

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the SCAQMD rule listed in Table 1 of this preamble, which is designed to decrease NO_x and VOC emissions from industries such as petroleum refineries, sulphur recovery plants, and hydrogen production plants by controlling and minimizing flaring and flare related emissions in the South Coast Air Basin. The EPA has made, and will continue to make, these materials available through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” The EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate

matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 29, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0208; FRL-11678-01-OCSPP]

RIN 2070-ZA16

Tetraacetythylenediamine (TAED), and Its Metabolite Diacetythylenediamine (DAED); Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to exempt residues of the antimicrobial pesticide ingredient Tetraacetythylenediamine (TAED), including its metabolites and degradates, from the requirement of a tolerance when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), in order to implement the tolerance actions EPA identified during its review of these chemicals as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: Comments must be received on or before May 7, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2023-0208, 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 Confidential Business Information (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>.

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

FOR FURTHER INFORMATION CONTACT:

Anita Pease, Antimicrobials Division (7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-0736; email address: pease.anita@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 a 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:

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).
- Restaurant kitchen cleaning services (NAICS code 561720).
- Milk production, dairy cattle (NAICS code 112120).
- Food processing machinery and equipment merchant wholesalers (NAICS code 423830).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. What action is the Agency taking?

EPA is proposing to establish an exemption from the requirement of a

tolerance for residues of the antimicrobial pesticide tetraacetythylenediamine (TAED) and its metabolites and degradates on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

EPA is proposing this tolerance action to implement the tolerance changes identified as necessary during the registration review processes to cover these pesticide chemical residues when used in antimicrobial formulations consistent with current label use directions. Registration review documents, such as the draft risk assessment, typically identify certain tolerance actions, including modifications to reflect current use patterns, meet safety findings, and change commodity names and groupings that may be necessary or appropriate to cover pesticide chemical residues or reflect current EPA policy.

For the pesticide chemicals at issue in this rulemaking, EPA issued the *TAED Interim Registration Review Decision* (TAED ID) in April 2020. Electronic copies of the TAED ID and other documents are available in EPA docket number EPA-HQ-OPP-2013-0608, which can be found on <https://www.regulations.gov>. EPA's risk assessment for TAED contains the Agency's assessment of the potential risk associated with current product uses, and based on the findings of that risk assessment, the TAED ID identified the need to establish exemptions from the requirement of a tolerance for residues of tetraacetythylenediamine (TAED) when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils.

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

Section 408(e) of the FFDCA authorizes EPA to establish exemptions from the requirement of a tolerance. 21 U.S.C. 346a(e)(1)(B). Before issuing the final exemption, EPA is required to issue a proposed rulemaking and provide a comment period of "not less than 60 days". *Id.* at 346a(e)(2).

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment, modification, and revocation of tolerances and exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Residues of pesticides in or on food that are not covered by a tolerance

or exemption are deemed unsafe, 21 U.S.C. 408(a), and any food containing unsafe residues is considered "adulterated" under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a). For a food-use pesticide to be sold and distributed in the United States, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA, 7 U.S.C. 136 *et seq.* Moreover, residues of food-use pesticides not registered in the United States must also be covered by a U.S. tolerance or exemption in order for commodities treated with those pesticides to be imported into the United States.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of 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(c)(2)(A)(ii) of the 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." 21 U.S.C. 346a(c)(2)(A)(ii). This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) of the FFDCA requires EPA, when making a safety determination concerning an exemption, to take into account, among other relevant considerations, the considerations listed in section 408(b)(2)(C) and (D) of the FFDCA. Section 408(b)(2)(C) of the 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. . . ." Section 408(b)(2)(D) identifies various factors, including available information on aggregate and cumulative exposure, for EPA consideration in making a safety determination.

C. When do these actions become effective?

EPA is proposing that these tolerance actions become effective on the date of publication of the final rule in the **Federal Register**.

III. Proposed Rule

EPA is proposing this rule to implement the tolerance actions

identified in the TAED ID. EPA, on its own initiative, is proposing to establish the necessary exemption under 40 CFR 180.940(a), which would cover all food-contact uses of tetraacetythylenediamine (TAED), from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

In order to establish tolerances or exemptions from the requirement of a tolerance, EPA is required to determine that each tolerance or exemption meets the safety standard of FFDCFA. In its risk assessment supporting the TAED ID, EPA considered the potential risks from exposure to tetraacetythylenediamine (TAED) from registered uses and concluded that those uses did not present risks of concern. See U.S. EPA, Registration Review Draft Risk Assessment for: TAED, available at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2013-0608.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCFA 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 to support the establishment of an exemption from the requirement of a tolerance for residues of tetraacetythylenediamine (TAED) and its metabolites and degradates.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction

with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime.

EPA's risk assessment for tetraacetythylenediamine (TAED), can be found in full at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2013-0608. That risk assessment explains EPA's analysis of the toxicity of the pesticide chemicals as well as the selection of toxicological points of departure and levels of concern for use in evaluating the risk posed by human exposure to the pesticide.

TAED exhibits low hazard via the oral route of exposure. The Agency anticipates exposures to negligible levels of TAED residues from food transfer based on the chemical properties and the rapid degradation of the chemical to form peroxyacetic acid (PAA). TAED is a bleach activator and reacts with an oxygen activator (e.g., sodium percarbonate) and undergoes rapid hydrolysis under alkaline conditions to yield PAA, hydrogen peroxide, and diacetythylenediamine (DAED). A short-lived, intermediate triacetyl ethylene diamine (triAED) is formed prior to DAED. The remaining acetyl groups on DAED cannot be further displaced by peroxide. TAED is essentially a carrier molecule for PAA, the active moiety. When formed, PAA and hydrogen peroxide are extremely powerful oxidizers and are the active components that will exhibit pesticidal activity.

In addition, EPA's risk assessment considered exposure to TAED based on the maximum label rate for commercial use of TAED as an antimicrobial or biochemical product.

Based on the Agency's risk assessment, no dietary or aggregate risks of concern were identified for tetraacetythylenediamine (TAED) or its metabolites or degradates. The physical-chemical properties of both TAED and DAED are very similar and TAED largely metabolizes to DAED *in vivo*. DAED is expected to be of similar or less toxicity than TAED and will be present in reduced quantities compared to TAED. Although TAED use may result in indirect dietary food contact, based on its chemical properties, TAED is expected to rapidly form peracetic acid to impart antimicrobial action needed to disinfect or sanitize surfaces.

Residues of peracetic acid have been determined to be safe, as confirmed by the Peroxy Compounds Registration Review Case. Information regarding the Peroxy Compounds Registration Review Case can be found using docket ID EPA-HQ-OPP-2009-0546 at <https://www.regulations.gov>. Therefore, the Agency anticipates negligible residues to be available for transfer to food and a quantitative chronic dietary exposure and risk assessment was not conducted.

Based on the lack of any aggregate risks of concern, EPA concludes that this exemption from the requirement of a tolerance for residues of TAED, including its metabolites and degradates, is safe, *i.e.*, there is a reasonable certainty that no harm will result from aggregate exposures to TAED, when used in accordance with the terms of the respective exemptions. In addition, due to the lack of toxicity, EPA has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues, in accordance with FFDCFA section 408(b)(2)(C).

V. Conclusion

Therefore, EPA is proposing to establish an exemption in 40 CFR 180.940(a) for residues of the antimicrobial pesticide ingredient TAED, including its metabolites and degradates, from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

VI. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to exempt residues of the antimicrobial pesticide ingredient TAED, including its metabolites and degradates, from the requirement of a tolerance under FFDCFA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions (e.g., establishment and modification of a tolerance and tolerance 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). 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 by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); 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 establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations 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. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the **Federal Register** of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL-5753-1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed 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. 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: February 29, 2024.

Michael Goodis,
Deputy Director, Office of Pesticide Programs.

Therefore, 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. In § 180.940, amend table 1 to paragraph (a) by adding, in alphabetical order, an entry for “Tetraacetythylenediamine (TAED)” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

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TABLE 1 TO PARAGRAPH (a)

Pesticide chemical	CAS reg. No.	Limits
* * * * *	* * * * *	* * * * *
Tetraacetythylenediamine (TAED)	10543-57-4	None.
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