Service continues to encourage mailers to use one of the various merchandise return services products for return merchandise, instead of using Business Reply Mail, which is primarily intended for use with letter and flat sized pieces. The Postal Service currently offers a Merchandise Return Service (MRS) web-tool (API) interface that permits all mailers to create their MRS labels with the required IMpb. The Postal Service will continue to consider additional enhancements for all return services to make it easier for companies of all sizes to do business with us.

III. Features of the Final Rule

The Postal Service continues to enhance its operational capability to scan IMpbs, encoded with routing and tracking information, via automated mail processing equipment and Intelligent Mail scanning devices, and to provide tracking information to the mailers. Full implementation of the Postal Service's package visibility strategy relies on the availability of piece-level information provided through the widespread use of IMpb.

Recent changes to mailing standards now require the use of IMpb on all commercial parcels (excluding parcels paid for using BRM service). The Postal Service now advances its package visibility strategy by requiring a unique IMpb on cartons, parcels, or Priority Mail pieces of any shape, preprinted or with labels affixed to be returned using BRM service.

For the purposes of this requirement, a BRM carton is defined as a parcel-shaped mailpiece with a BRM label either printed directly on the mailpiece or affixed by the end user prior to mailing. BRM permit holders would not be required to submit shipping manifests to support these mailpieces. BRM labels would be required to use a unique Mailer ID (MID) for BRM parcels and a concatenated IMpb construct that includes the ZIP+4®routing code. The barcodes must be unique for 180 days. BRM cartons and parcels will use IMpb service type codes for Merchandise Return Service for Priority Mail or First-Class Mail®, based on the product used. The Postal Service will provide an exception process—for mailers of small BRM cartons and parcels lacking sufficient label space to apply an IMpb barcode meeting the ¾-inch height requirement—to submit barcodes of at least ½-inch in height for USPS testing and approval. This exception process will be administered by the National Customer Service Center (NCSC), as part of the normal package barcode approval process. At this time, no other changes would be made to the BRM standards in DMM 505.1 applicable to all other mail shapes.

Noncompliant Mailpieces: The Postal Service will assess a per-piece IMpb non-compliance fee on all BRM parcels not bearing an IMpb and returned using Priority Mail. The proposed effective date for the per-piece fee on First-Class Mail parcels being returns using BRM would be predicated on the Postal Service filing a notice with, and receiving approval from, the Postal Regulatory Commission. Thus, the non-compliance fee starts immediately with Priority Mail pieces only.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

For the reasons stated in the preamble, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

505 Return Services

1.0 Business Reply Mail (BRM)

* * * * *

1.4 General Information

1.4.1 Description

[Insert a new fourth sentence in 1.4.1 to read as follows:]

* * * All BRM labels intended for use on cartons, mailpieces meeting the physical characteristics of a parcel in DMM 201, or a Priority Mail item of any shape, must meet the standards under 1.7.10.

* * *

* * * * *

1.7 Mailpiece Characteristics

* * * * *

[Insert new 1.7.10 to read as follows:]

1.7.10 Labels for Parcels

BRM labels intended for use on cartons, mailpieces meeting the physical standards of a parcel under DMM 201, or a Priority Mail item of any shape, must also bear an IMpb prepared under 708.5.0 and meet the technical standards in the Parcel Labeling Guide available on RIBBS.

* * * * *

1.8 Format Elements

1.8.1 General

[Revise the text of the first and second sentences of 1.8.1 to read as follows:] Except for BRM labels for parcels as provided under 1.7.10, all pieces of BRM are subject to these format elements. For all other BRM pieces, an Intelligent Mail barcode (IMb) is not required, except for QBRM prices; if an IMb is used, it must be printed and placed as shown in Exhibit 1.8.1. * * *

* * * * *

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–29479 Filed 12–16–14; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0662; FRL–9918–99]

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 that 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 December 17, 2014, except for the amendment to § 180.661 in amendatory instruction number 3, which is effective June 17, 2015. Objections and requests for hearings must be received on or before February 17, 2015, 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–2013–0662, 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* 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–2013–0662 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 February 17, 2015. 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–2013–0662, by one of the following methods:

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

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 May 23, 2014 (79 FR 29729) (FRL–9910–29), 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 3F8190) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.661 be amended by establishing tolerances 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 following commodities: Beef, byproducts at 0.70 parts per million (ppm); beef, fat at 0.10 ppm; beef, meat at 0.10 ppm; grain, cereal, forage, group 16 at 1.5 ppm; cotton, gin by-products at 0.80 ppm; cotton, seed at 0.01 ppm; egg at 0.15 ppm; grain, cereal group 15, except rice at 0.03 ppm; grain, cereal, fodder, hay and straw, group 16 at 2.0 ppm; hog, fat at 0.05 ppm; hog, meat at 0.10 ppm; hog, meat byproducts at 0.70 ppm; milk at 0.10 ppm; peanuts at 0.09 ppm; poultry, fat at 0.10 ppm; poultry, meat at 0.10 ppm; poultry, meat byproducts at 0.20 ppm; and soybean, seed at 0.04 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.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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. 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 multi-generation 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 document entitled ''Fluopyram: Human Health Risk Assessment for Proposed New Use as a Soil/In-Furrow Treatment for Cotton and Peanut, and as a Seed Treatment to Cotton and Soybean, Plus a Proposal for Amended Inadvertent Tolerances for the Crop Group 15 Cereal Grains and Crop Group 16 Forage, Fodder, and Straw of Cereal Grains'' in docket ID number EPA–HQ–OPP–2013–0662.

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 entitled ''Fluopyram: Human Health Risk Assessment for Proposed New Use as a Soil/In-Furrow Treatment for Cotton and Peanut, and as a Seed Treatment to Cotton and Soybean, Plus a Proposal for Amended Inadvertent Tolerances for the Crop Group 15 Cereal Grains and Crop Group 16 Forage, Fodder, and Straw of Cereal Grains'' in docket ID number EPA–HQ–OPP–2013–0662.

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 and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	An endpoint attributable to a single dose exposure has not been identified for this subpopulation.		
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.
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.

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

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation).	Classification: 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). RfD = reference dose. 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 percent crop treated (PCT), 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 field-trial residue levels, the assumption of 100 PCT, 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. The chronic RfD is derived using the NOAEL of 1.2 mg/kg/day as the ''point of departure'' which is below the dose of 11 mg/kg/day that caused cell proliferation in the liver (*i.e.,* a key event in tumor formation) and the subsequent liver tumors at a higher dose (89 mg/kg/day). Therefore, the Agency believes the chronic assessment will be protective of any cancer risk; therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluopyram. Tolerance level residues or average field-trial residues and 100 PCT were assumed for all food commodities.

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/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are estimated to be 19.4 parts per billion (ppb) for surface water and 87.5 ppb for ground water. The chronic exposures for non-cancer assessments are estimated to be 4.9 ppb for surface water and 76.8 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 87.5 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 76.8 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 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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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.

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. Therefore, there is no need for a developmental neurotoxicity study or additional uncertainty factors (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 and chronic dietary exposure assessment was performed using tolerance level residues or average field-trial residues for all crops. Both acute and chronic assessments assumed 100 PCT 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 4.4% 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 38% of the cPAD for all infants, the population group receiving the greatest exposure. There are no residential uses for fluopyram. 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). Because there are no residential uses, short-term residential exposures are not likely to occur, and therefore fluopyram is not expected to pose a short-term aggregate risk.

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 there are no residential uses, intermediate-term residential exposures are not likely to occur, and therefore fluopyram is not expected to pose an intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A. and the lack of a chronic risk, 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 multi-residue method DFG Method S 19, a gas chromatography with mass selective detection (GC/MSD) method, is adequate 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, is adequate 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 enforcement methods 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. Thus, adequate enforcement methodologies (DFG Method S 19 and Method 01079) are available to enforce the tolerance expression.

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. As required by FFDCA section 408(b)(4), EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex) in its tolerance decisions. The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex MRL for peanut is 0.03 mg/kg, which is lower than the U.S. tolerance as amended for peanuts at 0.09 ppm. The U.S. peanut tolerance cannot be harmonized at 0.03 because following the approved label directions could result in residues above 0.03 ppm.

There are Codex MRLs for the livestock commodities that are higher than the U.S. tolerances for livestock commodities. The lowering of the tolerances for the cereal grains (group 15), and cereal grains forages, stovers, and straws (group 16), all as rotational crops, resulted in considerably less fluopyram in the livestock diets than under the previous tolerances. As a result, the tolerances for the livestock commodities were lowered. Calculated values were adjusted slightly to harmonize with Canada for all livestock commodity tolerances/MRLs but could not be harmonized with Codex MRLs, which are generally higher (5X–60X), because they are based on a different residue definition, do not reflect the North American Free Trade Agreement (NAFTA) plant commodity use patterns, and do not consider the Maximum Reasonably Based Diet.

C. Response to Comments

Two comments were received in response to the notice of filing of Bayer CropScience's application. Both commenters objected to the increase of chemical residues generally and one commenter expressed additional concerns about the carcinogenic effects of chemicals in general on humans. The Agency understands the commenters' concerns regarding toxic chemicals and their potential effects on humans. Pursuant to its authority under the FFDCA, and as discussed further in this preamble, EPA conducted a comprehensive assessment of fluopyram, which included an assessment on the carcinogenic potential of fluopyram. Based on its assessment of the available data, the Agency has concluded that fluopyram is not likely to be a carcinogen and that there is a reasonable certainty that no harm will result from aggregate exposure to residues of fluopyram.

D. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for cotton gin byproducts and for cereal grain forage group 16 that differ from the petitioned-for tolerances. The petitioned-for tolerances differ from the tolerances for cotton gin byproducts and for cereal grain forage group 16. The petition requested a tolerance of 0.80 ppm for cotton gin byproducts, but based on residue data provided and using the Organization for Economic Cooperation and Development (OECD) statistical calculation, EPA is establishing a tolerance level of 0.70 ppm. The petition also requested two different tolerances for the cereal grain forage, fodder, stover, and straw group 16: 1.5 ppm for forage and 2.0 ppm for hay, fodder, and straw. Only one tolerance is possible for the group, so the Agency is establishing the tolerance at 2.0 ppm to cover residues within that crop group.

EPA is establishing tolerances for fat, meat, and meat byproducts of cattle, hog, and poultry; egg; and milk lower than the petition requested based on a recalculation of the livestock dietary burdens and adjusted upwards to harmonize with Canada. The Agency is revising the commodity terms to ''cattle, fat''; ''cattle, meat''; and ''cattle, meat byproducts'' to be consistent with the food commodity vocabulary used for tolerances.

E. Trade Considerations

A few of the tolerance actions result in reductions of existing tolerance levels; therefore, EPA is delaying the effective date of the following tolerance actions for 6 months to allow a reasonable interval for producers in exporting member countries of the World Trade Organization's Sanitary and Phytosanitary Measures Agreement to adapt to the requirements of these modified tolerances. The tolerance actions subject to the 6-month delay are effective June 17, 2015 are as follows: Modifying tolerances in § 180.661(a)(2) for cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.40 ppm; egg at 0.06 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproducts at 0.03 ppm; milk at 0.06 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; and poultry, meat byproducts at 0.10 ppm; modifying tolerances in § 180.661(d) for grain, cereal, group 15, except rice at 1.5 ppm to grain, cereal, except rice, group 15 at 0.03 ppm; establishing tolerances in § 180.661(d) for grain, cereal, forage, fodder and straw, group 16 at 2.0 ppm; and removing tolerances from § 180.661(d) for grain, cereal, forage, fodder and straw, group 16, except rice; forage at 4.0 ppm; grain, cereal, forage, fodder and straw, group 16, except rice; hay, straw and stover at 7.0 ppm; and soybean, seed at 0.10 ppm.

V. Conclusion

Therefore, tolerances are established for residues of 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 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.40 ppm; cotton, gin byproducts at 0.70 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.06 ppm; grain, cereal, except rice, group 15 at 0.03 ppm; grain, cereal, forage, fodder and straw, group 16 at 2.0 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproducts at 0.03 ppm; milk at 0.06 ppm; peanuts at 0.09 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.10; and soybean, seed at 0.04 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: December 9, 2014.

G. Jeffrey 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. In § 180.661 (effective December 17, 2014):

■ a. Add alphabetically ''Cotton, gin byproducts''; ''Cotton, undelinted seed''; and ''Soybean, seed'' to the table in paragraph (a)(1).

■ b. Revise the entry for ''Peanut'' in the table in paragraph (a)(1).

■ c. Remove the entries ''Cotton, gin byproducts'' and ''Cotton, undelinted seed,'' in the table in paragraph (d).

The additions and revision read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	0.70
Cotton, undelinted seed	0.01
* * * * *	
Peanut	0.09
* * * * *	
Soybean, seed	0.04
* * * * *	

* * * * *

■ 3. In § 180.661 (effective June 17, 2015):

■ a. Revise in the table in paragraph (a)(2) the following entries listed in the table below.

■ b. Add alphabetically ''Grain, cereal, except rice, group 15'' and ''Grain, cereal, forage, fodder and straw, group 16'' to the table in paragraph (d).

■ c. Remove the entries ''Grain, cereal, forage, fodder and straw, group 16, except rice; forage''; ''Grain, cereal, forage, fodder and straw, group 16, except rice; hay, straw and stover''; and ''Grain, cereal, group 15, except rice'' in the table in paragraph (d).

The additions and revisions read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.40
Egg	0.06
* * * * *	
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.03
* * * * *	
Milk	0.06
Poultry, fat	0.03
Poultry, meat	0.03
Poultry, meat byproducts	0.10
* * * * *	

* * * * *

(d) * * *

Commodity	Parts per million
* * * * *	
Grain, cereal, except rice, group 15	0.03
Grain, cereal, forage, fodder and straw, group 16	2.0
* * * * *	

[FR Doc. 2014–29480 Filed 12–16–14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0352; FRL–9919–35]

Natamycin; Amendment to an Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide natamycin in or on pineapples. DSM Food Specialties B.V. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of natamycin in or on pineapple.

DATES: This regulation is effective December 17, 2014. Objections and requests for hearings must be received on or before February 17, 2015, 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–2014–0352, 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington,