

N.J.A.C. 7:27–22.8. Air quality simulation modeling and risk assessment
 N.J.A.C. 7:27–22.9. Compliance plans
 N.J.A.C. 7:27–22.10. Completeness reviews
 N.J.A.C. 7:27–22.11. Public comment
 N.J.A.C. 7:27–22.12. EPA comment
 N.J.A.C. 7:27–22.13. Final action on an application
 N.J.A.C. 7:27–22.14. General operating permits
 N.J.A.C. 7:27–22.15. Temporary facility operating permits
 N.J.A.C. 7:27–22.16. Operating permit contents
 N.J.A.C. 7:27–22.17. Permit shield
 N.J.A.C. 7:27–22.18. Source emissions testing and monitoring
 N.J.A.C. 7:27–22.19. Recordkeeping, reporting and compliance certification
 N.J.A.C. 7:27–22.20. Administrative amendments
 N.J.A.C. 7:27–22.21. Changes to insignificant source operations
 N.J.A.C. 7:27–22.22. Seven-day-notice changes
 N.J.A.C. 7:27–22.23. Minor modifications
 N.J.A.C. 7:27–22.24. Significant modifications
 N.J.A.C. 7:27–22.24A. Reconstruction
 N.J.A.C. 7:27–22.25. Department initiated operating permit modifications
 N.J.A.C. 7:27–22.26. MACT and GACT standards
 N.J.A.C. 7:27–22.27. Operating scenarios
 N.J.A.C. 7:27–22.28A. Emissions trading
 N.J.A.C. 7:27–22.28B. Facility-specific emissions averaging programs
 N.J.A.C. 7:27–22.29. Facilities subject to acid deposition control
 N.J.A.C. 7:27–22.30. Renewals
 N.J.A.C. 7:27–22.31. Fees
 N.J.A.C. 7:27–22.32. Hearings and appeals
 N.J.A.C. 7:27–22.33. Preconstruction review
 N.J.A.C. 7:27–22.34. Early reduction of HAP emissions
 N.J.A.C. 7:27–22.35. Advances in the art of air pollution
 Appendix
 Table A

Chapter 27B Subchapter 1—Sampling and Analytical Procedures for Determining Emissions of Particles From Manufacturing Processes and From Combustion of Fuels (Effective 6/21/1976)

N.J.A.C. 7:27B–1.1. Definitions
 N.J.A.C. 7:27B–1.2. Acceptable test methods
 N.J.A.C. 7:27B–1.3. Operating conditions during the test
 N.J.A.C. 7:27B–1.4. Sampling facilities to be provided by the person responsible for emissions
 N.J.A.C. 7:27B–1.5. Sampling train
 N.J.A.C. 7:27B–1.6. Performance test principle
 N.J.A.C. 7:27B–1.7. General testing requirements
 N.J.A.C. 7:27B–1.8. Required test data
 N.J.A.C. 7:27B–1.9. Preparation for sampling
 N.J.A.C. 7:27B–1.10. Sampling
 N.J.A.C. 7:27B–1.11. Sample recovery
 N.J.A.C. 7:27B–1.12. Analysis
 N.J.A.C. 7:27B–1.13. Calculations
 N.J.A.C. 7:27B–1.14. Validation of test

Chapter 27B Subchapter 2—Procedures for Visual Determination of the Opacity (Percent) and Shade or Appearance (Ringelmann Number) of Emissions From Sources (Effective 6/21/1976)

N.J.A.C. 7:27B–2.1. Definitions
 N.J.A.C. 7:27B–2.2. Acceptable observation methods
 N.J.A.C. 7:27B–2.3. Observation principle
 N.J.A.C. 7:27B–2.4. General observation requirements
 N.J.A.C. 7:27B–2.5. Required observation data
 N.J.A.C. 7:27B–2.6. Certification
 References
 Appendix

Chapter 27B Subchapter 3—Air Test Method 3: Sampling and Analytical Procedures for the Determination of Volatile Organic Compounds From Source Operations (Effective 12/1/2008)

N.J.A.C. 7:27B–3.1. Definitions
 N.J.A.C. 7:27B–3.2. Sampling and analytical protocol: acceptable test methods
 N.J.A.C. 7:27B–3.3. Operating conditions during the test
 N.J.A.C. 7:27B–3.4. Sampling facilities
 N.J.A.C. 7:27B–3.5. Source operations and applicable test methods
 N.J.A.C. 7:27B–3.6. Procedures for the determinations of vapor pressures of a single known VOC or mixtures of known and/or unknown VOC
 N.J.A.C. 7:27B–3.7. Procedures for the direct measurement of volatile organic compounds using a flame ionization detector (FID), a photoionization detector (PID) or a non-dispersive infrared analyzer (NDIR)
 N.J.A.C. 7:27B–3.8. Procedures for the direct measurement of volatile organic compounds using a gas chromatograph (GC) with a flame ionization detector (FID) or other suitable detector
 N.J.A.C. 7:27B–3.9. Procedures for the sampling and remote analysis of known volatile organic compounds using a gas chromatograph (GC) with a flame ionization detector (FID) or other suitable detector
 N.J.A.C. 7:27B–3.10. Procedures for the determination of volatile organic compounds in surface coating formulations
 N.J.A.C. 7:27B–3.11. Procedures for the determination of volatile organic compounds emitted from transfer operations using a flame ionization detector (FID) or non-dispersive infrared analyzer (NDIR)
 N.J.A.C. 7:27B–3.12. Procedures for the determination of volatile organic compounds in cutback and emulsified asphalts
 N.J.A.C. 7:27B–3.13. Procedures for the determination of leak tightness of gasoline delivery vessels
 N.J.A.C. 7:27B–3.14. Procedures for the direct detection of fugitive volatile organic compound leaks
 N.J.A.C. 7:27B–3.15. Procedures for the direct detection of fugitive volatile organic compound leaks from gasoline tank trucks and vapor collection systems using a combustible gas detector

N.J.A.C. 7:27B–3.18. Test methods and sources incorporated by reference.

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[FR Doc. 2024–15327 Filed 7–15–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0278; FRL–12055–01–OCSPP]

Polytetrafluoroethylene; Revocation of the Tolerance Exemption When Used as an Inert Ingredient in Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to revoke the tolerance exemption for residues of polytetrafluoroethylene (CAS No. 9002–84–0) under the Federal Food, Drug, and Cosmetic Act (FFDCA) when used as an inert ingredient in pesticide formulations. EPA is proposing to revoke this tolerance exemption because polytetrafluoroethylene, which has been identified as a per- and polyfluoroalkyl substance (PFAS), is no longer used in any registered pesticide product.

DATES: Comments must be received on or before September 16, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2024–0278, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, 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), *e.g.*, agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), *e.g.*, cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), *e.g.*, agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), *e.g.*, agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 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(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-2024-0278 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 September 16, 2024.

EPA's Office of Administrative Law Judges (OALJ), where the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Service and Filing", dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat

submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf/HomePage?ReadForm.

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-2024-0278, 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

A. What action is the Agency taking?

EPA is proposing to revoke the tolerance exemption in 40 CFR 180.960 for polytetrafluoroethylene (CAS No. 9002-84-0) when used as an inert ingredient in pesticide formulations. This is being proposed because polytetrafluoroethylene has been identified as a per- and polyfluoroalkyl substance (PFAS), and it is no longer used in any registered pesticide product.

B. What is the Agency's authority for taking this action?

EPA is proposing this action pursuant to its authority under section 408 of the FFDCa, 21 U.S.C. 346a. Under section 408(e) of the FFDCa, EPA may issue a rule revoking tolerances after providing

notice of a proposed rulemaking and a period of not less than 60 days for public comment. 21 U.S.C. 346a(e).

C. When does this action become effective?

EPA is proposing that this action become effective six months after the date of publication of the final rule in the **Federal Register**. EPA is proposing this effective date for this action to allow a reasonable interval for producers in exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements of the final rule.

Any commodities treated with polytetrafluoroethylene in the channels of trade following the tolerance exemption revocation shall be subject to FFDCa section 408(l)(5), 21 U.S.C. 346a(l)(5). Under this section, any residues of this pesticide in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that the residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA and the residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption, unless EPA determines that consumption of legally treated food during the period of its likely availability in commerce will pose unreasonable dietary risk. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

III. Proposed Rule

EPA is proposing to revoke the tolerance exemption for use of polytetrafluoroethylene (CAS No. 9002-84-0), also known as Teflon[®], as an inert ingredient in pesticide products under the 40 CFR 180.960. This action is being taken because polytetrafluoroethylene, which has been identified as a per- and polyfluoroalkyl substance (PFAS), is no longer used in any registered pesticide product.

PFAS are synthetic organic compounds that do not occur naturally in the environment but have widespread use in commerce. The strong carbon-fluorine bonds of PFAS make some of them resistant to degradation and thus highly persistent in the environment. Some PFAS have been detected in wildlife and in humans, indicating that at least some PFAS have the ability to bioaccumulate. All pesticide products registered in the United States that

initially used polytetrafluoroethylene as an inert ingredient have been cancelled or reformulated to no longer contain polytetrafluoroethylene. Therefore, there are no current registrations for pesticide products containing polytetrafluoroethylene as an inert ingredient.

After the close of the comment period, EPA will consider all comments received and determine an appropriate final action.

IV. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revoke a specific tolerance exemption under its authority in FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted this type of action (*e.g.*, tolerance exemption revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993) and updated by Executive Order 14094, entitled “Modernizing Regulatory Review” (88 FR 21879, April 11, 2023). Because this proposed rule has been exempted from review under Executive Order 12866, due to its lack of significance, this proposed rule 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). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) or 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.*). Nor does it require any special considerations as required under Executive Order 14096, entitled “Revitalizing our Nation’s Commitment to Environmental Justice for All” (88 FR 25251, April 26, 2023); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule 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*).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might

significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published in the **Federal Register** of December 17, 1997 (62 FR 66020) (FRL–5753–1) and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticide named in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document titled “RFA/SBREFA Certification for Import Tolerance Revocation” is available in the docket of this proposed rule.) Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA’s previous analysis. Any comments about the Agency’s determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Executive Order 13132, requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food

retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175, does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: July 10, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be 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. Amend § 180.960, by removing the inert ingredient “polytetrafluoroethylene” identified by CAS No. 9002–84–0 from Table 1 to § 180.960.

[FR Doc. 2024–15564 Filed 7–15–24; 8:45 am]

BILLING CODE 6560–50–P