



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0448; FRL-9967-33]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benzovindiflupyr in or on the bulb onion subgroup 3-07A, the green onion subgroup 3-07B, and increases an existing tolerance on sugarcane. Interregional Research Project Number 4 (IR-4) and Syngenta Crop Protection 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-2016-0448, 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-2016-0448 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-2016-0448, 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 October 18, 2016 (81 FR 71668) (FRL-9952-19), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8483) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201-W, Princeton, NJ 08540. The petition requested that 40 CFR 180.686 be amended by establishing tolerances for residues of the fungicide benzovindiflupyr (N-[9-(dichloromethylene)-1,2,3,4-tetrahydro-

1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide) in or on onion, bulb, subgroup 3-07A at 0.02 parts per million (ppm), and onion, green, subgroup 3-07B at 0.4 ppm.

In the **Federal Register** of July 26, 2017 (82 FR 34664) (FRL-9963-50), 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 6F8499) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested to establish a tolerance in 40 CFR part 180 for residues of the fungicide benzovindiflupyr in or on Sugarcane, cane, at 0.3 ppm.

The documents referenced summaries of the petitions prepared by Syngenta Crop Protection, LLC, the registrant, which are available in the dockets EPA-HQ-OPP-2016-0448 and EPA-HQ-OPP-2016-0752 at <http://www.regulations.gov>. There were no comments received in response to either notice of filing.

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.

The rat is the most sensitive species tested, and the target organs of benzovindiflupyr are the liver, thyroid, and kidneys. Hepatotoxicity was manifested as changes in liver weights, liver hypertrophy, and decreased triglycerides. The kidney effects were tubular cell pigment deposits, changes in the tubular basophilia, and increased urea. Enlargement and focal c-cell hyperplasia of the thyroid were observed. An increased incidence of cell hypertrophy in the pituitary pars distalis was noted in the F1 generation males and females in the 2-generation reproductive toxicity rat study.

Mouse studies revealed distended large intestines, soft feces and hyperplasia of the colon and caecum. Indications of general malaise including decreased body weight and food consumption, decreased activity, decreased grip strength, piloerection, decreased response to stimulus, hunched posture, gait changes and/or ataxia were reported in the rat and mouse studies. In several studies, females tended to be more sensitive than males and effects were generally seen at lower doses with gavage dosing than with dietary dosing.

There are no concerns for developmental or reproductive toxicity following benzovindiflupyr exposure. Decreased fetal weight and ossification in the rat developmental toxicity studies occurred at maternally toxic doses. There were no maternal or fetal adverse effects in the rabbit developmental study. In rat reproduction studies, offspring effects (decreased body weight, liver and pituitary effects) occurred at 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 2-generation reproduction toxicity study, this effect did not result in reduced 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.

No evidence of specific neurotoxicity was observed in the acute oral (gavage) and sub-chronic oral (dietary) neurotoxicity (ACN and SCN) studies in rats, conducted on the benzovindiflupyr technical product. Although benzovindiflupyr caused decreased

activity and decreased grip strength in the neurotoxicity studies, there was no supportive neuro-histopathology in any study to indicate a specific neurotoxic effect.

The mouse immunotoxicity study was negative by the T-cell Dependent Antigen Response (TDAR) assay in the mouse.

No systemic effects were noted at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) in the 28-day dermal rat study.

The Agency classified benzovindiflupyr as showing “*Suggestive Evidence of Carcinogenic Potential*” based on the presence of granular cell tumors of the brain in male rats only at the highest dose tested. The Agency concluded that a non-genotoxic mode of action for thyroid tumors observed in male rats has been established as a result of upregulation of uridine diphosphate glucuronyltransferase (UDPGT), increased clearance of T3 and T4 hormones, and increased TSH levels, resulting in increased thyroid cell proliferation, which progress to form thyroid tumors. There was no evidence of carcinogenicity in female rats or in male or female mice. In addition, there is no concern for 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 the document titled “*Benzovindiflupyr. Human Health Risk Assessment for the Proposed Use on Onion, Bulb Subgroup 3-07A; Onion,*

Green, Subgroup 3-07B; and Sugarcane” on pages 32-38 in docket ID number EPA-HQ-OPP-2016-0448.

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 benzovindiflupyr used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of October 2, 2015 (80 FR 59627) (FRL-9933-03).

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 as well as all existing benzovindiflupyr tolerances in 40 CFR 180.686. 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 2003-2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to benzovindiflupyr; therefore, a separate dietary cancer risk assessment was not performed.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for benzovindiflupyr. 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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Surface Water Concentration Calculator (SWCC) model and the Pesticide Root Zone Model Ground Water (PRZM-GW) model, the estimated drinking water concentrations (EDWCs) of benzovindiflupyr for acute exposures are estimated to be 8.41 parts per billion (ppb) for surface water and 0.14 ppb for ground water and for chronic exposures are estimated to be 5.41 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 the acute dietary risk assessment, the water concentration value of 8.41 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 5.41 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).

Benzovindiflupyr is currently registered for the following uses that could result in residential exposures: turf and ornamentals. EPA assessed residential exposure using the following assumptions: For handlers, exposure is expected as a result of application to turf and ornamentals. Post-application exposure is also expected as a result of being in an environment that has been previously treated with benzovindiflupyr. Both handler and post-application exposure is short-term in duration; there are no intermediate- or long term-exposures expected from the residential uses of benzovindiflupyr. Only residential handler inhalation and post-application incidental oral exposure scenarios have been quantitatively assessed since no dermal hazard was identified. Residential handler short-term inhalation MOEs are well above the LOC of 100 for all scenarios assessed and are not of concern (inhalation MOEs are $\geq 180,000$). Residential post-application (incidental oral) MOEs for children ranged from 8,000 to 3,600,000 on the day of application, using default input values, and are not of concern (LOC = 100).

The residential scenarios used for the benzovindiflupyr aggregate assessments were as follows: Adults: Inhalation exposures from treating ornamentals with a manually pressurized handwand or backpack sprayer; Children 1 to < 2 years old: Post-application hand-to-mouth exposures from treated turf. These scenarios resulted in the highest residential exposures and are considered protective of other exposure scenarios.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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://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.* There was no evidence of quantitative or qualitative susceptibility in fetuses or offspring in the rat and rabbit developmental studies or in the 2-generation rat reproduction study. Benzovindiflupyr produced effects in rat fetuses (i.e., decreased fetal weight and ossification) in developmental toxicity studies 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. The LOAELs and NOAELs for the rat developmental and rat reproduction studies were clearly defined.

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. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to benzovindiflupyr in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as 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 43% 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 benzovindiflupyr from food and water will utilize 19% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3.,

regarding residential use patterns, chronic residential exposure to residues of 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 2100 for adults and 510 for children. 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).

An intermediate-term adverse effect was identified; however, benzovindiflupyr 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 benzovindiflupyr.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk. As there is no chronic risk of concern, EPA does not expect any cancer risk to the U.S. population from aggregate exposure to benzovindiflupyr..

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

An adequate analytical method is available to enforce the proposed tolerances for benzovindiflupyr in plant and livestock commodities. A Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) multi-residue method (EN15662:2009) was developed for the determination of residues of benzovindiflupyr via liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS).

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for benzovindiflupyr.

V. Conclusion

Therefore, tolerances are established for residues of benzovindiflupyr, including its metabolites and degradates, in or on onion, bulb, subgroup 3-07A at 0.02 ppm; onion, green, subgroup 3-07B at 0.40 ppm; and the existing “sugarcane, cane” tolerance is increased from 0.04 ppm to 0.30 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDC 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: October 12, 2017.

Michael L. Goodis,

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 § 180.686, amend the table in paragraph (a) by:

- i. Adding alphabetically the commodities “Onion, bulb, subgroup 3-07A”, “Onion, green, subgroup 3-07B”, and
- ii. Revising the commodity “Sugarcane, cane”.

The additions and revisions read as follows:

§ 180.686 Benzovindiflupyr; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Onion, bulb, subgroup 3-07A	0.02
Onion, green, subgroup 3-07B	0.40
****	***
Sugarcane, cane	0.30
****	***

* * * * *

[FR Doc. 2017-24109 Filed: 11/13/2017 8:45 am; Publication Date: 11/14/2017]