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[Rules and Regulations]

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[FR Doc No: 2021-02516]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0066 and EPA-HQ-OPP-2019-0586; FRL-10017-32]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

benzovindiflupyr in or on lowbush blueberries, ginseng, and sugar beet

roots, leaves, and dried pulp. 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 February 9, 2021. Objections and

requests for hearings must be received on or before April 12, 2021, 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 dockets for this action, identified by docket

identification (ID) numbers EPA-HQ-OPP-2020-0066 and EPA-HQ-OPP-2019-

0586, are available at [http://www.regulations.gov](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.

Due to the public health concerns related to COVID-19, the EPA

Docket Center (EPA/DC) and Reading Room is closed to visitors with

limited exceptions. The staff continues to provide remote customer

service via email, phone, and webform. For the latest status

information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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](mailto: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

Publishing 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 numbers EPA-HQ-OPP-2020-0066 and EPA-HQ-OPP-2019-0586 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 April 12, 2021. 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 numbers EPA-HQ-OPP-2020-0066 and EPA-

HQ-OPP-2019-0586, by one of the following methods:

Federal eRulemaking Portal: [http://www.regulations.gov](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

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dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the Federal Register of April 15, 2020 (85 FR 20910) (FRL-10006-

54), 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

9E8806) by IR-4, IR-4 Project Headquarters, Rutgers, The State

University of New Jersey, 500 College Road East, Suite 201W, Princeton,

NJ 08540. The petition requested that 40 CFR part 180 be amended by

establishing tolerances for residues of 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 the raw

agricultural commodities Blueberry, lowbush at 2 parts per million

(ppm) and Ginseng at 0.3 ppm. That document referenced a summary of the

petition prepared by Syngenta, the registrant, which is available in

the docket EPA-HQ-OPP-2020-0066, [http://www.regulations.gov](http://www.regulations.gov/). There were

no comments received in response to the notice of filing.

In the Federal Register of February 4, 2020 (85 FR 6129) (FRL-

10003-17), 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

9F8772) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro,

NC, 27419. The petition requested that 40 CFR part 180 be amended by

establishing tolerances for residues of benzovindiflupyr in or on the

raw agricultural commodities Beet, sugar, dried pulp at 0.15 ppm; Beet,

sugar, roots at 0.08 ppm; and Beet, sugar, tops at 0.06 ppm. That

document referenced a summary of the petition prepared by Syngenta, the

registrant, which is available in the docket EPA-HQ-OPP-2019-0586,

[http://www.regulations.gov](http://www.regulations.gov/). One relevant comment was received in

response to the notice of filing. EPA's response to this comment is

discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is

establishing several tolerances at different levels than were

petitioned for and is also modifying a commodity definition. The reason

for these changes is 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.

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 rulemakings of the same pesticide

chemical. Where scientific information concerning a particular chemical

remains unchanged, the content of those sections would not vary between

tolerance rulemakings 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 some updates have occurred to accommodate exposures from

the petitioned-for tolerances and reflect changes to the non-dietary,

non-occupational exposure assessment. The updates are discussed in this

section; for a description of the rest of the EPA approach to and

assumptions for the exposure assessment, see 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 uses of benzovindiflupyr on lowbush

blueberry, ginseng, and sugar beet. The assessment used the same

assumptions concerning 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, and thus have not changed since the last

assessment.

There have been two updates to the residential exposure assessment

since the June 22, 2018 final rule. The updated assessment no longer

assesses risks to residential handlers, since the label requirements

for handlers to wear specific clothing and to use personal protective

equipment (PPE) are presumed to indicate that these products are not

intended for homeowner use; thus, there is no residential handler

exposure. The consideration of the new turf use does not change

previous conclusions about post-application risk exposures.

EPA's conclusions concerning cumulative risk remain unchanged from

the June 22, 2018 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude

that there is 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

dietary exposure estimates to the acute population adjusted dose (aPAD)

and the chronic population adjusted dose (cPAD). Short-, intermediate-,

and chronic-term risks are evaluated by comparing the estimated

aggregate food, water, and

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residential exposure to the appropriate points of departure to ensure

that an adequate margin of exposure (MOE) exists. For linear cancer

risks, EPA calculates the lifetime probability of acquiring cancer

given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100%

of the aPAD: They are 44% 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 19% of the cPAD for children 1 to 2 years old, the

population subgroup with the highest exposure estimate. Because the

chronic dietary risks are below EPA's level of concern, EPA also

concludes that benzovindiflupyr will not pose a cancer risk. The short-

term aggregate MOE (food, water, and residential) is 500 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 [http://www.regulations.gov](http://www.regulations.gov/) in the documents titled ``Benzovindiflupyr. Human

Health Risk Assessment for the Proposed New Food Use on Lowbush

Blueberries and Ginseng and New Non-Food Uses.'' in docket ID number

EPA-HQ-OPP-2020-0066 and ``Benzovindiflupyr. Human Health Risk

Assessment for the Proposed New Use on Sugar Beets'' in docket ID

number EPA-HQ-OPP-2019-0586.

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).

There are no benzovindiflupyr Codex MRLs established for

blueberries, ginseng, or sugar beets.

C. Response to Comments

Although three comments were submitted to the docket in response to

the February 4, 2020 Notice of Filing, only one specifically related to

this tolerance action. The commenter requested that EPA deny Syngenta's

request for tolerances for benzovindiflupyr on sugar beets out of a

concern for the general health impacts of pesticides.

Although the Agency recognizes that some individuals believe that

pesticides should be banned on agricultural crops, the existing legal

framework provided by section 408 of the FFDCA authorizes EPA to

establish tolerances when it determines that the tolerance is safe.

Upon consideration of the validity, completeness, and reliability of

the available data as well as other factors the FFDCA requires EPA to

consider, EPA has determined that the benzovindiflupyr tolerances are

safe. The commenter has provided no information indicating that a

safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

Based on available residue data and using the Organization for

Economic Cooperation and Development (OECD) calculator, EPA has

determined that it is appropriate to set the tolerance level for beet,

sugar, dried pulp at 0.6 ppm rather than as proposed at 0.15 ppm. Also,

the tolerance is being established on ``Beet, sugar, leaves'' rather

than ``Beet, sugar, tops'' to be consistent with Agency nomenclature;

this tolerance is being established at 0.07 ppm rather than 0.06 ppm.

V. Conclusion

Therefore, tolerances are established for residues of

benzovindiflupyr in or on beet, sugar, dried pulp at 0.6 ppm; beet

sugar, leaves at 0.07 ppm; beet, sugar, roots at 0.08 ppm; blueberry,

lowbush at 2 ppm; and 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), nor is it considered a

regulatory action under Executive Order 13771, entitled ``Reducing

Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3,

2017). This action does not contain any information collections subject

to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501

et seq.), nor does it require any special considerations under

Executive Order 12898, entitled ``Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income

Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis

of a petition under FFDCA section 408(d), such as the tolerances and

modifications 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

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Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.),

EPA will submit a report containing this rule and other required

information to the U.S. Senate, the U.S. House of Representatives, and

the Comptroller General of the United States prior to publication of

the rule in the Federal Register. This action is not a ``major rule''

as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and

recordkeeping requirements.

Dated: November 30, 2020.

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

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

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

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2. In Sec. 180.686, amend paragraph (a) by designating the table as

Table 1 to Paragraph (a) and adding, in alphabetical order, to newly

designated Table 1 the entries ``Beet, sugar, dried pulp''; ``Beet,

sugar, leaves''; ``Beet, sugar, roots''; ``Blueberry, lowbush''; and

``Ginseng'' to read as follows:

Sec. 180.686 Benzovindiflupyr; tolerances for residues.

(a) \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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\* \* \* \* \*

Beet, sugar, dried pulp.................................... 0.6

Beet, sugar, leaves........................................ 0.07

Beet, sugar, roots......................................... 0.08

Blueberry, lowbush......................................... 2

\* \* \* \* \*

Ginseng.................................................... 0.3

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[FR Doc. 2021-02516 Filed 2-8-21; 8:45 am]

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