BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0421; FRL-9346-7]

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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0421. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9369; email address: *odiott.olga@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go *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-2010-0421in 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 that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0421, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35803) (FRL-8831-3), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7709) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR part 180 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)-1*H*-pyrazole-4-carboxamide, in or on multiple commodities. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing. Based on EPA's review of the data supporting the petition, BASF Company revised their petition (PP 0F7709) by:

1. Proposing tolerances for corn, pop, grain; corn, sweet kernels plus cobs with husks removed; and wheat, grain;

2. Decreasing or increasing the proposed tolerances for various commodities;

3. Deleting the proposed tolerance for vegetable, root, subgroup 1A and proposing a tolerance for beet, sugar; and

4. Proposing a tolerance for oilseeds, group 20.

The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 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.

In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March, 2005), 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:

- No treatment-related tumors were seen in male or female mice when tested at doses that were adequate to assess carcinogenicity (including the Limit Dose);
- Treatment-related liver tumors were seen in male rats at doses $\geq$ 250 parts per million (ppm) (11 milligrams/kilogram/day (mg/kg/day)) and in female rats at doses $\geq$ 1,500 ppm (82 mg/kg/day);
- Treatment-related thyroid follicular cell tumors were seen in male rats only at doses $\geq$ 1,500 ppm (68 mg/kg/day);
- There is no mutagenicity concern from *in vivo* or *in vitro* assays;

- The hypothesized mode of action (i.e., a non-genotoxic) for each tumor type (i.e., the liver and thyroid) was supported by adequate studies that clearly identified the sequence of key events, dose-response concordance and temporal relationship to the tumor types. The mode of action met the criteria established by the Agency.

The Agency has determined that the chronic population adjusted dose (cPAD) will adequately account for all chronic effects, including carcinogenicity, that could result from exposure to fluxapyroxad.

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 "Fluxapyroxad: Human Health Risk Assessment for Use of New Active Ingredient on Cereal Grains, Legume Vegetables (Succulent and Dry), Oil Seed Crops (Canola and Sunflower), Peanuts, Pome Fruit, Stone Fruit, Root and Tuber Vegetables (Potatoes and Sugar Beets), Fruiting Vegetables, and Cotton," at page 39 in docket ID number EPA-HQ-OPP-2010-0421-0005.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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

Table—Summary of Toxicological Doses and Endpoints for Fluxapyroxad for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety	RfD, PAD, LOC for Risk	Study and Toxicological Effects

	Factors	Assessment	
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 = 10x FQPA SF = 1x	aRfD = 1.25 mg/kg/day aPAD = 1.25 mg/kg/day	Acute neurotoxicity study in rats LOAEL = 500 mg/kg/day based on decreased motor activity (both sexes) and decreased rearing (males only)
Chronic dietary (All populations)	NOAEL= 2.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 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)
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. 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 U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, tolerance level residues adjusted to account for metabolites of concern, 100 percent crop treated (PCT) assumptions, and Dietary Exposure Evaluation Model (DEEM) default and empirical processing factors were used.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. 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. Highest average field trial (HAFT) residues for parent plus metabolite were used for all plant commodities. For livestock commodities, tolerance level residues adjusted to account for metabolites of concern were used.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that 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*. EPA did not use anticipated residue or PCT information in the acute dietary assessment for fluxapyroxad. Tolerance level residues and 100 PCT information were assumed for all food commodities. For the chronic dietary assessment tolerance level residues and 100 PCT information were assumed for livestock commodities. HAFT residues for parent plus metabolite were used for all plant commodities.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present

action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The 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 First Index Reservoir Screening Tool (FIRST), and the Screening Concentration in Ground Water (SCI-GROW) models , the estimated drinking water concentrations (EDWCs) of fluxapyroxad for acute exposures are estimated to be 14.1 parts per billion (ppb) for surface water and 0.087 ppb for ground water. For chronic exposures the EDWCs are estimated to be 6.7 ppb for surface water and 0.087 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The EDWCs of 14.1 ppb for surface water and 0.087 ppb for ground water were used for the acute and the chronic dietary assessments, respectively.

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 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 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 prenatal 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.

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. 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 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 fluxapyroxad will occupy 6% 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 fluxapyroxad from food and water will utilize 48% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for fluxapyroxad.

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 not registered for any use patterns that would result in short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD.

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). Fluxapyroxad is not registered for any use patterns that would result in intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD.

5. *Aggregate cancer risk for U.S. population*. In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), 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. As noted above, chronic exposure to fluxapyroxad from food and water will utilize 48% of the cPAD for children 1-2 years 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 and the metabolites M700F008 and M700F048, so the method also serves as the confirmatory method.

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.

C. Revisions to Petitioned-For Tolerances

Based on EPA's review, BASF Company revised their petition (PP 0F7709) by:

1. Proposing tolerances for corn, pop, grain; corn, sweet kernels plus cobs with husks removed; and wheat, grain. Tolerances for these commodities were originally proposed as part of the respective crop group tolerances, but the Agency determined that separate tolerances are needed because of differences between the needed tolerances and the proposed crop group tolerances.

2. Decreasing or increasing the proposed tolerances for various commodities.

3. Deleting the proposed tolerance for vegetable, root, subgroup 1A and proposing a tolerance for beet, sugar. The submitted data are not sufficient to support a tolerance for the proposed subgroup 1A, but it supports a tolerance for beet, sugar.

4. Deleting tolerances that the Agency determined are not needed and/or are covered by other proposed tolerances.

5. Proposing a tolerance for oilseeds, group 20. The registrant had proposed tolerances for all the representative commodities for crop group 20 and the submitted data supports establishment of the group tolerance.

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)-1*H*-pyrazole-4-carboxamide, as requested in the revised petition.

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) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: May 2, 2012

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. Add §180.666 to subpart C to read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) *General*. Tolerances are established for 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)-1*H*-pyrazole-4-carboxamide in or on the commodity.

Commodity	Parts per million
Apple, wet pomace	2.0
Beet, sugar	0.1
Beet, sugar, dried pulp	0.1
Beet, sugar, tops	7.0
Cattle, fat	0.05
Cattle, meat	0.01
Cattle, meat byproducts	0.03
Corn, field, grain	0.01
Corn, oil	0.03
Corn, pop, grain	0.01

Corn, sweet, kernels plus cobs with husks removed	0.15
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Egg	0.002
Fruit, pome, group 11	0.8
Fruit, stone, group 12	2.0
Goat, fat	0.05
Goat, meat	0.01
Goat, meat byproducts	0.03
Grain, aspirated fractions	20.0
Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat)	3.0
Grain, cereal, forage, fodder and straw, group 16	20
Horse, fat	0.05
Horse, meat	0.01
Horse, meat byproducts	0.03
Milk	0.005
Oilseeds, group 20	0.9
Pea and bean, dried shelled except	0.4

soybean, subgroup 6C	
Pea and bean, succulent shelled, subgroup 6B	0.5
Peanut	0.01
Peanut, refined oil	0.02
Plum, prune	3.0
Potato, wet peel	0.1
Rice, bran	4.5
Rice, hulls	8.0
Sheep, fat	0.05
Sheep, meat	0.01
Sheep, meat byproducts	0.03
Soybean, hulls	0.3
Soybean, seed	0.15
Vegetable, foliage of legume, group 7	30
Vegetables, fruiting, group 8	0.7
Vegetable, legume, edible podded, subgroup 6A	2.0
Vegetable, tuberous and corm, subgroup 1C	0.02
Wheat, bran	0.6
Wheat, grain	0.3

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

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

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

[FR Doc. 2012-11602 Filed 05/11/2012 at 8:45 am; Publication Date: 05/14/2012]