

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 9, 2012.

**Steven Bradbury,**

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.655 is added to read as follows:

**§ 180.655 Flazasulfuron; tolerances for residues.**

(a) *General.* Tolerances are established for residues of flazasulfuron, 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 flazasulfuron [N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide].

Commodity	Parts per million
Fruit, citrus, group 10-10 .....	0.01
Grape .....	0.01
Sugarcane .....	0.01

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

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

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

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0364; FRL-9336-9]

**Fluopyram; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluopyram in or on multiple commodities which are

identified and discussed later in this document. Bayer Crop Science requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 24, 2012. Objections and requests for hearings must be received on or before April 24, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0364. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Lisa Jones, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-9424; email address: [jones.lisa@epa.gov](mailto:jones.lisa@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

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

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

This listing is not intended to be exhaustive, but rather to provide a guide

for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocsp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0364 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 24, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0364, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200

Pennsylvania Ave. NW., Washington, DC 20460-0001.

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

## II. Summary of Petitioned-For Tolerance

In the *Federal Register* of January 6, 2010 (75 FR 864) (FRL-8801-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions (PP 8F7358 and 8F7463) by Bayer Crop Science, 2.T.W. Alexander Drive, Research Triangle Park, NC 27709.

Petition 8F7358 requested that 40 CFR part 180 be amended by establishing tolerances on 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 following commodities: Grape at 2.0 parts per million (ppm); strawberry at 2.0 ppm; and tomato at 1.0 ppm. A subsequent petition 8F7463 requested that 40 CFR part 180 be amended by establishing additional tolerances on 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 following commodities: Alfalfa, forage at 0.25 ppm; alfalfa, hay at 0.80 ppm; almond, hulls at 8.0 ppm; apple, wet pomace at 2.5 ppm; artichoke at 2.0 ppm; banana at 1.0 ppm; beet, sugar, roots at 0.10 ppm; berry, low growing, subgroup 13-07G at 2.0 ppm; Brassica, head and stem, subgroup 5A at 3.0 ppm; Brassica, leafy greens, subgroup 5B at 35 ppm; bushberries, subgroup 13-07B at 10 ppm; caneberries, subgroup 13-07A at 5.0 ppm; citrus, oil at 10 ppm; corn, sweet, kernel plus cob with husk removed at 0.10 ppm; cotton, gin byproducts at 0.05 ppm; cotton, undelinted seed at 0.10 ppm; fruit, citrus, group 10 at 1.0 ppm; fruit, pome, group 11 at 1.0 ppm; fruit, small, vine, climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; fruit, stone, group 12 at 2.0 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, forage at 8.0 ppm; grain, cereal, forage, fodder and straw, group

16, except rice, hay, straw and stover at 14 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, aspirated fractions at 50 ppm; grain, cereal, group 15, except rice and sweet corn at 3.0 ppm; grape, raisin at 3.5 ppm; grass, forage, fodder and hay, group 17, forage at 80 ppm; grass, forage, fodder and hay, group 17, hay at 30 ppm; herbs, subgroup 19A, fresh at 50 ppm; herbs, subgroup 19A, dried at 260 ppm; hop, dried cones at 100 ppm; nut, tree, group (including pistachio) 14 at 0.05 ppm; okra at 8.0 ppm; oilseed, group 20, except cotton at 5.0 ppm; onion, bulb, subgroup 3-07A at 0.30 ppm; onion, green, subgroup 3-07B at 20 ppm; peanut at 0.05 ppm; peanut, hay at 50 ppm, pepper, non-bell at 8.0 ppm; potato, processed potato waste at 0.15 ppm; soybean, aspirated fractions at 70 ppm; soybean, forage at 8.0 ppm; soybean, hay at 30 ppm; soybean, hulls at 0.40 ppm; soybean, seed at 0.30 ppm; spices, except black pepper, subgroup 19B at 100 ppm; vegetable, cucurbit, group 9 at 1.0 ppm; vegetable, foliage of legume, except soybean, subgroup 7A, forage at 30 ppm; vegetable, foliage of legume, except soybean, subgroup 7A, hay at 75 ppm; vegetable, foliage of legume, except soybean, subgroup 7A, vines at 16 ppm; vegetable, fruiting, except non-bell pepper, group 8 at 1.0 ppm; vegetable, leafy, except Brassica, group 4 at 35 ppm; vegetable, leaves of root and tuber, group 2 at 30 ppm; vegetable, legume, edible podded, subgroup 6A at 2.0 ppm; vegetable, legume, succulent shelled, subgroup 6B at 0.20 ppm; vegetable, pea and bean, dried shelled (except soybean), subgroup 6C at 0.50 ppm; vegetable, root and tuber, except sugar beet, subgroup 1B at 0.50 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm.

This petition (8F7463) also requested that 40 CFR part 180 be amended by establishing tolerances on 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 following commodities: Cattle, fat at 0.10 ppm; cattle, meat at 0.10 ppm; cattle, meat byproducts, except liver at 0.10 ppm; cattle, liver at 1.2 ppm; eggs at 0.1 ppm; goat, fat at 0.10 ppm; goat, meat at 0.10 ppm; goat, meat byproducts, except liver at 0.10 ppm; goat, liver at 1.2 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.01 ppm; hog, liver at 0.15 ppm; horse, fat at 0.10 ppm; horse, meat at 0.10 ppm; horse, meat byproducts, except liver at 0.10

ppm; horse, liver at 1.2 ppm, milk at 1.2 ppm; poultry, fat at 0.05 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.20 ppm; sheep, fat at 0.10 ppm; sheep, meat at 0.10 ppm; sheep, meat byproducts, except liver at 0.10 ppm; and sheep, liver at 1.2 ppm.

That notice referenced a summary of the petitions prepared by Bayer Crop Science, the registrant, which is available in the docket, <http://www.regulations.gov>.

One comment was received from a private citizen who opposed the manufacturing and selling of this product due to the lack of available bee information. This comment is considered irrelevant because the safety standard for approving tolerances under section 408 of the FFDCA is directed solely at the safety of the pesticide residues in food to the food consumer and does not permit consideration of environmental effects on bees.

Based upon review of the data supporting the petitions, EPA has revised tolerance levels. Subsequently, the petitions have been further modified per Bayer Crop Science's request to withdraw a majority of the primary crops initially proposed for this action, and expanded the original rotatable crops of alfalfa and cotton to include canola, soybean, and cereals grains except rice, December 8, 2011 (76 FR 76676) (FRL-9328-8). The reason for these changes is explained in Unit IV.D.START.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue \* \* \*"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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. In the carcinogenicity study, increased liver tumors were also observed in female rats. Liver effects in rodents were seen at lower dose levels than those in the dogs. 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.

Fluopyram is classified as "Likely to be Carcinogenic to Humans" and a unit risk, Q1\*, of  $1.55 \times 10^{-2}$  (mg/kg/day)<sup>-1</sup>

was used for the linear low dose extrapolation of cancer risk based on liver tumors in female rats; thyroid tumors were also observed in male mice. 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 "Fluopyram: Human Health Risk Assessment for Proposed Uses on Apples, Bananas (Import only), Cherries (Sweet and Tart), Dried Beans, Peanuts, Potatoes, Strawberries, Sugar Beets, Tree Nuts, Watermelon, and Wine Grapes" beginning at Appendix A, pages 41–47 in docket ID number EPA–HQ–OPP–2009–0364.

**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>.

The details for selecting toxicity endpoints and points of departure for various exposure scenarios can be found at <http://www.regulations.gov> in the document "Fluopyram: Human Health Risk Assessment for Proposed Uses on Apples, Bananas (Import only), Cherries (Sweet and Tart), Dried Beans, Peanuts, Potatoes, Strawberries, Sugar Beets, Tree Nuts, Watermelon, and Wine Grapes" in Appendix A on pages 47–66 in docket ID number EPA–HQ–OPP–2009–0364.

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

**TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOPYRAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

Exposure/scenario	Point of departure	Uncertainty/ FQPA safety factors	RfD, PAD, Level of concern for risk assessment	Study and toxicological effects
Acute Dietary (General Population, including Infants and Children).	NOAEL= 50 mg/kg/day .....	UF <sub>A</sub> = 10X ..... UF <sub>H</sub> =10X FQPA SF=1X	aRfD = 0.50 mg/kg/day ..... aPAD = 0.50 mg/kg/day	Acute Neurotoxicity Study in Rats. The LOAEL of 100 mg/kg in females is based on decreased motor and locomotor activity in females. The LOAEL in males was 125 mg/kg/day.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOPYRAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure	Uncertainty/ FQPA safety factors	RfD, PAD, Level of concern for risk assessment	Study and toxicological effects
Acute Dietary (Females 13–49 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 <sub>A</sub> = 10X ..... UF <sub>H</sub> = 10X FQPA SF=1X	cRfD = 0.012 mg/kg/day ... cPAD = 0.012 mg/kg/day	Combined Chronic/Carcinogenicity in Rats. The LOAEL of 6.0 mg/kg/day is based on follicular cell hypertrophy in the thyroid, and increased liver weight with gross pathological and histopathological findings.
Cancer (oral, dermal, inhalation).	Based on the liver tumor in female rats, EPA classified fluopyram as a “Likely to be Carcinogenic to Human” and recommended the use of linear low dose extrapolation model for risk assessment using a unit risk, Q <sub>1</sub> * = 1.55 × 10 <sup>-2</sup> (mg/kg/day) <sup>-1</sup> .			

Point of Departure (POD) = A data point or an estimated point that is 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<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose (a = acute, c = chronic). mg/kg/day = milligrams/kilogram/day.

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. 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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute dietary analysis included tolerance residue levels, 100% crop treated assumption 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 1994–1996 and 1998 CSFII. The chronic dietary analysis included average residue levels from crop field trials, 100% crop treated assumption, and processing factors (empirical and default).

iii. Cancer. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk

assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that fluopyram should be classified as “Likely to be Carcinogenic to Humans” and a linear approach has been used to quantify cancer risk. The cancer dietary analysis included average residue levels from crop field trials, processing factors (empirical and default, commercial and household), and percent crop treated (PCT) estimates.

iv. Anticipated residue and PCT information. EPA used tolerance level residues and assumed 100% crop treated in the acute dietary assessment for fluopyram. For the chronic dietary assessment, EPA used average residues from field trials and 100% CT information. The cancer dietary risk assessment used average residues from field trials and projected percent crop treated estimates based on processing factors.

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 new uses as follows:

Almonds: 33%; apples: 40%; barley: 22%; dry beans: 7%; cherry: 49%; cotton: 7%; grapes: 79%; oats: 23%; peanuts: 67%; potatoes: 64%; rapeseed: 73%; rye: 63%; sorghum: 12%; soybeans: 1%; strawberries: 71%; sugar beets: 48%; watermelon: 54%; and wheat: 1%.

EPA's estimate of the percent crop treated for the new uses of fluopyram represents the upper bound of use expected during the pesticide's initial 5 years of registration; that is, the percent crop treated for fluopyram is a threshold of use that EPA is reasonably certain will not be exceeded for this registered use site. The percent crop treated for use in the chronic dietary assessment is calculated as the average percent crop treated of the market leader or leaders (i.e., the pesticides with the greatest percent crop treated) on that crop over the 3 most recent years of available data. The percent crop treated for use in the acute dietary assessment is the maximum observed percent crop treated over the same period. Comparisons are only made among pesticides of the same pesticide types (e.g., the market leader for fungicides on the use crop is selected for comparison with a new fungicide). The market leader included in the estimation may not be the same for each year since different pesticides may dominate at different times.

To calculate these percent crop treated values, EPA used recent data from the National Agricultural Statistics Service (NASS) 2002–2006, and recent proprietary data (2006–2010). The estimates for the primary crops are based on the market leader approach involving several registered fungicides, and the estimates for the rotational crops are based on acres of wheat, corn, sorghum, barley, oats, rye, millet, soybeans, canola, cotton, and alfalfa grown relative to the total acreage of dry beans and potatoes treated with fluopyram.

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>.

Environmental fate studies indicate that the parent fluopyram is stable under environmental conditions. Reported half-lives range from 89 days in field and aqueous photolysis studies to >1,000 days in aerobic/anaerobic water/sediment systems. Fluopyram is mobile in soil and can therefore, be expected to occur in surface water runoff and/or in ground water leachate. Upper-bound ground water estimates were derived using the Tier I Screening Concentration in Ground Water (SCI-GROW) model. Surface water estimates were partially refined by incorporating a foliar degradation rate into the Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model. The foliar decay rate was calculated from field trial studies in which residues were determined at various intervals following foliar application; no rain or irrigation occurring during the study period. All other inputs reflect high-end assumptions regarding application rates and percent cropped area (PCA) in the watershed.

Based on the Tier II PRZM/EXAMS and SCI-GROW models the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are 13 parts per billion (ppb) for surface water and 0.32 ppb for ground water. The EDWCs of fluopyram for chronic exposures for non-cancer assessments are estimated to be 4.9 ppb for surface water and 0.32 ppb for ground water and the EDWCs of fluopyram chronic exposures for cancer assessments are estimated to be 3.5 ppb for surface water and 0.32 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 13 ppb (1 in 10 year annual peak) based on a maximum application rate of 0.446 lb ai/A/season (cucumber) was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.9 ppb (1 in 10 year annual mean) based on a maximum application rate of 0.356 lb active ingredient/Acre (a.i./A)/season (potato) was used to access the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 3.5 ppb (1 in 30 year annual mean) based on a maximum application rate of 0.356 lb a.i./A/season (potato) was used to access the contribution of 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 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 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 prenatal or postnatal periods. Decreased fetal body weight was observed at levels equal to or greater than the maternal LOAEL in both rat and rabbit developmental studies. Likewise, body weight effects were seen in offspring at levels equal to the parental LOAEL in the rat 2-generation reproductive toxicity study.

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 and includes the immunotoxicity study and neurotoxicity screening battery.

ii. The fluopyram toxicology database did not demonstrate evidence of neurotoxicity. Although transient decreases in motor and locomotor activities in the acute neurotoxicity study on the day of treatment and limited use of hind-limbs and reduced motor activity in the rat chronic/carcinogenicity study were seen, 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 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. There is no indication that fluopyram is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluopyram results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or

in young rats in the multi-generation reproduction study.

iv. There are no residual uncertainties in the exposure database. Although extended field rotational crop studies are required as a condition of registration, the rotational crop tolerances used in the dietary risk assessment are not expected to underestimate exposure because they are based on crop residue results from direct foliar treatment as opposed to residues taken up by plants through roots from treated soil. The acute dietary exposure assessment was performed using tolerance level residues for all crops whereas the chronic dietary assessment included average field trial residue levels for all crops. Both acute and chronic assessments assumed 100% crop treated and 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. Residential exposures are not expected. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopyram in drinking water. These assessments will not underestimate the exposure and risks posed by fluopyram.

#### *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 8.8% of the aPAD for children 1 to 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 13% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for fluopyram.

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). Because no short-term adverse effect was identified; fluopyram is not expected to pose a short-term risk.

A short-term adverse effect was identified; however, fluopyram is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for fluopyram.

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). Because no intermediate-term effect was identified, fluopyram is not expected to pose an intermediate-term risk. An intermediate-term adverse effect was identified; however, fluopyram is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluopyram.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for the cancer risk assessment, EPA has concluded that exposure to fluopyram from food and water will result in a lifetime cancer risk of  $2.9 \times 10^{-6}$  for the general U.S. population. EPA generally considers cancer risks in the range of 1 in 1 million ( $1 \times 10^{-6}$ ) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between

$3 \times 10^{-7}$  and  $3 \times 10^{-6}$  are expressed as risks in the range of  $10^{-6}$ . Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of  $10^{-6}$  until the calculated risk exceeds approximately  $3 \times 10^{-6}$ . This is particularly the case where some conservatism is maintained in the exposure assessment.

Although the fluopyram exposure risk assessment is refined, it retains some conservatism due, among other things, to the use of field trial data to estimate residues in food and the use of high-end assumptions to estimate residues in water. Accordingly, EPA has concluded the cancer risk from aggregate exposure to fluopyram falls within the range of  $1 \times 10^{-6}$  and is thus negligible.

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, has been proposed for the enforcement of tolerances for fluopyram residues in or on crop commodities, and a high performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS), Method 01079, has been proposed 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 for each analyte in each matrix. The proposed enforcement method for plant commodities (DFG Method S19) and livestock commodities (Method 01079) are deemed adequate as enforcement methods. Adequate HPLC/MS/MS methods were used for data collection for crop and livestock commodities. The FDA multiresidue methods of PAM Vol. I are suitable for the determination of fluopyram in non-fatty matrices (using Section 302), but are not suitable for detection of AE C656948-benzamide residues. 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](mailto: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 FFDC section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex Maximum Residue Limits (CXLs) have been established for grape at 2 ppm and dried grapes (raisins) at 5 ppm; milk at 0.07 ppm; mammalian meat at 0.1 ppm, and edible offal mammalian (meat byproducts) at 0.7 ppm. For the purpose of international harmonization, EPA is establishing U.S. tolerances for wine grape at 2.0 ppm (raised from 1.4 ppm); milk at 0.07 ppm (raised from 0.06 ppm); and hog meat byproducts at 0.70 ppm (raised from 0.45 ppm).

The Codex MRL for grapes is based on field trials conducted in Europe, and is calculated by rounding up of the statistically determined 1.3 ppm to 2 ppm. A U.S. tolerance for dried grapes (raisins) is not needed as the tolerance request is for wine-type grapes only, which are not converted to raisins.

Harmonization of recommended U.S. tolerances for meat and meat byproducts (other than hog) with Codex MRLs cannot be achieved. The Codex MRL for livestock is calculated on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops) and the use of a reasonable worst case diet/feed approach (RWCF). The dietary burden was calculated using only grape pomace residue and 20% contribution to the Australian dairy and beef cattle diets. The U.S. tolerance was based on guidance "Revisions of Feedstuffs in (Table 1) OPPTS Test Guideline 860.1000" and "Guidance on Constructing Maximum Reasonably Balanced Diets (MRBD)". Based on the U.S. livestock diets (which does not include grape pomace) and the cattle feeding study, the meat byproduct

(cattle, goat horse, sheep) tolerances need to be set at 1.1 ppm, a higher level than the 0.7 Codex MRL for edible offal. Similarly, the U.S. meat tolerances for these animals need to be set higher than the Codex MRL (0.15 versus 0.1 ppm).

##### C. Revisions to Petitioned-For Tolerances

Because the Agency's preliminary risk assessment of fluopyram determined that aggregate exposure to fluopyram potentially exceeded safe levels, the petitioner withdrew tolerance proposals and registration requests for the following crops: Crop Group 1B Root vegetable; 1C Tuberos and corm vegetable (except potatoes and sugarbeet); Crop Group 2 Leaves of root and tuberous vegetables, Crop subgroups 3-07A and B Bulb vegetables; Crop Group 4 Leafy vegetables; Crop Group 5 Brassica; Crop Group 6A Edible legumes; Crop Group 6B Succulent beans and peas; Crop Group 6C (part) Dried peas and some dried beans, (except soybeans); Crop Group 7 Foliage of legume vegetables; Crop Group 8 Fruiting vegetables; Crop Group 10 Citrus; Crop Group 11 Pome fruit (except apple); Crop subgroups 13-07A and B Caneberries and Bushberries; Crop subgroup 13-07F Vine fruit (except wine grapes); Crop subgroup 13-07G Low growing berries (except strawberry); Crop Group 15 Cereal Grains (except for rotational purposes); Crop Group 16 Forage Cereals (except for rotational purposes); Crop Group 17 Grasses grown for forage or seed; Crop Group 18 Non grass animal feeds; Crop Group 19 Herbs and Spices; Crop Group 20 Oilseeds (except canola); Hops; Globe artichoke; Christmas Trees; Turf; and Ornamentals.

The petitioner subsequently, submitted a revised registration specifying uses only on the following crops: Apple; banana (no U.S. registration); bean, dry; beet, sugar, root; cherry (sweet and tart); grape, wine; nut tree crop group 14; peanut; pistachio; potatoes; strawberry; and watermelon. Based on the available field trial data, and NAFTA tolerance calculation procedures, the Agency recommended appropriate tolerance levels for individual commodities as opposed to levels proposed for crop groups. However, although the petitioner proposed a tolerance for "nut, tree, group 14 (including pistachio)" at 0.05 ppm, EPA determined that separate tolerances must be established for the tree nut crop group and pistachio because pistachio is not at this time included in crop group 14. The available data indicate that 0.05 ppm is an appropriate level for these tolerances.

The petitioner has proposed tolerances for combined residues of fluopyram and AE C656948-benzamide in egg; milk; the fat, meat, and meat byproducts of poultry; and the fat, liver, meat, and meat byproducts (except liver) of cattle, goat, hog, horse, and sheep. The estimated livestock dietary burden and available feeding study data indicate that most of the proposed tolerances for livestock commodities are too low. In addition, EPA no longer establishes separate tolerances for liver (it is accounted for in the meat byproducts of livestock animals). Based on the NAFTA calculator, the Agency recommended higher tolerances.

The revised registration permits crop rotation to alfalfa, cotton, canola, cereal grains (except rice), and soybean with certain restrictions. However, extensive field rotational crop data for these crops are not available. In the absence of sufficient rotational crop data, highly conservative target crop residue data were used for setting tolerance for rotational crops. The preference was to select an intermediate level between the confined accumulation/limited field rotational crop data and primary crop data for the target rotated crops so as to discourage potential misuse (i.e., direct foliar application) and provide adequate maximum residue levels for legal uses according to label instructions. Thus, pending extensive field rotational crop data, EPA recommends interim rotational crop tolerances be set at half of the calculated primary crop tolerances with a PBI of 30 days.

In addition, the Agency determined tolerances were not required for the following petitioned commodities: Beet, sugar, tops; corn, sweet, kernel plus cob with husk removed; grain, cereal, forage, fodder and straw, group 16, except rice, aspirated fractions; and soybean hulls, thus, these tolerances have been removed. Tolerances were not needed for the following reasons: the tolerance for the commodity corn, sweet, kernel plus cob with husk removed is covered under grain, cereal, group 15, except rice; Bayer withdrew their requests for tolerances for grain, cereal, forage, fodder and straw, group 16, except rice; aspirated fractions and soybean, hulls; and the sugar beet top tolerance was withdrawn because sugar beet tops are no longer considered a major livestock commodity.

Moreover, EPA is revising certain crop definitions (as proposed) for the following: almond, hulls; beet, sugar, roots; eggs; grain, cereal, group 15, except rice and sweet corn. The correct commodity terminology are almond, hull; beet, sugar, root; egg; and grain,

cereal, group 15, except rice, respectively.

#### V. Conclusion

Therefore, tolerances are established for residues of fluopyram, in or on multiple commodities as shown in the codified text below.

#### VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10,

1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

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

#### VII. Congressional Review Act

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

#### List of Subjects in 40 CFR Part 180

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

Dated: February 2, 2012.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.661 is added to subpart C 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, hull .....	8.0
Apple .....	0.30
Apple, wet pomace .....	0.60
Banana <sup>1</sup> .....	1.0
Bean, dry .....	0.09
Beet, sugar, root .....	0.04
Cherry .....	0.60
Grape, wine .....	2.0
Nut, tree, group 14 .....	0.05
Peanut .....	0.02
Pistachio .....	0.05
Potato .....	0.02
Potato, processed potato waste .....	0.08
Strawberry .....	1.5
Watermelon .....	1.0

<sup>1</sup> 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 .....	0.11
Cattle, meat .....	0.15
Cattle, meat byproducts .....	1.1
Egg .....	0.25
Goat, fat .....	0.11
Goat, meat .....	0.15
Goat, meat byproducts .....	1.1
Hog, fat .....	0.05
Hog, meat .....	0.05
Hog, meat byproducts .....	0.70
Horse, fat .....	0.11
Horse, meat .....	0.15
Horse, meat byproducts .....	1.1
Milk .....	0.07
Poultry, fat .....	0.20
Poultry, meat .....	0.15
Poultry, meat byproducts .....	0.60
Sheep, fat .....	0.11
Sheep, meat .....	0.15
Sheep, meat byproducts .....	1.1

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(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
Canola, seed .....	1.8
Cotton, gin byproducts .....	0.05
Cotton, undelinted seed .....	0.01
Grain, cereal, forage, fodder and straw, group 16, except rice; forage .....	4.0
Grain, cereal, forage, fodder and straw, group 16, except rice; hay, straw and stover ...	7.0
Grain, cereal, group 15, except rice .....	1.5
Soybean, forage .....	4.0
Soybean, hay .....	15
Soybean, seed .....	0.10

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BILLING CODE 6560-50-P

**DEPARTMENT OF DEFENSE**

**Defense Acquisition Regulations System**

**48 CFR Part 252**

**Defense Federal Acquisition Regulation Supplement; Technical Amendment**

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide needed editorial changes.

**DATES:** *Effective Date:* February 24, 2012.

**FOR FURTHER INFORMATION CONTACT:** Ms. Ynette Shelkin, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301-3060. Telephone 703-602-8384; facsimile 703-602-7887.

**SUPPLEMENTARY INFORMATION:** This final rule amends the DFARS as follows:

○ *252.212-7001* Revises the clause date and makes conforming changes to the dates of the DFARS clauses referenced in paragraphs (b)(20) and (c)(2) of the clause.

○ *252.227-7013* Revises the clause date and corrects paragraph numbers referenced in paragraphs (b)(2)(i)(A), (b)(4), and (b)(6) of the clause.

○ *252.227-7014* Revises the clause date and corrects paragraph numbers referenced in paragraphs (b)(4)(i) and (b)(6) of the clause.

**List of Subjects in 48 CFR Part 252**

Government procurement.

**Ynette R. Shelkin,**

*Editor, Defense Acquisition Regulations System.*

Therefore, 48 CFR part 252 is amended as follows:

**PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES**

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

**252.212-7001 [Amended]**

■ 2. Section 252.212-7001 is amended by removing the clause date “(JANUARY 2012)” and adding “(FEB 2012)” in its place, in paragraph (b)(20), removing “(SEP 2011)” and adding “(FEB 2012)” in its place, and in paragraph (c)(2), removing “(SEP 2011)” and adding “(FEB 2012)” in its place.

**252.227-7013 [Amended]**

■ 3. Section 252.227-7013 is amended by removing the clause date “(SEP 2011)” and adding “(FEB 2012)” in its place, in paragraph (b)(2)(i)(A), removing “as provided in paragraphs (b)(ii) and (b)(iv) through (b)(ix) of this clause” and adding “as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause” in its place, in paragraph (b)(4), removing “enumerated in paragraph (a)(13) of this clause” and adding “enumerated in paragraph (a)(14) of this clause” in its place, and in paragraph (b)(6), removing “in accordance with paragraph (a)(13)” and adding “in accordance with paragraph (a)(14)” in its place.

**252.227-7014 [Amended]**

■ 4. Section 252.227-7014 is amended by removing the clause date “(MAR 2011)” and adding “(FEB 2012)” in its place, in paragraph (b)(4)(i), removing “enumerated in paragraph (a)(14) of this clause or lesser rights in computer software documentation than are enumerated in paragraph (a)(13)” and adding “enumerated in paragraph (a)(15) of this clause or lesser rights in computer software documentation than are enumerated in paragraph (a)(14)” in its place, and in paragraph (b)(6), removing “made in accordance with paragraph (a)(14)” and adding “made in