PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart N—Idaho

■ 2. In § 52.670, the table in paragraph (e) is amended by adding an entry at the end of the table for ''Interstate Transport Requirements for the 2010 NO_2 NAAQS'' to read as follows:

§ 52.670 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED IDAHO NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or non-attainment area	State submittal date	EPA Approval date	Comments
*	*	*	*	*
Interstate Transport Requirements for the 2010 NO_2 NAAQS.	State-wide	12/24/2015	5/5/2016 [Insert **Federal Register** citation].	This action addresses the following CAA elements: 110(a)(2)(D)(i)(I).

* * * * *

[FR Doc. 2016–10452 Filed 5–4–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0324; FRL–9945–48]

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 May 5, 2016. Objections and requests for hearings must be received on or before July 5, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0324, 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–2015–0324 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 July 5, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0324, 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 August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8344) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.666 be amended by establishing tolerances for residues of the fungicide fluxapyroxad, in or on citrus, dried pulp at 2.7 parts per million (ppm); citrus oil at 19 ppm; fruit, citrus group 10–10 at 1.0 ppm; grass forage, fodder and hay group 17 at 30 ppm; non-grass animal feed, group 18 at 30 ppm; and poultry, fat at 0.005 ppm. The petition also requested that the existing tolerance for residues of fluxapyroxad on egg be amended from 0.002 ppm to 0.01 ppm and that the tolerance for inadvertent residues of fluxapyroxad on nongrass animal feeds, group 18 at 0.3 ppm be removed upon establishment of the superceding group 18 tolerance. That document 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 upon review of the data supporting the petition, EPA has recommended tolerances for poultry meat, poultry meat byproduct, and milk fat for which there were no established tolerances previously due to low dietary burden and falling under category 3 of CFR 180.6(a). The reason 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 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 tumorigenic 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 Fluxaproxad on Citrus Crop Group 10–10, Grass Crop Group 17, and Non-Grass Crop Group 18.'' on pp. 56 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 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.*

Summary of the toxicological endpoints for 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 DIETARY, RESIDENTIAL AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

Exposure/scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute Dietary (General Population, including Infants and Children and Females 13–49 years of age).	NOAEL = 125 mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 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	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 (1–30 days).	NOAEL = 7.3mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	90-day dietary study in rats. MIRD 47923567. LOAEL = 35.1 mg/kg/day based on thyroid follicular hypertrophy/hyperplasia.
Dermal Short- and Intermediate-Term.	No hazard identified.			
Inhalation, Short-Term (1–30 days) and Intermediate-term (1–6 months).	NOAEL = 7.3 mg/kg/day.	UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	90-day dietary study in rats. MIRD 47923567. LOAEL = 35.1 mg/kg/day based on thyroid follicular hypertrophy/hyperplasia.
Cancer (oral, dermal, inhalation).	Classification: Not likely to be carcinogenic to humans below a defined dose range.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOA = mode of action.

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 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues adjusted to account for the metabolites of concern (M700F008, and M700F010 (milk only)) and 100 percent crop treated (PCT) assumptions were used. DEEM default and empirical processing factors were used to modify the tolerance values.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. As to residue levels in food, a moderately refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Combined average residue for parent and highest residue for metabolite M700F008 and 100 PCT assumptions were used. For livestock commodities tolerance-level residues adjusted to account for the metabolites of concern (M700F008, M700F010) were used. An assumption of 100 PCT was also used for the chronic dietary analysis. DEEM default and empirical processing factors were used to modify the tolerance values.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluxapyroxad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

The Agency did not use PCT information in the dietary assessment for fluxapyroxad; 100 PCT was 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 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 Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluxapyroxad for acute exposures are 127 ppb parts per billion (ppb) for surface water and 203 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are 127 ppb for surface water and 188 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 value of 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).

There are no residential exposure associated with the proposed uses in this action; however, there are existing turf uses that were previously assessed for fluxapyroxad. Although the Agency had conducted a residential exposure assessment for previous fluxapyroxad actions, the Agency completed an updated turf assessment to reflecting an update in the single maximum application rate from 2.47 pounds active ingredient/gallon (lb ai/gallon) to 0.005 lb ai/gallon. The present assessment assumed the following exposure scenarios:

- *Residential handler:* The Agency assessed inhalation exposures to adults from applications only because fluxapyroxad does not pose a dermal risk. Residential handler exposure is expected to be short-term in duration. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.
- *Post-application exposures:* Dermal exposures were not assessed because there is no identified systemic dermal hazard for fluxapyroxad. Post-application inhalation exposure while engaged in activities on or around previously treated turf is generally not quantitatively assessed. The combination of low vapor pressure for chemicals typically used as active ingredients in outdoor residential pesticide products and dilution in outdoor air is likely to result in minimal inhalation exposure. Incidental oral exposure for children is anticipated. The quantitative oral exposure/risk assessment for residential post-application exposures is based on the incidental oral scenario for children 1<2.

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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply

an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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.

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. Although an acute neurotoxicity study showed decreased rearing and motor activity, this occurred on the day of dosing only 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. 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 residue database is adequate. The dietary risk assessment is conservative and will not underestimate dietary exposure to fluxapyroxad. There are residential uses proposed for fluxapyroxad and the assessment will not underestimate residential exposure via handler for adults and incidental oral for children. 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 post application exposure of children as well as incidental oral exposure of toddlers. There are residential uses proposed for fluxapyroxad and the assessment will not underestimate residential exposure via handler for adults and incidental oral for children.

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 12% 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 66% of the cPAD for infants (< 1 year old). 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 1139 for adults and 431 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.* As discussed in Unit III.A., EPA has 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. Because the Agency has determined fluxapyroxad will not cause a chronic risk, the Agency concludes that fluxapyroxad will not pose a cancer risk for the U.S. population.

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

There are suitable residue analytical methods available for enforcement of fluxapyroxad tolerances (BASF Methods L0137/01 for plants and L0140/02 for animal matrices) which have been radio-validated and have underwent successful validation by an independent laboratory. These are liquid chromatography with tandem mass spectrometry (LC/MS/MS) methods and monitor two ion transitions. The Limit of Quantitation (LOQ) for BASF method L0137/01 is 0.01 ppm for various matrices. The LOQ for BASF method L0140/02 is 0.01 ppm for liver and muscle, and 0.001 ppm for milk and eggs.

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

B. International Residue Limits

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

There are no Codex MRLs for citrus or grass and non-grass animal feed at present. US and Codex use different dietary burden evaluations and calculations which result in US tolerances for residues in ruminant meat byproduct, milk, and milk fat generally much lower than corresponding Codex MRLs.

C. Revisions to Petitioned-for Tolerances

EPA is establishing tolerances for milk fat and poultry meat, and meat byproduct that the applicant did not request. There have been no established tolerances for poultry tissues because residues were not expected to be found in those tissues due to the low dietary burden; *i.e.,* category 3 of 40 CFR 180.6(a) applied for those poultry matrices previously. However, because of expectation of higher residues on the feed items associated with the proposed uses (mainly grass and non-grass), the livestock dietary burdens have increased, and residues are now expected to be transferred to poultry tissues. Consequently, the Agency is establishing poultry tolerances. Similarly, due to the higher livestock dietary burdens, EPA is establishing a new tolerance for residues in milk fat, and increasing current tolerances on milk, ruminant fat and meat byproduct (to include fat and meat byproduct of cattle, goat, horse and sheep). EPA is also establishing higher tolerances than what the applicant proposed for grass (group 17), citrus oil, dried pulp, and poultry fat. The difference in the group 17 grass tolerance is due to the fact that EPA is using residues from 0-day postharvest interval (PHI) from grass samples (instead of 14-day PHI used by the applicant). With regard to citrus oil, the difference between the petitioned-for and established tolerance is due to the use of the highest average field trial (HAFT) data by EPA (instead of median used by the applicant), times processing factor. Dried pulp tolerance difference is due to EPA rounding of the calculated tolerance. Lastly, the difference in the tolerance in poultry fat is due to recalculating dietary burden for livestock, taking into account residues on feed commodities from (0-day PHI) grass, alfalfa and clover which resulted in higher than previously calculated dietary burdens and therefore higher tolerances.

V. Conclusion

Therefore, tolerances are established for residues of fluxapyroxad, in or on cattle, fat at 0.06 ppm; cattle, meat byproduct at 0.04 ppm; citrus, dried pulp at 3.0 ppm; citrus, oil at 40 ppm; fruit, citrus, group 10–10 at 1.0 ppm; goat, fat at 0.06 ppm; goat, meat byproduct at 0.04 ppm; grass, forage, fodder, and hay, group 17 at 40 ppm; horse, fat at 0.06 ppm; horse, meat byproduct at 0.04 ppm; milk at 0.01 ppm; milk, fat at 0.15 ppm; non-grass animal feeds, group 18 at 30 ppm; poultry, fat, poultry, meat and meat byproduct, each at 0.01 ppm; sheep, fat at 0.06 ppm; and sheep, meat byproduct at 0.04 ppm. Finally, the Agency is removing the tolerance for inadvertent residues of fluxapyroxad on non-grass animal feeds, group 18 contained in paragraph (d) of section 180.666, as it is subsumed by the tolerance for non-grass animal feeds, group 18 being established in paragraph (a) of the same section.

VI. Statutory and Executive Order Reviews

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

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 26, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.666, amend the table in paragraph (a) as follows:
■ i. Add alphabetically the entries ''Citrus, dried pulp'', ''Citrus, oil'', ''Fruit, citrus, group 10–10'', ''Grass forage, fodder and hay, group 17'', ''Milk, fat'', ''Non-grass animal feed, group 18'', ''Poultry, fat'', ''Poultry, meat'' and ''Poultry, meat byproduct''.
■ ii. Revise the following entries ''Cattle, fat'', ''Cattle, meat byproduct'', ''Egg'', ''Goat, fat'', ''Goat, meat byproduct'', ''Horse, fat'', ''Horse, meat byproduct'', ''Milk'', ''Sheep, fat,'' and ''Sheep, meat byproduct''.
■ iii. Remove from the table in paragraph (d) the entry ''non-grass animal feeds, group 18''.

The amendments read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cattle, fat	0.06
* * * * *	
Cattle, meat byproduct	0.04
Citrus, dried pulp	3.0
Citrus, oil	40
* * * * *	
Egg	0.01
Fruit, citrus, group 10–10	1.0
* * * * *	
Grass, forage, fodder and hay, group 17	40
Goat, fat	0.06
* * * * *	
Goat, meat byproduct	0.04
* * * * *	
Horse, fat	0.06
* * * * *	
Horse, meat byproduct	0.04
Milk	0.01
Milk, fat	0.15
Non-grass animal feed, group 18	30
* * * * *	
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproduct	0.01
* * * * *	
Sheep, fat	0.06
* * * * *	
Sheep, meat byproduct	0.04
* * * * *	

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[FR Doc. 2016–10581 Filed 5–4–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0213; FRL–9945–58]

Butanedioic Acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, Disodium Salts; 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6) when used as an inert ingredient (surfactant) in pesticides applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 limited to maximum concentration of 10% by weight in pesticide formulations. Keller and Heckman LLP on behalf of Cytec Industries, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts.

DATES: This regulation is effective May 5, 2016. Objections and requests for hearings must be received on or before July 5, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0213, 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