

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. Amend § 16.1 by revising paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(1) The statutory provisions are as follows:

TABLE 1 TO PARAGRAPH (b)(1)

Section 304(g) of the Federal Food, Drug, and Cosmetic Act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.980(g) of this chapter).

Section 304(h) of the Federal Food, Drug, and Cosmetic Act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

Section 515(e)(1) of the Federal Food, Drug, and Cosmetic Act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the Federal Food, Drug, and Cosmetic Act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the Federal Food, Drug, and Cosmetic Act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the Federal Food, Drug, and Cosmetic Act relating to revocation of a notice of completion of a product development protocol.

Section 516(b) of the Federal Food, Drug, and Cosmetic Act regarding a proposed regulation to ban a medical device with a special effective date.

Section 518(b) of the Federal Food, Drug, and Cosmetic Act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the Federal Food, Drug, and Cosmetic Act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the Federal Food, Drug, and Cosmetic Act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(2)(E) of the Federal Food, Drug, and Cosmetic Act relating to exemptions or variances from tobacco product manufacturing practice requirements.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

* * * * *

§ 16.1 [Amended]

■ 3. Effective December 18, 2025, in § 16.1, amend paragraph (b)(2) by redesignating table 1 to paragraph (b)(2) as table 2 to paragraph (b)(2).

Dated: September 6, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–21231 Filed 9–19–24; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2024–0032; FRL–11685–02–R9]

Air Plan Revisions; California; San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Diego County Air Pollution Control District (SDCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns a rule submitted to address section 185 of the Clean Air Act (CAA or “Act”).

DATES: This rule is effective October 21, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2024–0032. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact

the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kira Wiesinger, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; phone: (415) 972–3827; email: wiesinger.kira@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us” and “our” refer to the EPA.

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I. Proposed Action

On April 2, 2024 (89 FR 22648), the EPA proposed to approve the following rule into the California SIP.

TABLE 1—SUBMITTED RULE

Local agency	Rule	Rule title	Adopted	Submitted
SDCAPCD	45	Federally Mandated Ozone Nonattainment Fees.	06/09/2022	07/20/2022

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period. During this period, we received two comments from members of the public. One comment was supportive of our proposed action. We thank the commenter for their support and input. The other comment was not germane to this action.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of SDCAPCD Rule 45, “Federally Mandated Ozone Nonattainment Fees,” adopted on June 9, 2022, which addresses the CAA section 185 fee program requirements. The EPA has made, and will continue to make, these documents available through 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).

V. 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 action merely approves state law as meeting federal requirements and does not impose

additional requirements beyond those imposed by state law. For that reason, this 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 approves 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, February 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and

permitted by law. The EPA defines 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 EJ 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 EJ for communities with EJ concerns.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 19, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and

recordkeeping requirements, Volatile organic compounds.

Dated: September 16, 2024.

Martha Guzman Aceves,
Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(615) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(615) The following regulation was submitted electronically on July 20, 2022, by the Governor's designee as an attachment to a letter of the same date.

(i) *Incorporation by reference.*

(A) San Diego County Air Pollution Control District.

(1) Rule 45, "Federally Mandated Ozone Nonattainment Fees," adopted on June 9, 2022.

(2) [Reserved]

(B) [Reserved]

(ii) [Reserved]

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[FR Doc. 2024–21494 Filed 9–19–24; 8:45 am]

BILLING CODE 6560–50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 1068

General Compliance Provisions for Highway, Stationary, and Nonroad Programs

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 40 of the Code of Federal Regulations, Part 1060 to End, revised as of July 1, 2024, amend § 1068.250 by reinstating paragraph (i) to read as follows:

§ 1068.250 Extending compliance deadlines for small businesses under hardship.

* * * * *

(i) We may include reasonable requirements on an approval granted under this section, including provisions to recover or otherwise address the lost environmental benefit. For example, we may require that you meet a less stringent emission standard or buy and use available emission credits.

* * * * *

[FR Doc. 2024–21640 Filed 9–19–24; 8:45 am]

BILLING CODE 0099–10-P

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 300–3, 301–11, 301–50, 301–52, 301–70, 301–71, and 301–73

[FTR Case 2023–03; Docket No. GSA–FTR–2023–0023, Sequence No. 2]

RIN 3090–AK66

Federal Travel Regulation; Updating Glossary of Terms and E-Gov Travel Service Requirements

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: GSA is issuing a final rule amending the Federal Travel Regulation (FTR) to remove outdated information on deployment of the original E-Gov Travel Service (ETS) contract as agencies prepare for the next generation of ETS, known as ETSNext, to provide updated policy, and make miscellaneous editorial corrections.

DATES: Effective October 21, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl D. McClain-Barnes, Office of Government-wide Policy at 202–208–4334 or email at travelpolicy@gsa.gov for clarification of content. For information pertaining to the status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov. Please cite FTR case 2023–03.

SUPPLEMENTARY INFORMATION:

I. Background

In November 2003, GSA's Federal Acquisition Service awarded master contracts for the first iteration of ETS, a web-based end-to-end travel management service. GSA published FTR Amendment 2003–07 (68 FR 71026) in December 2003, to amend the FTR on the required use of the new travel service. The original ETS implementation policies included

timelines with specific dates for agencies to deploy ETS and migrate to the new platform. This information regarding ETS implementation is no longer needed because all mandatory users have deployed ETS (either initially, or upon expiration of an exception to its use) since it became available to civilian agencies in the first quarter of 2004.

Contracts awarded under ETS2, the second iteration of ETS, are set to expire in June 2027. GSA published a proposed rule (88 FR 89650) on December 28, 2023, seeking to amend the FTR to remove outdated policy and provide updated policy as agencies prepare for the implementation of the next generation of ETS known as "E-Gov Travel Service, Next Generation" or "ETSNext" for short. Accordingly, this rule finalizes the proposed changes to FTR parts 300–3, 301–11, 301–50, 301–52, 301–70, 301–71, and 301–73. GSA is also amending the FTR to make minor editorial changes for clarity.

Specifically, GSA is relocating a definitional term at § 301–50.6, namely "online self-service booking tool," to part 300–3, "Glossary of Terms," and updating the definition; renaming the term "Online booking tool (OBT);" and renumbering sections in part 301–50 in logical order. GSA is further updating the "Glossary of Terms" by capitalizing the initialism "ETS" in the body of the definition of "E-Gov Travel Service (ETS)" to be consistent with the definition heading.

GSA is also removing and reserving § 301–73.101 and relocating relevant language from note 1 of the section regarding agency funding responsibility for ETS to a note to § 301–73.2. Further, GSA is revising the note to § 301–73.106 to remove duplicate text regarding travel agent services that align with present requirements for ETS2, but may not align with the terms of successor travel management service contract(s). Finally, GSA is adding a reference to the "extenuating circumstances" exception to the use of ETS and Travel Management Service (TMS) to existing exceptions at §§ 301–50.4 and 301–73.102.

II. Discussion of the Final Rule

A. Summary of Significant Changes

GSA has not made any significant changes to the regulatory language from the proposed to final rule. However, of note, the proposed rule duplicated some technical changes to an FTR final rule that took effect on April 16, 2024 (89 FR 12250); GSA removed these duplicate technical changes from this final rule as