VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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), or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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 exemption 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).

VIII. 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: November 14, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, add alphabetically the inert ingredient to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Calcium formate (CAS Reg. No. 544–17–2)		Carrier
* * * * * * *		

[FR Doc. 2018–26353 Filed 12–3–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0538; FRL–9982–42]

Bixafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019 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–2016–0538, 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: Michael Goodis, 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.*

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–2016–0538 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 4, 2019. 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–2016–0538, 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 November 30, 2016 (81 FR 86312) (FRL–9954–06), 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 6F8475) by FMC Corporation. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide bixafen, *N*-(3′,4′-dichloro-5-fluoro[1,1′-biphenyl]-2-yl)-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide, in or on cattle, fat at 0.5 parts per million (ppm); cattle, kidney at 0.3 ppm; cattle, liver at 1.5 ppm; cattle, muscle at 0.15 ppm; grain, aspirated fractions at 80 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), forage at 4.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), hay at 5.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), stover at 6.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), straw at 7.0 ppm; grain, cereal, group 15 (except rice and sorghum) at 0.15 ppm; milk at 0.1 ppm; oilseed, rapeseed subgroup 20A at 0.15 ppm; peanut, hay at 10.0 ppm; peanut, nutmeat at 0.02 ppm; peanut, refined oil at 0.04 ppm; poultry, eggs at 0.02 ppm; poultry, fat at 0.02 ppm; poultry, liver at 0.02 ppm; poultry, muscle at 0.02 ppm; sorghum, grain at 3.0 ppm; soybean, hulls at 0.15 ppm; soybean, seed at 0.06 ppm; sugar beet, dried pulp at 1.0 ppm; vegetable, root subgroup 1A at 0.2 ppm and vegetable, tuberous and corm subgroup 1C at 0.02 ppm. That document referenced a summary of the petition prepared by FMC 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 is establishing tolerances that vary from those proposed. 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 bixafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bixafen 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.

Following repeated oral administration of bixafen, the liver was the primary target organ in mice, rats and dogs. Increased liver weights and hepatocellular hypertrophy were observed in all species tested and were considered to reflect hepatic microsomal enzyme induction. Also, in several studies, there was evidence for liver toxicity based on clinical chemistry changes (increased serum alkaline phosphatase and cholesterol, decreased serum albumin) and histopathological changes (hepatocellular pigmentation, degeneration and necrosis). In mice and rats, the thyroid was an additional target in the subchronic and chronic studies, with effects such as increased thyroid weight, follicular cell hypertrophy and follicular cell hyperplasia observed. Thyroid toxicity was seen only in the presence of liver effects, either adverse effects (such as hepatocellular single-cell degeneration/necrosis) or adaptive effects (such as increased liver weights with enzyme changes, hepatocellular hypertrophy). This correlation suggested they thyroid effects are secondary to the liver effects via enhanced hepatic clearance of thyroid hormones. This suggestion was supported by a 14-day mechanistic study in rats in which a marked induction of phase I and II hepatic enzymes, a slight reduction of thyroid hormone (T3, T4) levels and a significant increase of TSH levels were observed at 150 mg/kg bodyweight per day, the only dose tested. Since thyroid toxicity was seen in the absence of adverse liver effects in studies such as the subchronic and chronic rat studies, a primary adverse effect on the thyroid cannot be ruled out. However, no studies are available to address potential susceptibility in the young to potential thyroid toxicity. As a result, the need for a Comparative Thyroid Assay (CTA) was considered. However, given risk estimates are well below the Agency's level of concern (LOC) even when using conservative exposure assumptions, the Agency concluded that a CTA is not required at this time. This conclusion, however, may be revisited should the use pattern change or if updated risk estimates reach a point where the PODs used in the risk assessment are no longer protective of potential life-stage susceptibility.

From the prenatal developmental studies, it is apparent that evidence of increased quantitative susceptibility in offspring was observed in the database. The prenatal developmental study in the rat showed decreased fetal body weights at a dose that produced no adverse effects in the dam. Similarly, the prenatal developmental study in the rabbit showed decreased fetal body weight in the absence of maternal toxicity. In the rat 2-generation reproduction study, however, parental toxicity (decreased body weight and increased liver weight with centrilobular and diffuse hypertrophy) and offspring toxicity (decreased F_1 and F_2 pup body weights) occurred at the same dose level.

An acute neurotoxicity study in the adult rat indicated decreased motor activity in both sexes and decreased rearing counts in females at a high dose level (1,000 mg/kg/day). A subchronic neurotoxicity study was not available, and no evidence of neurotoxicity was observed in other studies in the database.

Bixafen did not produce evidence of mutagenicity or clastogenicity in the required battery of studies. The available mouse carcinogenicity study produced no treatment-related tumors in the presence of other toxicity such as organ weight changes with histopathology in both the liver and thyroid. Thus, bixafen is classified as ''not likely to be carcinogenic to humans.''

Bixafen has low acute oral, dermal, and inhalation toxicity. Bixafen is not an acute eye irritant and is neither a dermal irritant nor a dermal sensitizer. Specific information on the studies received and the nature of the adverse effects caused by bixafen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document Bixafen. Human Health Risk Assessment for Section 3 Registration and Tolerance Requests for a New Active Ingredient Proposed for Use on Cereal Grains, Group 15 (Except Rice); Forage, Fodder and Straw of Cereal Grains, Group 16 (Except Rice); Peanut; Soybean; Root Vegetable Subgroup 1A; and Tuberous and Corm Vegetable Subgroup 1C at pages 14—23 in docket ID number EPA–HQ–OPP–2016–0538.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIXAFEN 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).	NOAEL = 250 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day. aPAD = 2.5 mg/kg/day	Acute Neurotoxicity Study in rats; MRID 49877279. LOAEL = 1,000 mg/kg/day based on statistically significant decreases in motor activity in both sexes and decreased rearing counts in females approximately 4 hours following a single oral dose.

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

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL = 2.8 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day. cPAD = 0.03 mg/kg/ day	Chronic/Carcinogenicity Studies in Rats; MRIDs 49877272, 49877273. LOAEL = 17.4 mg/kg/day based on thyroid effects (follicular cell hypertrophy, alteration of the thyroid colloid at interim and terminal sacrifice).
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be carcinogenic to humans'' based on an absence of tumors in the rat chronic/ oncogenicity and mouse carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. mg/kg/day = milligram/kilogram/day. 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 bixafen, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from bixafen 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 bixafen. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on tolerance-level residues and 100% crop treated (100 PCT) estimates for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on tolerance-level residues and 100 PCT estimates for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that bixafen 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.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for bixafen. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for bixafen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bixafen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The Tier II Pesticide in Water Calculator (PWC version 1.52) and Tier I Pesticide Root Zone Model Ground Water (PRZM GW) was used for calculating surface water and ground water EDWCs respectively. The driver for drinking water exposure is from surface water and the EDWC of bixafen for acute exposure is estimated to be 16.3 parts per billion (ppb). For chronic exposure for non-cancer assessment, it is estimated to be 15.2 ppb for surface 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 16.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 15.2 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).

Bixafen is not proposed nor is it 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 bixafen to share a common mechanism of toxicity with any other substances, and bixafen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bixafen 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal developmental toxicity studies showed effects in the fetus (decreased body weights) at dose levels that were lower than that of the observed maternal toxicity (decreased body weights). However, concerns for potential pre- and postnatal susceptibility from the developmental and reproduction studies are low because clear NOAELs and LOAELs exist for these developmental effects, and the PODs and endpoints selected for risk assessment are protective of potential toxicity in offspring.

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 bixafen is considered complete at this time. The following acceptable studies are available to support this determination: A prenatal developmental toxicity study in rabbits, a prenatal developmental toxicity study in rats, a two-generation reproduction study in rats and an acute neurotoxicity study. The following study waivers were accepted, and it was determined that these studies are not required at this time: subchronic inhalation, subchronic neurotoxicity, and an immunotoxicity study. As summarized in Unit III.A., EPA determined that the CTA study is not required at this time.

ii. An acute neurotoxicity study in the adult rat indicated decreased motor activity in both sexes and decreased rearing counts in females at a high dose level (1,000 mg/kg/day). A subchronic neurotoxicity study was not available, and no evidence of neurotoxicity was observed in other studies in the database. Concern for neurotoxicity is low, and thus no developmental neurotoxicity study or FQPA 10X SF is necessary, because (1) signs of neurotoxicity in the database occur only at a high dose level, do not include neuropathology; (2) a clear and well-defined NOAEL has been established; and (3) the PODs used for risk assessment are protective of neurotoxicity seen in the database.

iii. There is evidence of increased prenatal quantitative susceptibility of the developing offspring in the toxicology database for bixafen. Developmental toxicity (reduced fetal body weight) was seen at doses that caused no maternal toxicity in both rats and rabbits. However, clear NOAELs and LOAELs exist for these developmental effects, and the endpoints and PODs selected for risk assessment are protective of these effects. In the 2-generation reproduction toxicity study, toxicity in the offspring (decreased F_1 and F_2 pup body weights) occurred at the same level where parental toxicity (decreased body weight) was observed, and susceptibility was not demonstrated. The subchronic and chronic rat studies in the database indicate thyroid toxicity (epithelial cell hypertrophy) at the LOAELs, and no studies are available to address potential susceptibility in the young to potential thyroid toxicity. As a result, the need for a CTA was considered. However, given risk estimates are well below the Agency's level of concern even when using conservative exposure assumptions and that further refinement of exposure estimates would yield even greater margins of safety, the Agency concluded that a CTA is not required at this time.

iv. There are no residual uncertainties identified in the exposure databases. The unrefined dietary risk assessments are based on high-end assumptions such as tolerance-level residues, 100PCT assumptions, and modeled, high-end estimates of residues in drinking water. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bixafen in drinking water. These assessments will not underestimate the exposure and risks posed by bixafen.

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 bixafen will occupy <1% of the aPAD for children 1–2 years of age, 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 bixafen from food and water will utilize 20% of the cPAD for children 1–2 years of age the population group receiving the greatest exposure.

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

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, bixafen is not proposed 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 bixafen.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bixafen is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bixafen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Analytical Methods 00983 and 01063, high- performance liquid chromatography methods with tandem mass spectrometry detection (LC/MS/MS)) is available as an enforcement method for determination of residues of bixafen and its metabolite bixafen-desmethyl.

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 established MRLs for bixafen in or on barley and oats at 0.4 ppm; the U.S. tolerance for grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm is harmonized with those MRLs. Codex has also established MRLs for rye, wheat, and wheat bran at 0.05 ppm, which is not harmonized with the U.S. tolerances for group 15 because use consistent with approved labeling could result in exceedances. Codex has also established MRLs for barley straw and fodder, dry at 20 ppm; oat straw and fodder, dry at 20 ppm; rye straw and fodder, dry at 20 ppm; and wheat straw and fodder, dry at 20 ppm. The U.S. tolerance for grain, cereal, forage, fodder and straw, group 16, except rice at 20 ppm is harmonized with those Codex MRLs.

Additionally, the Codex has established MRLs for bixafen in or on cattle, fat at 2 ppm; cattle, meat byproducts at 4 ppm; cattle, muscle at 2 ppm; goat, fat at 2 ppm; goat, meat byproducts at 4 ppm; goat, muscle at 2 ppm; horse, fat at 2 ppm; horse, meat byproducts at 4 ppm; horse, muscle at 2 ppm; milk at 0.2 ppm; sheep, fat at 2 ppm; sheep, meat byproducts at 4 ppm; and sheep, muscle at 2 ppm. These MRLs are significantly higher than the tolerances being established for bixafen on the same commodities in the United States. The U.S. tolerances are based on calculated dietary burden that supports a lower residue level in fat, muscle, and meat byproducts commodities. Therefore, these tolerances are not harmonized because such high tolerances could mask instances of misuse by U.S. growers. As noted in the next section, the Agency is not establishing tolerances for milk fats and poultry commodities in harmony with Codex MRLs for milk fats, poultry, edible offal, poultry fats, and poultry meat because the Agency has determined that use consistent with the approved pesticide will not result in residues in milk fats and poultry commodities.

C. Revisions to Petitioned-For Tolerances

Several proposed tolerances requested by the petitioner are different from those being established by EPA. For soybean seed; peanut; peanut, hay; vegetable, tuberous and corm (subgroup 1C); and vegetable, root, subgroup 1A, tolerance values were calculated using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures and field trial residue data. The combination provided a different tolerance value than the proposed values. EPA is establishing a tolerance for grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm instead of 0.15 ppm and for grain, cereal, forage, fodder and straw, group 16, except rice at 20 ppm, rather than the requested tolerances for forage at 4.0 ppm, hay at 5.0 ppm, stover at 6.0 ppm, straw at 7.0 ppm in order to harmonize with Codex MRLs. Since the tolerance of 20 ppm for group 16 covers the residues on forage, hay, stover, and straw forms of the group 16 commodities, EPA has determined that separate tolerances are unnecessary.

Additionally, while tolerances were proposed on liver and kidney for livestock commodities, EPA is establishing tolerances on meat byproducts, which are inclusive of kidney and liver. EPA is further establishing lower tolerances for residues in fat, muscle and meat byproducts in cattle, based on the calculated dietary burdens paired with low residue transfer rates into ruminant commodities. The tolerance on milk is also established at a lower level (0.04 ppm versus the 0.10 ppm proposed tolerance). This recommendation is also based on the calculated dietary burdens paired with low residue transfer rates into ruminant commodities.

Under EPA's regulations (40 CFR 180.6), EPA assessed whether residues on raw agricultural commodities would result in possible residues entering the diet of man through the ingestion of milk, eggs, meat, and/or poultry produced by animals fed agricultural products bearing such residues. As a result of that assessment, EPA determined that quantifiable residues are expected in commodities from cattle, horses, goats, and sheep and is establishing tolerances for residues in fat, muscle and meat byproducts in horse, goat and sheep. EPA also determined that there is no reasonable expectation of residues in or on milk fats and poultry products; therefore, no tolerances on milk fats and poultry commodities are needed.

Additionally, the proposed use and associated tolerance on Rapeseed subgroup 20A (canola) was subsequently withdrawn by the petitioner; therefore, the Agency is not establishing a tolerance on that subgroup because it is not needed.

The Agency is not establishing a tolerance for peanut, refined oil as requested because the residue data indicate that anticipated residues in the peanut, refined oil are lower than, and will be covered by, the tolerance for peanut.

Finally, the Agency is establishing a tolerance for radish, tops, even though it was not requested by the petitioner. Under EPA's regulations (40 CFR 180.40(f)(1)(i)(B)), EPA will not establish a crop group tolerance unless all necessary tolerances are established, including tolerances for raw commodities not covered by the crop group and derivative of commodities in the group. In this case, EPA is establishing a tolerance for root vegetables, subgroup 1A, which includes radish. Due to the presence of residues on radish tops, EPA is establishing a necessary tolerance on radish tops to facilitate the establishment of the subgroup 1A tolerance.

V. Conclusion

Therefore, tolerances are established for residues of bixafen in or on beet, sugar, dried pulp at 1.0 ppm; cattle, fat at 0.08 ppm; cattle, meat byproducts at 0.40 ppm; cattle, muscle at 0.08 ppm; goat, fat at 0.08 ppm; goat, meat byproducts at 0.40 ppm; goat, muscle at 0.08 ppm; grain, aspirated grain fractions at 80 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice at 20 ppm; grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm; horse, fat at 0.08 ppm; horse, meat byproducts at 0.40 ppm; horse, muscle

at 0.08 ppm; milk at 0.04 ppm; peanut at 0.01 ppm; peanut, hay at 8.0 ppm; radish, tops at 3.0 ppm; sheep, fat at 0.08 ppm; sheep, meat byproducts at 0.40 ppm; sheep, muscle at 0.08 ppm; sorghum, grain, grain at 3.0 ppm; soybean, hulls at 0.15 ppm; soybean, seed at 0.04 ppm; vegetable, root subgroup 1A at 0.30 ppm; and vegetable, tuberous and corm subgroup 1C at 0.01 ppm.

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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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: November 13, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Add § 180.702 to subpart C to read as follows:

§ 180.702 Bixafen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide bixafen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bixafen, *N*-(3,4-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide, in or on the commodity.

Commodity	Parts per million
Beet, sugar, dried pulp	1.0
Grain, aspirated grain fractions	80
Grain, cereal, forage, fodder, and straw, group 16, except rice	20
Grain, cereal, group 15, except rice and grain sorghum	0.40
Peanut	0.01
Peanut, hay	8.0
Radish, tops	3.0
Sorghum, grain, grain	3.0
Soybean, hulls	0.15
Soybean, seed	0.04
Vegetable, root, subgroup 1A	0.30
Vegetable, tuberous and corm, subgroup 1C	0.01

(2) Tolerances are established for residues of the fungicide bixafen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of bixafen, *N*-(3,4-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide, and its desmethyl metabolite, *N*-(3′,4′-dichloro-5-fluoro[1,1′-biphenyl]-2-yl)-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide, calculated as the stoichiometric equivalent of bixafen, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.08
Cattle, meat byproducts	0.40
Cattle, muscle	0.08
Goat, fat	0.08
Goat, meat byproducts	0.40
Goat, muscle	0.08
Horse, fat	0.08
Horse, meat byproducts	0.40
Horse, muscle	0.08
Milk	0.04
Sheep, fat	0.08
Sheep, meat byproducts	0.40
Sheep, muscle	0.08

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

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

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

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