40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating Permits, Reporting and recordkeeping requirements.

Dated: February 6, 2024.

David Cash,

Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart H—Connecticut

■ 2. Section 52.370 is amended by adding paragraph (c)(130) to read as follows:

§ 52.370 Identification of plan.

* * * * *

(c) * * *

(130) Revisions to the State Implementation Plan submitted by the Connecticut Department of Environmental Protection on November 30, 2023.

(i) *Incorporation by reference.*

(A) Regulations of Connecticut State Agencies Section 22a–174–1, ''Definitions,'' (106), definition of ''Severe non-attainment area for ozone.''

(B) Reserved.

(ii) *Additional materials.*

(A) Letter from CT DEEP submitted to EPA on November 30, 2023, entitled ''State Implementation Plan Revision Concerning the Definition of Severe Non-Attainment Area for Ozone.''

(B) Reserved.

■ 3. In § 52.385 amended Table 52.385 by adding a sixth entry for ''22a–174–1'' before the entry for ''22a–174–2'' to read as follows:

§ 52.385 EPA-approved Connecticut regulations.

* * * * *

TABLE 52.385—EPA-APPROVED REGULATIONS

Connecticut State citation	Title/subject	Dates		Federal Register citation	Section 52.370	Comments/description
		Date adopted by State	Date approved by EPA			
*	*	*	*	*	*	*
22a–174–1	Definitions	11/13/2023	2/12/2024	[Insert **Federal Register** citation].	(c)(130)	Modified definition of ''severe non-attainment area for ozone''.
*	*	*	*	*	*	*

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 4. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 5. Amend Appendix A to Part 70 under ''Connecticut'' by adding paragraph (b) to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs * * *

Connecticut

* * * * *

(b) Connecticut Department of Environmental Protection submitted revisions on November 30, 2023 to Regulations of Connecticut State Agencies Section 22a–174–1, ''Definitions,'' definition of ''Severe non-attainment area for ozone.'' This rule amendment contained in this submittal is necessary to make the current definition as stringent as the reclassified severe nonattainment area in the State of Connecticut. The State is hereby granted approval effective on March 13, 2024.

[FR Doc. 2024–02700 Filed 2–9–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0781; FRL–11563–01–OCSPP]

U1-AGTX-Ta1b-QA Protein; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the U1-AGTX-Ta1b-QA protein in or on all food commodities when used in accordance with label directions and good agricultural practices. Vestaron Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance for residues of the U1-AGTX-Ta1b-QA protein in and on all food commodities. This regulation eliminates the need to establish a maximum permissible level for residues of U1-AGTX-Ta1b-QA protein under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective February 12, 2024. Objections and requests for hearings must be received on or before April 12, 2024, 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–2021–0781, is available at *https://www.regulations.gov.* Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison Le, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; 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 180 through the Federal Register Office's e-CFR site at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180?toc=1.*

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–2021–0781 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, 2024. 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–2021–0781, 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/where-send-comments-epa-dockets.*

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

II. Background and Statutory Findings

In the **Federal Register** of March 22, 2022 (87 FR 16133) (FRL–9410–11–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 tolerance petition (PP 1F8923) by Vestaron Corporation, 600 Park Offices Dr., Suite 117, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of U1-AGTX-Ta1b-QA protein. That document referenced a summary of the petition prepared by the petitioner Vestaron Corporation, which is available in the docket, *https://www.regulations.gov.* EPA received one comment on the notice of filing. EPA's response to this comment is discussed in Unit VII.C.

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 evaluated the available toxicological and exposure data on U1-AGTX-Ta1b-QA protein and considered their validity, completeness, and reliability, as well as 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 ''Human Health Risk Assessment in Support of the Registration of 'Basin' End Use Product Containing the New Active Ingredient U1-AGTX-Ta1b-QA (8.5%) and Associated Petition to Establish a Permanent Tolerance Exemption'' (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES.**

Available data have demonstrated that, with regard to humans, U1-AGTX-Ta1b-QA protein is not anticipated to be toxic or allergenic via any reasonably foreseeable route of exposure. U1-AGTX-Ta1b-QA protein is a modified form of agatoxin protein derived from the venom of the hobo spider (*Eratigena agrestis*) that is intended for control of insects and mites. In insects, the reported mode-of-action of U1-AGTX-Ta1b-QA is allosteric inhibition of a non-desensitizing nicotinic acetylcholine receptor, a neural receptor responsible for signal transduction and function. The U1-AGTX-Ta1b-QA protein binds to a non-signaling portion of the target (allosteric) site, altering the three-dimensional structure of the neural receptor. According to the Center of Disease Control (*https://www.cdc.gov/niosh/topics/spiders/types.html*), the venom, from which the active ingredient is derived, is not recognized as toxic to humans. Products formulated with U1AGTX-Ta1b-QA will be used for foliar applications to plants or as a dip/immersion for roots or cuttings.

Toxicological data provided by the petitioner indicate that U1-AGTX-Ta1b-QA has low acute toxicity via the oral, dermal, inhalation, route and it is not a dermal or eye irritant. This conclusion is further supported by the results of the 90-day oral toxicity study, prenatal development toxicity studies, and the absence of genotoxicity in a bacterial

reverse mutation test. In addition, the protein sequence of U1-AGTX-Ta1b-QA does not show significant homology to known allergens and thus there is no indication of allergenic cross-reactivity.

Dietary exposure could occur if U1-AGTX-Ta1b-QA is used on crops used for food. However, any risks associated with dietary exposures are expected to be negligible due to the following hazard and exposure considerations: U1-AGTX-Ta1b-QA (1) has a low overall toxicity profile including low toxicity via the oral route of exposure; (2) does not exhibit protein homology to putative or known allergens; (3) does not show any prenatal developmental toxicity or genetic toxicity; and (4) as described, was derived from the venom of the hobo spider, which is not recognized as toxic to humans. In addition, food crops undergo a post-harvest washing process to remove soil and surface residues, which will therefore reduce the amounts of U1-AGTX-Ta1b-QA on the treated crops. Root dip and cutting immersions, specifically, are expected to result in negligible exposure of above-ground grown plant parts used for food since these applications occur prior to planting and residues are not expected to persist on the growing plant. Exposure through drinking water is expected to be negligible as U1-AGTX-Ta1b-QA, as a protein, is expected to be susceptible to biodegradation in the environment as well as water treatment processes.

Non-occupational exposure could occur if bystanders are present in areas treated with products containing U1-AGTX-Ta1b-QA protein. However, submitted data have shown that U1-AGTX-Ta1b-QA is expected to have low toxicity via the oral, dermal, and inhalation routes of exposure, is minimally irritating to the eyes and skin, and is not a dermal sensitizer; therefore, any risks from non-occupational exposure are expected to be negligible.

Based upon the evaluation in the Human Health Risk Assessment, which found no risk of concern from aggregate exposure to U1-AGTX-Ta1b-QA, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of U1-AGTX-Ta1b-QA. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. In addition, because no threshold effects have been identified for infants and children, EPA determined that an additional Food Quality Protection Act (FQPA) safety factor is not necessary to protect infants and children from anticipated residues of U1-AGTX-Ta1b-QA.

B. Analytical Enforcement Methodology

An analytical method is not required for U1-AGTX-Ta1b-QA since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation based on a lack of adverse effects.

C. Response To Comment

One comment was received during the public comment period for the notice of filing. The commentor provided general objections to EPA establishing exemptions from tolerance for pesticides but did not provide any specific or substantive objections to the petition to exempt U1-AGTX-Ta1b-QA protein. Based on its review of the data and other information submitted in support of the tolerance exemption petition (as described above in Unit III.A), EPA has determined that a tolerance exemption for U1-AGTX-Ta1b-QA protein is safe under the FFDCA. Therefore, EPA is establishing a tolerance exemption for residues of U1-AGTX-Ta1b-QA protein applied to food commodities.

D. Conclusion

Based on the conclusions detailed in Unit III.A., an exemption from the requirement of a tolerance is established for residues of U1-AGTX-Ta1b-QA protein in or on all food commodities when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action establishes an exemption 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 exemption from the requirement of a 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).

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: January 29, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended 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. Add § 180.1406 to subpart D to read as follows:

§ 180.1406 U1-AGTX-Ta1b-QA protein; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of U1-AGTX-Ta1b-QA protein in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2024–02787 Filed 2–9–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, and 600

[CMS–1784–F2]

RIN 0938–AV07

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction and correcting amendment.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the November 16, 2023 issue of the **Federal Register**, entitled ''Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program'' (referred to hereafter as the ''CY 2024 PFS final rule''). The effective date was January 1, 2024.

DATES: This correcting document is effective February 12, 2024 and is applicable beginning January 1, 2024.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for the following issues: caregiver training services, community health integration services, and principal illness navigation services; telehealth and other services involving communications technology; PFS conversion factor; and PFS payment for evaluation and management services.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment.

Frank Whelan (410) 786–1302, for issues related to Medicare and Medicaid Provider and Supplier Enrollment

Renee O'Neill, (410) 786–8821, *MIPSEngagementTeam@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2023–24184 of November 16, 2023, the CY 2024 PFS final rule (88 FR 78818), there were technical errors that are identified and corrected in this correcting document. These corrections are applicable as if they had been included in the CY 2024 PFS final rule, which was effective January 1, 2024.

II. Summary of Errors

A. Summary of Errors in the Preamble

1. On page 78867, in the table titled ''TABLE 11: CY 2024 Medicare Telehealth Services List'' which continues through page 78871, we inadvertently omitted four rows of services.

2. On page 78876, second column, fourth full paragraph, line 2, we inadvertently omitted qualifying language before the reference to telehealth services and neglected to include a reference to further background information.

3. On page 78918, third column, second full paragraph, second sentence, we neglected to include a clarifying phrase.

4. On page 78920, first column, first full paragraph, we inadvertently omitted a clarifying phrase.

5. On page 78944, first column, first full paragraph we inadvertently included incorrect language in the final code descriptor for HCPCS code G0023.

6. On page 78949, first column, first full paragraph, we made a typographical error when finalizing limitations on PIN services.

7. On pages 78956 through 78957 in the table titled ''TABLE 14: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes,'' the code descriptor listed for HCPCS code G0019 inadvertently was not updated to reflect the final code descriptors as stated in the preamble text.

8. On pages 78958 through 78959 in the table titled ''TABLE 14: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes,'' the code descriptors listed for HCPCS codes G0022 and G0023 inadvertently were not updated to reflect the final code descriptors as stated in the preamble text.

9. On pages 78959 through 78960 in the table titled ''TABLE 14: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes,'' the code descriptor listed for HCPCS code G0140 inadvertently was not updated to reflect the final code descriptor as stated in the preamble text.

10. On page 78975, we inadvertently omitted a sentence to restate the final policy we adopted for the inherent complexity add-on code (G2211).

11. On page 79075, third column, first full paragraph, line 19, two G-codes for PIN services were inadvertently omitted.

12. On page 79112 in the table titled, ''TABLE 28: Final APP Reporting Requirements and Quality Performance Standard for Performance Year 2024 and Subsequent Performance Years'', we inadvertently included language regarding a MIPS Quality performance category score.

13. On page 79112 in the table titled, ''TABLE 28: Final APP Reporting Requirements and Quality Performance Standard for Performance Year 2024 and Subsequent Performance Years'', we made a typographical error in identifying the APP measure.

14. On page 79113 in the table titled, ''TABLE 29: Measures included in the APP Measure Set for Performance Year 2024 and Subsequent Performance