BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0638; FRL-9906-70]

Fluxapyroxad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0638, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the

telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

B. How Can I Get Electronic Access to Other Related Information?

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

OCSPP test guidelines are cited, insert the following: 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-2012-0638 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 [*insert date 60 days after date of publication in the* **Federal Register.** Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0638, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL-9372-6), January 16, 2013 (78 FR 3377) (FRL-9375-4), and July 19, 2013 (78 FR 43115) (FRL-9392-9), EPA issued notices pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F8053, PP 2F8058 and PP 3F8161 by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC, 27709. The petitions requested that 40 CFR 180.666 be amended by establishing tolerances for residues of the fungicide fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, in or on almond at 0.05 parts per million (ppm); almond, hulls at 4.0 ppm; berry, low growing, subgroup 13–07G at 4.0 ppm; bushberry, subgroup 13–07B at 6.0 ppm; caneberry, subgroup 13–07A at 6.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm; grapes at 2.0 ppm; grapes, raisin at 5.7 ppm; pecans at 0.05 ppm; rice, bran at 8.5 ppm; rice, grain at 5.0 ppm; rice, hulls strawberry at 4.0 ppm; sugarcane, cane at 3.0 ppm; vegetable, *brassica* leafy, group 5 at 3.0 ppm; vegetable, bulb, group 3–07 at 0.8 ppm; vegetable, cucurbit, group 9 at 0.4 ppm; vegetable, leafy, except *brassica,* group 4 at 15.0 ppm; vegetable, root, except sugar

beet, subgroup 1B at 0.7 ppm (PP 2F8053); nongrass animal feeds, group 18 at 0.5 ppm; mint at 0.05 ppm (PP 2F8058); and by amending the tolerance for fruit, stone, group 12 from 2.0 ppm to 3.0 ppm (PP 3F8161). The documents referenced summaries of the petitions prepared by BASF Corporation, the registrant, which are available in dockets EPA-HQ-OPP-2012-0638 (PP 2F8053), EPA-HQ-OPP-2012-0924 (PP 2F8058), and EPA-HQ-OPP-2013-0477 (PP 3F8161), *http://www.regulations.gov*.

Based on EPA's review of the data supporting the petitions, BASF Corporation revised their petition PP 2F8053 by proposing tolerances for fish-freshwater finfish; fish-shelfish, crustacean; and hog, meat byproducts; and by decreasing, increasing, or deleting previously proposed tolerances for various commodities, as follows: Almond at 0.02 parts per million (ppm); almond, hulls at 4.0 ppm; berry, low growing, subgroup 13-07G at 4.0 ppm; bushberry, subgroup 13-07B at 7.0 ppm; caneberry, subgroup 13-07A at 5.0 ppm; fish-freshwater finfish at 0.01 ppm; fish-shellfish, crustacean at 0.01 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; grape, raisin at 5.7 ppm; hog, meat byproducts at 0.01 ppm; pecan at 0.06 ppm; rice, bran at 8.5 ppm; rice, grain at 5.0 ppm; rice, hulls at 15.0 ppm; sugarcane, cane at 3.0 ppm; vegetable, brassica leafy, group 5 at 4.0 ppm; vegetable, bulb, group 3-07 at 1.5 ppm; vegetable, cucurbit, group 9 at 0.5 ppm; vegetable, leafy, except brassica, group 4 at 30.0 ppm; vegetable, root, except sugarbeet, subgroup 1B at 0.9 ppm. EPA issued a notice announcing the filing of the revised petition in the **Federal Register** of November 27, 2013 (78 FR 70906) (FRL-9902-87). That document referenced a summary of the revised petition prepared by BASF, which is available in docket EPA-HQ-OPP-2012-0638.

Three comments were received on the notices of filing. EPA's response to the comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluxapyroxad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluxapyroxad 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.

Fluxapyroxad is of low acute toxicity by the oral, dermal and inhalation routes, is not irritating to the eyes and skin, and is not a dermal sensitizer. The primary target organ for fluxapyroxad exposure via the oral route is the liver with secondary toxicity in the thyroid for rats only. Liver toxicity was observed in rats, mice, and dogs, with rats as the most sensitive species for all durations of exposure. In rats, adaptive effects of hepatocellular hypertrophy and increased liver weights and changes in liver enzyme activities were first observed. As the dose or duration of exposure to fluxapyroxad increased, clinical chemistry changes related to liver function also occurred, followed by hepatocellular necrosis, neoplastic changes in the liver, and tumors. Thyroid effects were observed only in rats. These effects were secondary to changes in liver enzyme regulation, which increased metabolism of thyroid hormone, resulting in changes in thyroid hormones, thyroid follicular hypertrophy and hyperplasia, and thyroid tumor formation. Tumors were not observed in species other than rats or in organs other than the liver and thyroid.

Fluxapyroxad is classified as "Not likely to be Carcinogenic to Humans" based on convincing evidence that carcinogenic effects are not likely below a defined dose range. There is no mutagenicity concern from *in vivo* or *in vitro* assays. The hypothesized mode of action (i.e., a non-genotoxic) for treatment related tumors (i.e., the liver and thyroid) was supported by a full panel of *in vitro* and *in vivo* studies that showed no evidence of genotoxicity, together with mechanistic studies in the liver and thyroid of rats that

satisfied stringent criteria for establishing tumorgenic modes of action. The studies clearly identified the sequence of key events, dose-response concordance and temporal relationship to the tumor types. The Agency has determined that the chronic population adjusted dose (PAD) will adequately account for all chronic effects, including carcinogenicity that could result from exposure to fluxapyroxad because the points of departure (POD) for the chronic population adjusted dose (cPAD) is based on the most sensitive endpoint, liver effects. Effects in the liver preceded liver tumors and the effects observed in the thyroid (in rats only) were believed to be secondary to the liver effects.

No evidence of neurotoxicity was observed in response to repeated administration of fluxapyroxad. An acute neurotoxicity study showed decreased rearing and motor activity. This occurred on the day of dosing only and in the absence of histopathological effects or alterations in brain weights. This indicated that any neurotoxic effects of fluxapyroxad are likely to be transient and reversible due to alterations in neuropharmacology and not from neuronal damage. There were no neurotoxic effects observed in the subchronic dietary toxicity study. No evidence of reproductive toxicity was observed. Developmental effects observed in both rats and mice (thyroid follicular hypertrophy and hyperplasia in rats and decreased defecation, food consumption, body weight/body weight gain, and increased litter loss in rabbits) occurred at the same doses as those that caused adverse effects in maternal animals, indicating no quantitative susceptibility. Since the maternal toxicities of thyroid hormone perturbation in rats and systemic toxicity in rabbits likely contributed to the observed developmental effects there is low concern for qualitative susceptibility. An immunotoxicity study in mice showed no evidence of immunotoxic effects from fluxapyroxad.

Subchronic oral toxicity studies in rats, developmental toxicity studies in rabbits, and *in vitro* and *in vivo* genotoxicity studies were performed for fluxapyroxad metabolites F700F001, M700F002, and M700F048. Like fluxapyroxad, no genotoxic effects were observed for any of these metabolites. All three metabolites displayed lower subchronic toxicity via the oral route than fluxapyroxad, with evidence of non-specific toxicity (decreased body weight) observed only for M700F0048 at the limit dose. Only M700F0048 exhibited developmental toxicity at doses similar to those that caused developmental effects in rabbits with fluxapyroxad treatment. However, these effects (abortions and resorptions) were of a different nature than for fluxapyroxad (paw hyperflexion) and are considered secondary to maternal toxicity. The Agency considers these studies sufficient for hazard identification and characterization and concludes that these metabolites do not have hazards that exceed those of fluxapyroxad in nature, severity, or potency.

Specific information on the studies received and the nature of the adverse effects caused by fluxapyroxad 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, "Human Health Risk Assessment for Use of Fluxapyroxad on Numerous Crops" at pp. 52 in docket ID number EPA-HQ-OPP-2012-0638.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a PAD or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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

Table 1.--Summary of Toxicological Doses and Endpoints for Fluxapyroxad for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children, and females 13-49 years of age)	NOAEL = 125 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day aPAD = 1.25mg/kg/day	Acute neurotoxicity study in rats. LOAEL = 500 mg/kg/day based on decreased motor activity and decreased rearing
Chronic dietary (All populations)	NOAEL= 2.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.021 mg/kg/day cPAD = 0.021 mg/kg/day	Chronic toxicity/carcinogenicity study in rats. LOAEL = 11 mg/kg/day based on non-neoplastic changes in the liver (foci, masses)

Incidental oral short-term (1 to 30 days)	NOAEL= 9 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	28-day oral toxicity study in rats. LOAEL = 176 mg/kg/day based on changes in thyroid hormones and thyroid follicular hypertrophy/hyperplasia
Dermal short- and intermediate-term (1 day to 6 months)	No hazard identified		28-day dermal toxicity study in rats. LOAEL = Not observed
Inhalation short-term (1 to 30 days)	NOAEL= 9 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	28-day oral toxicity study in rats. LOAEL = 176 mg/kg/day based on changes in thyroid hormones and thyroid follicular hypertrophy/hyperplasia
Inhalation intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL = 7.3 mg/kg/day UF_A = 10 x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	90-day dietary study in rats. LOAEL = 35.1 mg/kg/day based on thyroid follicular hypertrophy/hyperplasia
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans at doses sufficient to induce liver and/or thyroid tumors. Quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity		

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 fluxapyroxad, EPA considered exposure under the petitioned-for tolerances as well as all existing fluxapyroxad tolerances in 40 CFR 180.666. EPA assessed dietary exposures from fluxapyroxad 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 fluxapyroxad. 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 used tolerance level residues adjusted upward to account for metabolites of concern not included in the tolerance expression, 100 percent crop treated (PCT) assumptions, and dietary exposure evaluation model (DEEM) default and empirical processing factors.

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, a moderately refined chronic dietary exposure analysis was performed. An assumption of 100 PCT and DEEM default and empirical processing factors were used for the chronic dietary analysis. Combined average field trial residues for parent and highest average field trial residues for metabolites of concern were used for all plant commodities. For livestock commodities tolerance level residues adjusted upward to account for metabolites of concern not included in the tolerance expression were used.

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

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the

anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluxapyroxad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluxapyroxad. 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 Tier 1 Rice Model and the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluxapyroxad for acute exposures are estimated to be 127 parts per billion (ppb) for surface water and 203 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 127 ppb for surface water and 184 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 203 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 184 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). Fluxapyroxad is registered for the following uses that could result in residential exposures: residential turf. EPA assessed residential exposure using the following assumptions: Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Since no dermal hazard was identified for fluxapyroxad, MOEs were calculated for the inhalation route of exposure only.

Both adults and children may be exposed to fluxapyroxad residues from contact with treated lawns. Adult postapplication exposures were not quantitatively assessed since no dermal hazard was identified for fluxapyroxad and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil. Post application hand-to-mouth and object-to-mouth exposures are expected to be short-term (1 to 30 days) in duration due to the intermittent nature of applications in residential environments. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fluxapyroxad to share a common mechanism of toxicity with any other substances, and fluxapyroxad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluxapyroxad 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 website 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*. No evidence of quantitative susceptibility was observed in a reproductive and developmental toxicity study in rats or in

developmental toxicity studies in rats and rabbits. Developmental toxicity data in rats showed decreased body weight and body weight gain in the offspring at the same dose levels that caused thyroid follicular hypertrophy/hyperplasia in parental animals. Effects in rabbits were limited to paw hyperflexion, a malformation that is not considered to result from a single exposure and that usually reverses as the animal matures. Developmental effects observed in both rats and rabbits occurred at the same doses as those that caused adverse effects in maternal animals, indicating no quantitative susceptibility. The Agency has low concern for developmental toxicity because the observed effects were of low severity, were likely secondary to maternal toxicity, and demonstrated clear NOAELs. Further, the NOAELs for these effects were at dose levels higher than the points of departure selected for risk assessment for repeat- exposure scenarios. Therefore, based on the available data and the selection of risk assessment endpoints that are protective of developmental effects, there are no residual uncertainties with regard to pre- and/or postnatal toxicity.

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 fluxapyroxad is complete. Although no subchronic inhalation data is available EPA has waived that data requirement based on, among other things, its conclusion that even if an additional 10X safety factor was applied, inhalation exposure would not raise a risk of concern.

ii. There is no indication that fluxapyroxad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for

neurotoxicity. Neither the acute or the subchronic neurotoxicity studies indicated specific neurotoxicity responses to fluxapyroxad. Because fluxapyroxad can disrupt thyroid hormone levels, the Agency considered the potential for fluxapyroxad to cause developmental neurotoxicity as a result of thyroid hormone disruption, which is more sensitive endpoint than the endpoints used in a developmental neurotoxicity study. Based on its evaluation of thyroid hormone data submitted for fluxapyroxad and the ontogeny of thyroid hormone metabolism, the Agency has determined that adverse thyroid hormone disruptions in the young are unlikely to occur at dose levels as low as the points of departure chosen for risk assessment. The Agency has low concern for neurotoxic effects of fluxapyroxad at any life stage.

iii. Based on the developmental and reproductive toxicity studies discussed in Unit III.D.2., there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or field trial residue data. The dietary risk assessment is based on reliable data, is conservative and will not underestimate dietary exposure to fluxapyroxad. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluxapyroxad in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluxapyroxad.

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 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 fluxapyroxad will occupy 12% of the aPAD for children 3-5 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 fluxapyroxad from food and water will utilize 64 % of the cPAD for infants (< 1year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluxapyroxad 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). Fluxapyroxad is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluxapyroxad. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water,

and residential exposures result in aggregate MOEs of 320 for adults and 560 for children. Because EPA's level of concern for fluxapyroxad is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however**,** fluxapyroxad 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluxapyroxad.

5. *Aggregate cancer risk for U.S. population*. EPA classified fluxapyroxad as "Not likely to be Carcinogenic to Humans" based on convincing evidence that carcinogenic effects are not likely below a defined dose range. The Agency has determined that the quantification of risk using the cPAD for fluxapyroxad will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluxapyroxad. The POD for the cPAD is based on the most sensitive endpoint, liver effects. Effects in the liver preceded liver tumors and the effects observed in the thyroid (in rats only) were believed to be secondary to the liver effects. As noted

above, chronic exposure to fluxapyroxad from food and water will utilize 64% of the cPAD for infants (< 1year old) the population group receiving the greatest exposure.

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 fluxapyroxad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A Liquid Chromatography-Mass Spectrometer/Mass Spectrometer (LC/MS/MS) method is available as an enforcement method. This method uses reversed-phase High Pressure Liquid Chromatography (HPLC) with gradient elution, and includes 2 ion transitions to be monitored for the parent fluxapyroxad.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for fluxapyroxad on the commodities subject in this notice.

C. Response to Comments

Three anonymous public comments were received opposing establishment of the requested tolerances. The first commenter alleges that there is already too much toxicity from pesticide chemicals in the US and EPA should not allow more pesticide residues on food. The second commenter claims that a data gap exists for maximum residues of fluxapyroxad in wheat and for accumulation of fluxapyroxad residues in soil and argues that EPA should require testing of pesticides when combined with other pesticides. The third anonymous commenter states that the U.S. should no longer allow the importation of pet foods from China. The Department of Utility, City of Sacramento, California submitted a comment on the application by BASF to register fluxapyroxad for use on rice under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. Several issues in that comment pertain to EPA's risk assessment for the fluxapyroxad tolerance petition. The Department of Utility expresses concern with the potential human health effects of breakdown products (metabolites, degradates, transformations products) that occur both prior and subsequent to water treatment, the effects of water treatment on the removal of fluxapyroxad residues, and the potential synergistic effects from exposure to multiple rice pesticides in drinking water.

The anonymous commenters either raise irrelevant or non-specific issues, make unsubstantiated claims, or are mistaken in their allegations. General claims regarding the

toxicity of other pesticides and objections to the import of pet food from China do not raise safety concerns regarding EPA's assessment of the risk from aggregate exposure to fluxapyroxad. With regard to potential cumulative effects from the interaction of fluxapyroxad with other substances, EPA has addressed this issue in Unit III. C. 4., above. Finally, the commenter who claims there are data gaps is mistaken. The Agency determined that the available residue chemistry data for fluxapyroxad are sufficient to support the established tolerances for registered wheat uses. No data gaps were identified for wheat commodities or for rotational crop commodities. Additionally, the fluxapyroxad product label statements restrict crop rotation to commodities listed on the label.

The remaining comments raised by Sacramento's Department of Utility express concerns with EPA's examination of breakdown products from fluxapyroxad, and fluxapyroxad residue removal through water treatment in a drinking water plant. EPA possesses a full complement of standard metabolism and environmental fate studies on fluxapyroxad, as specified under 40 C.F.R. 158.1300 and 158.1410. These include hydrolysis (OCSPP Guideline 835.2120), aqueous photolysis (OCSPP Guideline 835.2240), aerobic soil metabolism, and aerobic aquatic metabolism studies (OCSPP Guidelines 835.4100/4200 and 835.4300/4400). While these studies provide general information on the fate of fluxapyroxad and its metabolites in the environment, they do not directly address the chemicals' fate during drinking water treatment, and were therefore used only for qualitative characterization of such effects. The studies show that fluxapyroxad is stable to hydrolysis and aquatic degradation, therefore the chemical is not expected to degrade during drinking water treatment, and/or subsequent delivery of

treated water to the consumer's tap. Because fluxapyroxad is moderately to slightly mobile in soils, treatment methods such as sedimentation, flocculation, and activated carbon filtration are expected to have some effect at removing fluxapyroxad. Available studies also show that fluxapyroxad does not degrade via photolysis, therefore where ultraviolet light is used as a means of disinfection, enhanced degradation of fluxapyroxad is not expected to occur. The chemical structure of fluxapyroxad does not appear to include any moieties where oxidation due to water chlorination could result in the formation of an obviously more-toxic transformation product, such as an oxon. EPA possesses toxicity data on various fluxapyroxad metabolites and degradates. The data indicate that none of these metabolites are more toxic than parent fluxapyroxad, and they were therefore not considered as separate entities in dietary or drinking water risk assessments. In conclusion, based upon the available information, EPA believes that it has adequately taken drinking water treatment into account in addressing potential human health risks from fluxapyroxad. EPA does not routinely require data on the effects of water treatment processes on pesticides. Rather, in assessing risks, EPA generally employs (as it did with fluxapyroxad) estimates of pesticide concentrations in source (untreated) water as a surrogate for concentrations in consumed water. This approach is inherently conservative, and is therefore expected to be protective of public health.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petitions, petition PP 2F8058 was revised by decreasing the proposed tolerances for nongrass animal feeds, group 18 from 0.5 to 0.30 ppm; and mint from 0.05 to 0.01 ppm. In addition, the Agency is amending the existing tolerance for grain, cereal, group 15, by adding "except rice" to the

commodity definition. In lieu of the proposed tolerances for almonds and pecans, and since these are the representative commodities for the tree nut crop group, the Agency is establishing a tolerance for the tree nut crop group 14-12 at 0.06 ppm.

The Agency concluded that based on the residue data these changes are required to support the proposed uses. The Agency analyzed the field trial data for the respective commodities using the Organization for Economic Cooperation and Development tolerance calculation procedures to determine the appropriate tolerances.

V. Conclusion

Therefore, tolerances are established for residues of fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, as requested in the revised petitions.

VI. Statutory and Executive Order Reviews

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

Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 14, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.666:

a. Revise the following commodities in the table in paragraph (a): "Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat)" and "Fruit, stone, group 12."

b. Add alphabetically 21 commodities to the table in paragraph (a).

c. Revise paragraph (d).

The revisions and additions read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Almond, hulls	4.0
* * * * *	
Berry, low growing, subgroup 13-07G	4.0
Bushberry, subgroup 13-07B	7.0
Caneberry, subgroup 13-07A	5.0
* * * * *	
Fish-freshwater finfish	0.01
Fish-shellfish, crustacean	0.01
* * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
* * * * *	
Fruit, stone, group 12-12	3.0
* * * * *	
Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except rice; except wheat	3.0
* * * * *	
Grape, raisin	5.7
Hog, meat byproducts	0.01
* * * * *	
Nut, tree, group 14-12	0.06
* * * * *	
Rice, bran	8.5
Rice, grain	5.0
Rice, hulls	15.0
* * * * *	
Sugarcane, cane	3.0
* * * * *	
Vegetable, brassica leafy, group 5	4.0
Vegetable, bulb, group 3-07	1.5
Vegetable, cucurbit, group 9	0.50
* * * * *	
Vegetable, leafy, except brassica, group 4	30
* * * * *	
Vegetable, root, except sugarbeet, subgroup 1B	0.90
* * * * *	

* * * * *

(d) *Indirect or inadvertent residues*. Tolerances are established for the combined indirect or inadvertent residues of the fungicide fluxapyroxad, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide in or on the commodity.

Commodity	Parts per million
Nongrass animal feeds, group18	0.30
Peppermint , tops	0.01
Spearmint, tops	0.01

[FR Doc. 2014-04164 Filed 02/25/2014 at 8:45 am; Publication Date: 02/26/2014]