting for CPT code 99203.

b. Due to data errors, we incorrectly stated the CY 2016 proposed beneficiary coinsurance for CPT code 99203.

B. Summary of Errors in Regulation Text

On page 71375 of the CY 2016 PFS final rule with comment period, we made a typographical error in § 411.357(d)(1)(iv). In this paragraph, we inadvertently included the word ''for''.

On page 71377 of the CY 2016 PFS final rule with comment period, we made a typographical error in § 411.357(x)(1)(vi)(A). In this paragraph, we inadvertently omitted the word ''directly''.

C. Summary and Correction of Errors in the Addenda on the CMS Web site

Due to the errors identified and summarized in section II.A and B of this document, we are correcting errors in the work, PE or MP RVUs (or combinations of these RVUs) in Addendum B: CY 2016 Relative Value Units (RVUs) And Related Information Used In Determining Final Medicare Payments and Addendum C: CY 2016