ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0417; FRL–10088–01–OCSPP]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet, subgroup 1B. Syngenta requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 29, 2022. Objections and requests for hearings must be received on or before November 28, 2022 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–2021–0417, is available at *https://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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2021–0417 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 November 28, 2022. 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–2021–0417, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 22, 2021 (86 FR 52624) (FRL–8792–03–OCSPP), 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 1F8914) by Syngenta Crop Protection, LLC. The petition requested that 40 CFR 180.686 be amended by establishing tolerances for residues of the fungicide benzovindiflupyr, in or on vegetable, root, except sugar beet, subgroup 1B, and ginseng, at 0.6 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket ID number EPA–HQ–OPP–2021–0417 at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified a commodity definition, established the tolerance at an increased level, and removed the existing ginseng tolerance. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for benzovindiflupyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with benzovindiflupyr follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for benzovindiflupyr, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to benzovindiflupyr and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological profile of benzovindiflupyr, see Unit III.A. of the June 22, 2018, rulemaking (83 FR 29033) (FRL–9977–94).

Toxicological points of departure/Levels of concern. For a summary of the toxicological points of departure/levels of concern used for the safety assessment, see Unit III.B. of the October 2, 2015, rulemaking (80 FR 59627) (FRL–9933–03).

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the June 22, 2018, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of benzovindiflupyr on the commodities in Vegetable, root, except sugar beet, subgroup1B. The assessments used the same assumptions considering 100 percent crop treated and tolerance-level residues as the June 22, 2018, final rule. Drinking water exposures are not impacted by the new uses; the estimated drinking water concentrations are the same as in the June 22, 2018, final rule.

The proposed new use will not result in residential exposure, although there are existing residential uses that were previously assessed. The revisions to the residential exposure and risk assessments in the June 22, 2018, final rule were described in the February 9, 2021, final rule (86 FR 8704) (FRL–10017–32) and have not changed since then.

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.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to benzovindiflupyr and 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 not assumed that benzovindiflupyr has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the June 22, 2018, rulemaking for a discussion of the Agency's rationale for that determination.

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.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD: They are 16% of the aPAD for the general population and 43% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: They are 6.1% of the cPAD for the general population and 20% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Because the chronic dietary risks, which were quantified using a non-linear (*i.e.,* RfD) approach accounting for all chronic toxicity and any potential carcinogenic effects, are below EPA's level of concern, the Agency concludes that benzovindiflupyr will not pose a cancer risk. The short-term aggregate MOE (food, water, and residential) is 487 for children 1 to 2 years old. This MOE exceeds the target level of concern of 100, so it is not of concern. There are no intermediate or long-term residential exposures.

Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the documents titled ''Benzovindiflupyr. Human Health Risk Assessment for the Proposed New Food Use on Vegetable Root, Subgroup 1B (except sugar beets)'' in docket ID number EPA–HQ–OPP–2021–0417.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the June 22, 2018, rulemaking.

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 has not established an MRL for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet, subgroup 1B.

C. Revisions to Petitioned-For Tolerances

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. EPA is establishing the tolerance at 0.6 ppm for residues of benzovindiflupyr in or on Vegetable, root, except sugar beet,

subgroup 1B. The EPA determined a higher tolerance was required by calculating the recommended tolerance for carrot and radish data separately and using the highest recommended tolerance rather than calculating the recommended tolerance using the combined carrot and radish data as the registrant did. The Agency also revised the commodity definition to use standard terminology for the subgroup.

Additionally, the petition requested that ginseng be excluded from the tolerance for subgroup 1B. However, rather than exclude ginseng from this tolerance to avoid duplicative tolerances, EPA is removing the established tolerance of 0.3 ppm for residues of benzovindiflupyr in or on ginseng because it is included in the crop subgroup covered by this tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of benzovindiflupyr, in or on vegetable, root, except sugar beet, subgroup 1B at 0.6 ppm. In addition, EPA is removing the established tolerance for residues of benzovindiflupyr in or on ginseng at 0.3 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: September 22, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 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 1 to paragraph (a) by:
■ a. Removing the entry for ''Ginseng''; and
■ b. Adding in alphabetical order an entry ''Vegetable, root, except sugar beet, subgroup 1B''.

The addition reads as follows:

§ 180.686 Benzovindiflupyr; tolerances for residues

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TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	0.6
* * * * *	

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[FR Doc. 2022–21159 Filed 9–28–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

Standards for the Electronic Health Record Technology Incentive Program

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 42 of the Code of Federal Regulations, Parts 482 to End, revised as of October 1, 2021, revise § 495.22(e)(8)(i)(A)(*2*)(*ii*) to read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2018.

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(e) * * *
(8) * * *
(i) * * *
(A) * * *
(*2*) * * *