



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2021-0170; FRL-8908-01-OCSP]

Defensin Proteins Derived from Spinach in Citrus Plants; Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8 in or on citrus when used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit (EUP) No. 88232-EUP-1. Southern Gardens Citrus Nursery, LLC., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8. The temporary tolerance exemption expires on May 31, 2025.

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-2021-0170, 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.

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: Charles Smith, 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*.

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 174 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 FFDCFA 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-2021-0170 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-2021-0170, 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 March 22, 2021 (86 FR 15162) (FRL-10021-44), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1G8896) by Southern Gardens Citrus Nursery, LLC., 1820 Country Road 833, Clewiston, Florida 33440. The petition requested that the temporary tolerance exemption established in 40 CFR 174.535 be amended and extended for residues of defensin proteins SoD2, SoD2*, SoD7, and SoD8 derived from spinach. Because the temporary tolerance exemption expired before we could complete this action, we are treating this as a petition to reestablish a temporary tolerance exemption. The notice of filing referenced a summary of the petition prepared by the petitioner Southern Gardens Citrus, LLC., which is available in the docket for this action at <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Final Rule

A. EPA's safety determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, 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 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 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 reviewed the available toxicity and exposure data on spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8 and considered its validity, completeness and reliability, and the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Review of the application for renewal and extension of experimental use permit 88232-EUP-1 and extension of the associated temporary tolerance exemption for the defensin proteins SoD2, SoD2*, SoD7, and SoD8 derived from spinach (*Spinacia oleracea* L.) used as a plant-incorporated protectant in citrus plants at 40 CFR Part 174.535 for additional 4 years, until May 31, 2025” dated June 24, 2021 (Ref. 1). This document, as well as other relevant information, is available in docket for this action as described under **ADDRESSES**.

Based upon available data, EPA concludes that spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8, do not show evidence of toxicity (Ref. 2). Moreover, there is no significant similarity between spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8 and known toxins and allergens. In addition, the spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8 readily digest in simulated gastric fluids and therefore

cumulative, chronic, and acute effects are unlikely. Furthermore, the source of the defensin proteins, spinach, has long been part of the human diet and there have been no findings that indicate toxicity or allergenicity of spinach proteins (Ref. 2).

Given the lack of toxicity or allergenicity of the spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8, the Agency has not identified any toxicological endpoints for assessing risk. Due to the lack of any threshold effects, EPA has determined that the provision under FFDCA section 408(b)(2)(C) to retain a 10X safety factor for the protection of infants and children does not apply. Similarly, the lack of any toxic mode of action or toxic metabolites means that the provision requiring an assessment of cumulative effects does not apply.

Oral exposure to spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8 may occur from ingestion of citrus products, such as fruit and juice. In addition, people have had a long history of consumption of spinach and will continue to be exposed to defensin proteins through consumption of spinach. Based on the lack of adverse effects and the rapid digestibility of the proteins, however, the Agency does not anticipate any risk from reasonably foreseeable levels of exposure. Since the plant-incorporated protectant is integrated into the plant's genome, the Agency has concluded, based upon previous science reviews, that residues in drinking water will be extremely low or non-existent (Ref. 2). Non-occupational exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. In any event, there are no non-dietary non-occupational uses of SoD2, SoD2*, SoD7, and SoD8 as they are only used in agricultural settings.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical

limitation.

C. Conclusion

Based on its evaluation, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the spinach defensin proteins SoD2, SoD2*, SoD7, and SoD8. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as previously discussed, there is no indication of toxicity or allergenicity potential for the plant-incorporated protectant. Therefore, a temporary exemption from the requirement of a tolerance is established for residues of spinach defensin SoD2, SoD2*, SoD7, and SoD8 proteins in or on citrus when the proteins are used as a plant-incorporated protectant in citrus plants. This exemption is being established concurrently with an extension to the experimental use permit (EUP) No. 88232-EUP-1 and is therefore being established on a temporary basis. Both the EUP and temporary tolerance exemption will expire on May 31, 2025.

D. References

The following is a listing of documents that are specifically referenced in this document. These documents are available in the listed dockets at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) via the direct links below.

1. U.S. EPA, “Review of the application for renewal and extension of experimental use permit 88232-EUP-1 and extension of the associated temporary tolerance exemption for the defensin proteins SoD2, SoD2*, SoD7, and SoD8 derived from spinach (*Spinacia oleracea* L.) used as a plant-incorporated protectant in citrus plants at 40 CFR Part 174.535 for additional 4 years, until May 31, 2025.” June 24, 2021. <https://www.regulations.gov/document/EPA-HQ-OPP-2021-0170>.

2. U.S. EPA, “Review of Product Characterization, Toxicity Waiver Requests,

Allergenicity, and Human Health Data for Plant-Incorporated Protectants (PIPs):

Defensin proteins derived from spinach (*Spinach oleracea* L.) Sod2, Sod2*, Sod7, Sod8.”

April 24, 2018. <https://www.regulations.gov/document/EPA-HQ-OPP-2018-0040-0007>.

IV. Statutory and Executive Order Reviews

This action establishes a temporary exemption from the requirement of 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). 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 temporary tolerance exemption 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).

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 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 25, 2021.

Charles Smith,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 321(q), 346a and 371.

2. Revise § 174.535 to read as follows:

§174.535 Spinach Defensin proteins; temporary exemption from the requirement of a tolerance.

Residues of the defensin proteins SoD2, SoD2*, SoD7, and SoD8 derived from spinach (*Spinacia oleracea* L.) in or on citrus food commodities are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in citrus plants in accordance with the terms of Experimental Use Permit No. 88232-EUP-1. This temporary exemption from the requirement of a tolerance expires on May 31, 2025.