



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2017-0288 and EPA-HQ-OPP-2017-0283; FRL-9986-73]

### 6-Benzyladenine; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of 6-benzyladenine in or on avocados, peppers, tomatoes, cucumbers, melons, and squash. Interregional Research Project Number 4 and Valent BioSciences LLC have 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 dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2017-0288 and EPA-HQ-OPP-2017-0283, are 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:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@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 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](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 FFDC section 408(g), 21 U.S.C. 346a(g), 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-2017-0288 and EPA-HQ-OPP-2017-0283 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 numbers EPA-HQ-OPP-2017-0288 and EPA-HQ-OPP-2017-0283, 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. Background**

In the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL-9965-43), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions: PP 6E8526 by Interregional Research Project Number 4 (IR-4), Rutgers, State University of New Jersey, 681 U.S. Highway No. 1, S. North New Brunswick, NJ 08902; and PP 7F8548 by Valent BioSciences LLC (Valent), 870 Technology Way, Libertyville, IL 60048. Petition 6E8526 requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the plant growth regulator 6-benzyladenine, in or on avocados at 0.05 parts per million (ppm). Petition 7F8548 requested amendment of the current exemption from the requirement of tolerance for residues of 6-benzyladenine, 40 CFR 180.1150, to add fruiting vegetables (tomatoes and peppers) and cucurbit vegetables (cucumbers, melons, and squash). That document referenced summaries of the petitions prepared by Valent, the registrant, which are available in the respective dockets via, [www.regulations.gov](http://www.regulations.gov). Comments were received on the notice of filing, and the Agency's response can be found in Unit III.D.

Based upon review of the data supporting each petition, EPA is establishing tolerance levels for 6-benzyladenine on avocados, tomatoes, peppers, cucumbers, melons and squash in one final rule. The reasons for these changes are explained in Part III.E. of this document.

## **III. Final Rule**

### *A. EPA's Safety Determination*

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. EPA must take into account the factors set forth in FFDCa section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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 . . . .” Additionally, FFDCa section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicological and exposure data on 6-benzyladenine and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Federal Food, Drug, and Cosmetic Act (FFDCa) Safety Assessment for Tolerances for Residues of 6-benzyladenine.” This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data demonstrated that the predominant adverse effect from exposure to 6-benzyladenine was a significant reduction in body weight, including an increased susceptibility of body weight effects in fetuses and offspring. Despite these effects, EPA determined that reliable data show the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor was reduced to 1X. EPA conducted a quantitative aggregate risk assessment, taking into account chronic exposures to residues of 6-benzyladenine in food and drinking water (no residential exposures are anticipated) and concluded that risks do not exceed EPA’s level of concern.

Based upon its evaluation, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 6-benzyladenine. Therefore, tolerances are established for residues of 6-benzyladenine, in or on tomato, pepper, cucumber, melon, and squash at 0.01 ppm and in or on avocado at 0.02 ppm.

#### *B. Analytical Enforcement Methodology*

Adequate enforcement methodologies to quantitatively determine 6-benzyladenine residues by liquid chromatography/mass spectrometer/mass spectrometer (LC/MS/MS) (Meth-209, Determination of 6-Benzyladenine (6-BA) in Selected Fruiting Vegetable and Cucurbit Vegetable Raw Agricultural and Processed Commodities and Meth-210, Determination of 6-Benzyladenine (6-BA) in Selected Oily Crop Raw Agricultural Commodities) are available to enforce the tolerance expression. The methods 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](mailto:residuemethods@epa.gov).

#### *C. 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 an MRL for 6-benzyladenine; however, Canada and the European Union (EU) have set default MRLs at 0.1 ppm (Canada) and 0.01 ppm (EU), respectively.

#### *D. Response to Comments*

One comment was received in response to each of the petitions. Each comment generally opposed pesticide residues on food; only one mentioned 6-benzyladenine by name. Neither comment was accompanied by any substantiation or data supporting a conclusion that the tolerances being established in this action do not meet the FFDCA safety standard. Although EPA recognizes that some individuals would oppose any use of pesticides on food, section 408 of the FFDCA authorizes EPA to set tolerances for residues of pesticide chemicals in or on food when it determines that the tolerance meets the safety standard imposed by that statute. EPA has made that determination for the 6-benzyladenine tolerances established by this final rule.

#### *E. Revisions to Petitioned-For Tolerance and Tolerance Exemption*

The applicant requested a tolerance for residues of 6-benzyladenine on avocado at 0.05 ppm. Based on available residue data and using the Organisation for Economic Co-operation and Development (OECD) calculator, EPA has determined that a tolerance for residues of 6-benzyladenine on avocado at 0.02 ppm is appropriate. In addition, the applicant requested to amend the current exemption, 40CFR 180.1150, for residues of 6-benzyladenine by adding fruiting vegetables (tomatoes and peppers) and cucurbit vegetables (cucumbers, melons, and squash) at 20 parts per million (ppm) at a maximum of five applications (total 18.8 grams of active ingredient per acre per season) with a seven-day interval between applications. Due to the toxicological profile of the chemical and the measurable residues, EPA has concluded that a tolerance is the appropriate regulatory mechanism for covering residues of 6-benzyladenine under the FFDCA. Based on the available residue data and using the OECD calculator, EPA has

determined that tolerances for residues of 6-benzyladenine on tomato, pepper, cucumber, melon, and squash at 0.01 ppm are appropriate.

#### **IV. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to EPA. 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 action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions

of FFDCa section 408(n)(4). As such, EPA 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, EPA 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 EPA’s 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).

#### **V. 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 28, 2018.

Richard P. Keigwin, Jr.,  
*Director, Office of Pesticide Programs.*

Therefore, 40CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

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

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

2. Add § 180.703 to subpart C to read as follows:

**§ 180.703 6-benzyladenine; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the plant growth regulator, 6-benzyladenine in or on the commodities listed in the table below. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only 6-benzyladenine in or on the commodity.

Commodity	Parts per million
Avocado	0.02
Cucumber	0.01
Melon	0.01
Pepper	0.01
Squash	0.01
Tomato	0.01

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

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

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

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