60-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0203; FRL-10212-01-OCSPP]

Sulfur Dioxide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfur dioxide in or on blueberry. Interregional Research Project Number 4 (IR-4) requested this tolerance 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-2021-0203, 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: Daniel Rosenblatt, 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-2021-0203 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-2021-0203, 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 June 28, 2021 (86 FR 33922) (FRL-10025-08), 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 0E8894) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to amend 40 CFR part 180 by establishing tolerances for residues of sulfur dioxide, including its metabolite and degradates, in or on blueberry at 9 parts per million

(ppm). That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket, *https://www.regulations.gov*. Two comments were received on the notice of filing from the United States Department of Agriculture and the North American Blueberry Council. Both were in support of the action.

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 sulfur dioxide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with these inorganic sulfites follow.

A. Toxicological Profile

There is a large volume of published data detailing the toxicity of sulfur dioxide and sodium metabisulfite, and consequently the toxicity of these pesticides has been well established. Sodium metabisulfite pads generate sulfur dioxide gas which then reacts with

foods to quickly form sulfite. In addition to the use of sodium metabisulfite pads, direct application of sulfur dioxide gas is proposed for blueberry treatments. For both treatments, sulfite is the residue of concern in food and is determined by the analytical enforcement method. EPA's Office of Air Quality Planning and Standards (OAQPS) has worked extensively on sulfur dioxide, including setting national ambient air quality standards (NAAQS) for sulfur dioxide, a gaseous air pollutant. The U.S. Food and Drug Administration (FDA) has also performed an extensive review of sulfiting agents (including sulfur dioxide, sodium metabisulfite, and sodium bisulfite) that have been added to any food or to any ingredient in any food. For the dietary assessment, EPA is relying on the established FDA regulatory value for sulfite.

Sulfiting agents are used to add sulfites to foods and include sulfur dioxide, sodium metabisulfite, sodium bisulfite, sodium sulfite, potassium metabisulfite, and potassium bisulfite. Humans may experience sensitivity reactions following exposure to sulfites including, but not limited to, diarrhea, headache, difficulty breathing, vomiting and nausea, and abdominal pain and cramps. Asthmatics account for many, but not necessarily all, of the individuals who have a sensitivity to sulfites. Given the known effects to certain individuals within the population, the FDA requires that any food that contains a sulfiting agent at ≥ 10 ppm or mg/kg be declared as such on the food label.

Additional information on the toxicological profile can be found at *https://www.regulations.gov* in the document titled "Inorganic Sulfites. Human Health Risk Assessment in Support of a Section 3 Registration for Postharvest Fumigation of Blueberry" (hereinafter "Sulfur Dioxide Human Health Risk Assessment") in docket ID number EPA-HQ-OPP-2021-0203.

B. Toxicological Points of Departure/Levels of Concern

No appropriate toxicological endpoints were selected for sulfur dioxide. The Agency is relying on the FDA-established regulatory level of up to 10 ppm sulfite residues in foods.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to sulfur dioxide, EPA compared exposure from residues on blueberries to the FDA-established regulatory level. EPA assessed dietary exposures from these inorganic sulfites in food as follows:

Sulfite is the residue of concern for consumption of treated blueberries. A quantitative dietary assessment was not conducted for sulfite since no appropriate toxicological endpoints were selected. The Agency is relying on the FDA-established regulatory level of up to 10 ppm sulfite residues in foods. Residues of sulfites in blueberry from sulfur dioxide and sodium metabisulfite applications are expected to be below the 10 ppm level when applied as tested in the blueberry residue trials.

EPA did not use anticipated residue or PCT information in the dietary assessment for sulfur dioxide.

2. *Dietary exposure from drinking water*. No residues are expected in drinking water based on the current use pattern, which includes post-harvest fumigant treatment in a chamber and slow release or dual release pads that are placed in the clamshells used to distribute blueberries.

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).

There are no uses of sulfur dioxide or sodium metabisulfite resulting in direct residential exposures; therefore, residential exposure is not expected.

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."

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 the inorganic sulfites and any other substances and the inorganic sulfites do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that the inorganic sulfites have a common mechanism of toxicity with other substances.

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 Food Quality Protection Act Safety Factor (FQPA)(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.

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has also reviewed the available scientific data and other relevant information in support of regulations establishing the 10 ppm maximum permissible level for residues of sulfur dioxide to support a time-limited tolerance of sulfur dioxide residues in or on fig (September 14, 2011; 76 FR 56644) (FRL-8887-2). EPA also considered available

information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including sulfite sensitive individuals, infants, and children. EPA has concluded that there is sufficient toxicological information for sulfur dioxide to address risks to infants and children. In addition, the available information indicated that there is no evidence of increased quantitative or qualitative susceptibility of the offspring after in utero or postnatal exposure. Based on the lack of observed susceptibility, and since the current regulatory value for sulfites (10 ppm) takes into account the potential for sensitive populations, including infants and children, these regulatory values are considered protective, and no additional FQPA safety factor is required.

E. Aggregate Risks and Determination of Safety

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. There are no residential uses of sulfur dioxide or sodium metabisulfite, and exposures through drinking water are not expected based on the use pattern. Dietary exposures resulting from the proposed uses on blueberries are expected to be below the 10 ppm FDA-established regulatory level; therefore, there are no dietary risks of concern from these uses on blueberries.

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 exposure to inorganic sulfites resulting from the application of sulfur dioxide and sodium metabisulfite.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) method is available for enforcing sulfite tolerances in blueberries.

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).

There are no Codex MRLs for sulfur dioxide in or on blueberry.

V. Conclusion

Therefore, a tolerance is established for residues of sulfur dioxide in or on blueberry at 9 ppm. EPA is also removing the expired time-limited tolerance in paragraph (b) and reserving paragraph (b) as a housekeeping measure.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), 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 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: November 4, 2022.

Jennifer Saunders,

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 § 180.444:

a. Amend paragraph (a) by:

i. Designating the table as "Table 1 to paragraph (a)".

ii. Adding in alphabetical order the entry “Blueberry”.

b. Removing and reserving paragraph (b).

The addition reads as follows:

§ 180.444 Sulfur Dioxide; tolerances for residues.

(a) * * *

Table 1 to paragraph (a)

Commodity	Parts per million
Blueberry	9
* * * * * * *	

(b) [Reserved]

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[FR Doc. 2022-25014 Filed: 11/16/2022 8:45 am; Publication Date: 11/17/2022]