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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0141; FRL-9933-03]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benzovindiflupyr in or on multiple commodities that are identified and discussed later in this document. Syngenta Crop Protection, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0141, 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*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0141 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0141, 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 June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions (PP 2E8123 and 2F8121) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. Petition 2E8123 requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide, benzovindiflupyr in or on coffee, bean, green at 0.09 parts per million (ppm) and sugarcane, cane at 0.04 ppm. Petition 2F8121 requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide, benzovindiflupyr in or on apple, wet pomace at 0.6 ppm; barley, grain at 1.5 ppm; barley, hay at 15 ppm; barley, straw at 15 ppm; corn, field, grain at 0.02 ppm; corn, field, forage at 3 ppm; corn, field, stover at 15 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 15 ppm; corn, sweet, ear at 0.01 ppm; corn, sweet, forage at 4 ppm; corn, sweet, stover at 5 ppm; cottonseed, subgroup 20C at 0.15 ppm; cotton, gin byproducts at 3 ppm; vegetables, cucurbits, crop group 9 at 0.2 ppm; fruits, pome, crop group 11-10 at 0.2 ppm; fruits, small vines climbing, except fuzzy kiwi subgroup 13-07F at 1 ppm; grain, aspirated fractions at 7 ppm; oat, grain at 1.5 ppm; oat, hay at 15 ppm; oat, straw at 15 ppm; peas and bean, dried shelled, except soybean, subgroup 6C at 0.2 ppm; peas, hay at 7 ppm; peas, vine at 1.5 ppm; peanut, nutmeat at 0.01 ppm; peanut, hay at 15 ppm; potato, wet peel at 0.1 ppm; raisin at 4 ppm; rapeseed, subgroup 20A at 0.15 ppm; rye, grain at 0.1 ppm; rye, hay at 15 ppm; rye, straw at 10 ppm; soybean, seed at 0.07 ppm; soybean, forage at 15 ppm; soybean, hay at 50 ppm; vegetables, fruiting, crop group 8-10 at 0.8 ppm; vegetables, tuberous and corm subgroup 1C at 0.02 ppm; wheat, grain at 0.1 ppm; wheat, forage at 4 ppm; wheat, hay at 15 ppm; wheat, straw at 10 ppm; and at 0.01 ppm in or on the following animal commodities: cattle, goat, horse, and sheep fat, kidney, liver, meat, and meat byproducts; egg; hog, fat, liver, meat, and meat byproducts; milk; milk, fat; and poultry, byproducts, fat, liver, meat, and skin.

That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the requested tolerances and levels for the reasons 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 benzovindiflupyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with benzovindiflupyr 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.

Benzovindiflupyr has low acute toxicity by the dermal and inhalation routes, with moderate toxicity via the oral route. It is not a dermal sensitizer, but causes mild skin irritation and moderate eye irritation. The target organs for effects of benzovindifulpyr are the liver, thyroid, and kidneys.

Benzovindiflupyr produced effects in rat fetuses (i.e. decreased fetal weight and ossification) in developmental toxicity studies but only at maternally toxic doses. In the rabbit developmental study, there were no adverse effects in either the does or the fetuses at the highest dose tested. In reproduction studies, offspring effects occurred at doses higher than the doses causing parental effects; thus, there was no quantitative increase in sensitivity in rat pups. There are indications of reproductive toxicity in rats such as decreased follicle counts, but these effects did not result in reduced fertility.

No evidence of specific neurotoxicity was observed in the acute neurotoxicity (ACN) or subchronic neurotoxicity (SCN) studies. Benzovindiflupyr caused decreased activity and decreased grip strength in the neurotoxicity studies; however, there were no supportive neurohistopathology in any toxicological study, even at the highest doses tested.

There was no evidence of immune system toxicity in a study conducted in the mouse, or in any other toxicity studies in the database.

Benzovindiflupyr caused tumors in the thyroid in the chronic rat study at the highest dose tested. In mice, no tumor formation was observed. Benzovindiflupyr was negative in all mutagenicity studies. Based on the fact that evidence of tumors were found in only one species

at only the highest dose tested and lack of mutagenicity, the Agency has determined that using a non-linear approach (i.e., RfD; reference dose) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to benzovindiflupyr.

Specific information on the studies received and the nature of the adverse effects caused by benzovindiflupyr 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 Benzovindiflupyr New Active Ingredient Human Health Risk Assessment to Support the Proposed Uses on Cereals (wheat, triticale, barley, rye, and oat), Blueberries (non-bearing), Corn (field, pop, and sweet), Peanuts, Turf , and Ornamentals; Crop Groups 8-10, 9, and 11-10; Crop Subgroups 1C, 6C, 13-07F, 20A, and 20C; and Establishment of Tolerances on Imported Coffee and Sugarcane in docket ID number EPA-HQ-OPP-2013-0141.

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 benzovindiflupyr used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations, including infants and children)	NOAEL=10 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	Acute RfD = 0.10 mg/kg/day aPAD =0.10 mg/kg/day	Acute neurotoxicity screening battery (rat) NOAEL=10 mg/kg/day LOAEL = 30 mg/kg/day based on multiple clinical observations, decreases in mean body temperature, decreases in locomotor activity parameters, reduced food consumption and/or decreases in mean grip strength

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic dietary (All populations)	Parental/Off-spring NOAEL = 8.2 (females) mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF= 1x	Chronic RfD = 0.082 mg/kg/day cPAD = 0.082 mg/kg/day	2-generation reproduction study (rat) Parental/Offspring NOAEL = 8.2 mg/kg/day (F) LOAEL = 19.4 mg/kg/day (F) based on decreased body weight and decreased food consumption in parental animals as well as increases in liver weights, centrilobular hepatocellular hypertrophy, increased incidence of cell hypertrophy in the pars distalis of the pituitary, reduced body weight, delayed preputial separation, and decreased spleen weights in the F1 and/or F2 offspring.

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental oral Short –term (1-30 days)	Parental/Off-spring NOAEL = 8.2 (females) mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	Residential LOC for MOE = 100	2-generation reproduction toxicity study (rat) Parental/Offspring NOAEL = 8.2 mg/kg/day (F) LOAEL = 19.4 mg/kg/day (F) based on decreased body weight and decreased food consumption in parental animals as well as increases in liver weights, centrilobular hepatocellular hypertrophy, increased incidence of cell hypertrophy in the pars distalis of the pituitary, reduced body weight, delayed preputial separation, and decreased spleen weights in the F1 and/or

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
				F2 offspring.
Inhalation Short-term (1-30 days) and Intermediate-term (1-6 months)	Parental/Off-spring NOAEL: 8.2 mg/kg/day (F)	UF_A= 10x UF_H= 10x FQPA SF= 1x	Residential LOC for MOE = 100	2-generation reproduction study (rat) Parental/Offspring NOAEL = 8.2 mg/kg/day (F) LOAEL = 19.4 mg/kg/day (F) based on decreased body weight and decreased food consumption in parental animals as well as increases in liver weights, centrilobular hepatocellular hypertrophy, increased incidence of cell hypertrophy in the pars distalis of the pituitary, reduced body weight, delayed preputial separation, and decreased

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
				spleen weights in the F1 and/or F2 offspring.
Cancer (oral, dermal, inhalation)	The Agency is using a non-linear (RfD) approach to assess carcinogenic potential; the RfD would be protective of non-carcinogenic and carcinogenic effects observed in the rat carcinogenicity study or mode of action studies conducted at higher doses.			

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_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to benzovindiflupyr, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from benzovindiflupyr 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 benzovindiflupyr. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA), Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a highly conservative acute dietary risk assessment which used tolerance-level residues for food except for livestock commodities, anticipated residues (based on maximum theoretical diets) for livestock commodities, and 100% crop treated for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA, CSFII. As to residue levels in food, EPA conducted a highly conservative chronic dietary risk assessment which used tolerance-level residues for food, anticipated residues (based on maximum theoretical diets) for livestock commodities, and 100% crop treated for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach was appropriate for assessing cancer risk to benzovindiflupyr; therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Tolerance-level residues for food and anticipated residues (based on maximum theoretical diets) for livestock commodities were used and 100% CT was assumed for all 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 benzovindiflupyr in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of benzovindiflupyr. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of benzovindiflupyr for acute exposures are estimated to be 8.4 parts per billion (ppb) for surface water and 0.14 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 5.4 ppb for surface water and <0.14 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 8.4 parts per billion (ppb) for surface water was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.4 ppb for surface water 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).

Benzovindiflupyr is proposed for registration for the following uses that could result in residential exposures: turf (e.g. golf courses, recreational parks, home lawns, and sod farms) and

ornamentals (residential landscape areas). EPA assessed residential exposure using the following assumptions. The proposed uses of benzovindiflupyr on turf and ornamentals in a residential setting by homeowners may result in residential handler (adults who are involved in the pesticide application process) exposure.

Residential handler exposure is expected to be short-term (ST) in duration. Intermediate-term (IT) exposures are not likely because of the intermittent nature of applications by homeowners. In addition, since the toxicity endpoints and PODs are the same for all durations, the ST assessment will be protective of any longer term exposures that may result from residential uses. Since no dermal hazard was identified for benzovindiflupyr in the toxicological database, only inhalation exposure assessments were conducted for residential handlers.

There is the potential for post-application exposure to individuals (adults and children) as a result of being in an environment that has been previously treated with benzovindiflupyr. Post-application inhalation exposures while performing activities in previously treated turf or ornamentals are not expected and were not assessed primarily due to the very low vapor pressure and the expected dilution in outdoor air after an application has occurred. In addition, no dermal hazard was identified in the toxicity database for benzovindiflupyr and, therefore, a quantitative residential post-application dermal risk assessment is not required and was not completed. However, incidental oral exposures to children contacting treated turf have been assessed. Residential post-application exposures are generally considered to be intermittent and short-term in duration. Since the benzovindiflupyr toxicity endpoints and PODs are the same regardless of duration, the short-term assessment is protective of any longer term exposures that may occur from the residential uses of benzovindiflupyr. 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 benzovindiflupyr to share a common mechanism of toxicity with any other substances, and benzovindiflupyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that benzovindiflupyr 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*. Benzovindiflupyr produced effects in rat fetuses (i.e. decreased fetal weight and delayed ossification) in developmental toxicity studies at

maternally toxic doses (i.e., ataxia, hunched posture, and decreased activity); the Agency does not consider the fetal effects to be evidence of increased qualitative susceptibility since ossification is not considered to be a malformation and is reversible (based on the reproduction study), and maternal effects are fairly severe at the same dose levels. In the rabbit developmental study, there were no adverse effects in either the does or the fetuses at the highest dose tested. In rat reproduction studies, offspring effects occurred at higher doses higher than those causing parental effects, thus there was no quantitative increase in sensitivity in rat pups. There were no single-dose developmental effects identified in the developmental toxicity studies in rats or rabbits. Although decreases in growing follicle counts were noted in the reproduction toxicity study, this effect did not result in reduced functional fertility in the rat. Furthermore, the antral follicle counts at a later stage in development were not decreased, so the decreased growing follicle count effect is not considered adverse.

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 benzovindiflupyr is complete.

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

iii. There is no evidence that benzovindiflupyr results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to benzovindiflupyr in drinking water. EPA also made conservative assumptions for

dietary food exposures (residues on food and feed crops based on tolerance level residues, assuming 100% crop treated) resulting in high-end estimates of dietary food. EPA used similarly conservative assumptions based on conservative default (non-chemical specific) assumptions to assess postapplication exposure of children, including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by benzovindiflupyr.

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 benzovindiflupyr will occupy 30% of the aPAD for children 1-2 years old.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to benzovindiflupyr from food and water will utilize 14% of the cPAD for children 1-2 years old. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of benzovindiflupyr 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). Benzovindiflupyr 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 benzovindiflupyr. 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 ≥ 180,000 for all scenarios. Because EPA's level of concern for benzovindiflupyr 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). Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners and the likely short-term duration of exposures.

5. *Aggregate cancer risk for U.S. population*. Based on the results of the chronic risk assessment, the Agency does not expect benzovindiflupyr to pose a cancer risk.

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 benzovindiflupyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (A Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) multi-residue method (EN15662:2009)) is available to enforce the tolerance expression. 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 a MRL for benzovindiflupyr.

C. Response to Comments

EPA received a comment to the notice of filing, which requested that the Agency reconsider the acceptable residue levels of toxic chemicals on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Benzovindiflupyr was evaluated by undergoing a global joint review between the EPA, the Pest Management Regulatory Agency (PMRA) of Canada, and the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) of Mexico. Based upon review of the data supporting the petition and calculation procedures for tolerance determination, several tolerances modifications were required. Specifically, commodity definitions were modified for pea, hay; pea, vine; peanut, nutmeat; raisin; and potato, processed waste to reflect the current nomenclature used by the Agency. Several tolerance levels were adjusted to account for differences in the input data used for the calculation procedures for tolerance determination. For example, several trials considered to be independent trials by the petitioner were determined by the Agency to be replicate (not independent) trials and, as such, these data are inputed differently than data from independent trails. Based on this discrepancy, the Agency is establishing tolerances for the following commodities that are different from what the petitioner requested: Cattle, fat; cattle, liver; coffee, green bean; fruit, pome, group 11-10; goat, fat; goat, liver; horse, fat; horse, liver; milk, fat; pea and bean, dried shelled, except soybean, subgroup 6C; potato, processed waste; rye, straw; sheep, fat; sheep, liver; vegetable, cucurbit, group 9; vegetable, fruiting, group 8-10; wheat, grain; and wheat, straw. Also, based on the Agency's calculation, the available data supports reducing the raisin tolerance (from 4 ppm to 3 ppm) and increasing the aspirated grain fractions tolerance (from 7 ppm to 15 ppm).

A tolerance was recommended for lowbush variety of blueberry in non-cropping years following a 365-day PHI. However, no tolerance will be established on the basis that it would cover non-bearing blueberries which are considered to be a non-food use. Also, the petitioner did not include this use in their notice filing. Although the petitioner did not request a separate tolerance for tomato, dried, tomato processing study data show that residues concentrate in dried tomatoes (7.8X). To cover the higher residues and to harmonize with Canada, EPA is

establishing a tolerance for tomato, dried at 4 ppm. Finally, the applicant requested tolerances for apple, wet pomace. As a fruit, pome, group 11-10 tolerance of 0.2 ppm will cover any potential residues in processed apple, a separate tolerance is not needed.

V. Conclusion

Therefore, tolerances are established for residues of benzovindiflupyr, in or on barley, grain at 1.5 ppm; barley, hay at 15 ppm; barley, straw at 15 ppm; cattle, fat at 0.02 ppm; cattle, liver at 0.06 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.01 ppm; coffee, green bean at 0.09 ppm; corn, field, forage at 3.0 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 15 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 15 ppm; corn, sweet, forage at 4.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 5.0 ppm; cottonseed, subgroup 20C at 0.15 ppm; cotton, gin byproducts at 3.0 ppm; fruit, pome, group 11-10 at 0.20 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1 ppm; goat, fat at 0.02 ppm; goat, liver at 0.06 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.01 ppm; grain, aspirated fractions at 15 ppm; horse, fat at 0.02 ppm; horse, liver at 0.06 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.01 ppm; milk at 0.01 ppm; milk, fat at 0.02 ppm; oat, grain at 1.5 ppm; oat, hay at 15 ppm; oat, straw at 15 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.20 ppm; pea, field, hay at 7.0 ppm; pea, field, vine at 1.5 ppm; peanut at 0.01 ppm; peanut, hay at 15 ppm; potato, processed potato waste at 0.10 ppm; grape, raisin at 3.0 ppm; rapeseed, subgroup 20A at 0.15 ppm; rye, grain at 0.1 ppm; rye, hay at 15 ppm; rye, straw at 15 ppm; sheep, fat at 0.02 ppm; sheep, liver at 0.06 ppm; sheep, meat at 0.01 ppm; sheep meat byproducts, except liver at 0.01 ppm; soybean, forage at 15 ppm; soybean, hay at 50 ppm; soybean, hulls at 0.20 ppm; soybean, seed at 0.07 ppm; sugarcane, cane at 0.04 ppm; tomato, dried at 4.0 ppm; vegetable, cucurbit, group 9 at 0.30 ppm; vegetable, fruiting, group 8-10 at 1.5

ppm; vegetable, tuberous and corm, subgroup 1C at 0.02 ppm; wheat, forage at 4 ppm; wheat, grain at 0.10 ppm; wheat, hay at 15 ppm; and wheat, straw at 15 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). 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: August 28, 2015.

Jack E. Housenger,
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 § 180.686 to subpart C to read as follows:

§ 180.686 Benzovindiflupyr; tolerances for residues.

(a) *General*. Tolerances are established for residues of the fungicide benzovindiflupyr, 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 benzovindiflupyr (*N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide) in or on the commodity.

Commodity	Parts per million
Barley, grain	1.5
Barley, hay	15.0
Barley, straw	15.0
Cattle, fat	0.02
Cattle, liver	0.06
Cattle, meat	0.01
Cattle, meat byproducts, except liver	0.01
Coffee, green bean[1]	0.09
Corn, field, forage	3.0
Corn, field, grain	0.02
Corn, field, stover	15.0
Corn, pop, grain	0.02
Corn, pop, stover	15.0
Corn, sweet, forage	4.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	5.0
Cottonseed, subgroup 20C	0.15
Cotton, gin byproducts	3.0
Fruit, pome, group 11-10	0.20
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	1.0

Goat, fat	0.02
Goat, liver	0.06
Goat, meat	0.01
Goat, meat byproducts, except liver	0.01
Grain, aspirated fractions	15.0
Grape, raisin	3.0
Horse, fat	0.02
Horse, liver	0.06
Horse, meat	0.01
Horse, meat byproducts, except liver	0.01
Milk	0.01
Milk, fat	0.02
Oat, grain	1.5
Oat, hay	15.0
Oat, straw	15.0
Pea and bean, dried shelled, except soybean, subgroup 6C	0.20
Pea, field, hay	7.0
Pea, field, vine	1.5
Peanut	0.01
Peanut, hay	15.0
Potato, processed potato waste	0.10
Rapeseed, subgroup 20A	0.15
Rye, grain	0.1
Rye, hay	15.0
Rye, straw	15.0
Sheep, fat	0.02
Sheep, liver	0.06
Sheep, meat	0.01
Sheep meat byproducts, except liver	0.01
Soybean, forage	15.0
Soybean, hay	50.0
Soybean, hulls	0.20
Soybean, seed	0.07
Sugarcane, cane[1]	0.04
Tomato, dried	4.0
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8-10	1.5
Vegetable, tuberous and corm, subgroup 1C	0.02
Wheat, forage	4.0
Wheat, grain	0.10

Wheat, hay	15.0
Wheat, straw	15.0

[1]There is no U.S. registration for use of benzovindiflupyr.

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

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

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

[FR Doc. 2015-24467 Filed: 10/1/2015 08:45 am; Publication Date: 10/2/2015]