

§ 720.8 Confidentiality of statements.

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(e) If, after receiving all of the data that are necessary to make a determination about whether the identity of an ingredient is a trade secret, FDA tentatively decides to deny the request, the Agency will inform the person requesting trade secrecy of its tentative determination in writing. FDA will set forth the grounds upon which it relied in making this tentative determination. The petitioner may submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the Agency reconsider its decision in light of both the additional material and the information that it originally submitted.

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(g) A final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter constitutes final Agency action that is subject to judicial review under 5 U.S.C. Chapter 7. If suit is brought within 30 calendar days after such a determination, FDA will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts. If suit is not brought within 30 calendar days after a final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter, the records involved will be available for public disclosure in accordance with part 20 of this chapter.

Dated: August 31, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–19736 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0628]

Special Local Regulations; Marine Events Within the Seventh Coast Guard District

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Captain of the Port (COTP) Savannah, Georgia will enforce a special local regulation for the

Ironman Triathlon in Augusta, Georgia, on September 25, 2022, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated area for this event in Augusta, GA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.701 will be enforced for the location identified in Section (d), Item 3 of Table 1 to § 100.701, from 6:30 a.m. until 10:30 a.m., on September 25, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, contact Coast Guard Marine Safety Unit Savannah, Office of Waterways Management, by calling or emailing MSTC Ashley Schad, telephone 912–652–4353 ext 242, or email Ashley.M.Schad@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation in 33 CFR 100.701, Table 1 to § 100.701, Section (d), Item 3, for the Ironman Triathlon, from 6:30 a.m. to 10:30 a.m., on September 25, 2022.

This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District, 33 CFR 100.701, specifies the location of the regulated area for the Ironman Triathlon which encompasses portions of the Savannah River and its branches. During the enforcement periods, as reflected in 33 CFR 100.701(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

K.A. Broyles,

Commander, U.S. Coast Guard, Captain of the Port Savannah.

[FR Doc. 2022–19741 Filed 9–12–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0653]

Special Local Regulation; Marine Events Within the Eleventh Coast Guard District—San Diego Bayfair

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the waters of Mission Bay, CA, during the San Diego Bayfair on September 16, 2022, through September 18, 2022. This special local regulation is necessary to provide for the safety of the participants, crew, sponsor vessels of the event, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 for the location listed in Item 9 in table 1 to § 100.1101 will be enforced from 6 a.m. until 6 p.m., each day from September 16, 2022, through September 18, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Junior Grade Shera Kim, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the location identified in Item 9 in table 1 to § 100.1101, from 6 a.m. until 6 p.m., each day from September 16, 2022 through September 18, 2022, for the San Diego Bayfair in Mission Bay, CA. This action is being taken to provide for the safety of life on the navigable waterways during the event. Our regulation for recurring marine events in the San Diego Captain of the Port Zone, § 100.1101, Item No. 9 in table 1 to § 100.1101 specifies the location of the regulated area for the San Diego Bayfair, which encompasses portions of Mission Bay. Under the provisions of § 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area

unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: September 7, 2022.

J.W. Spittler,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2022–19764 Filed 9–12–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0443; FRL–10193–02–R1]

Air Plan Approval; Rhode Island; Prevention of Significant Deterioration Infrastructure State Implementation Plan Elements for the 2012 PM_{2.5} NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving three elements of a State Implementation Plan (SIP) revision, which was submitted by the State of Rhode Island on December 6, 2017. This revision addressed the infrastructure requirements of the Clean Air Act (CAA or the Act) for the 2012 annual fine particle (PM_{2.5}) National Ambient Air Quality Standard (NAAQS). On May 31, 2022, EPA approved much of the submission, but did not act on three elements related to the infrastructure requirement to have a comprehensive Prevention of Significant Deterioration (PSD) program. In today's action, EPA is approving the three remaining elements of the state's December 2017 infrastructure SIP submittal based on a previous EPA approval of Rhode Island's Air Pollution Control Regulation (APCR) No. 9. This action is being taken in accordance with the Clean Air Act.

DATES: This direct final rule will be effective November 14, 2022, unless EPA receives adverse comments by October 13, 2022. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the

Federal Register informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2017–0443 at <https://www.regulations.gov>, or via email to simcox.alison@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109–3912, tel. (617) 918–1684, email simcox.alison@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

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I. Background and Purpose

On December 6, 2017, Rhode Island submitted a SIP submission addressing the “infrastructure” SIP requirements of the Clean Air Act (CAA or Act) for the 2012 annual PM_{2.5}¹ NAAQS.

Infrastructure SIP requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA for implementation of the NAAQS. On February 1, 2019, EPA published a Notice of Proposed Rulemaking proposing to approve most elements of the submission and to conditionally approve the submission for the infrastructure SIP requirement in CAA sections 110(a)(2)(C), (D)(i)(II), and (J) to have a complete Prevention of Significant Deterioration (PSD) permitting program.² See 84 FR 1025.

On May 31, 2022 (87 FR 32316), EPA published a Notice of Final Rulemaking (NFRM) finalizing approval of most elements of the infrastructure SIP for the 2012 PM_{2.5} NAAQS but withdrawing the proposed conditional approvals of the above-mentioned requirements in section 110(a)(2)(C), (D)(i)(II), and (J) related to the state's PSD program and taking no further action on those elements. EPA stated that it would issue a separate action at a future date providing an evaluation of Rhode Island's SIP for these PSD-related requirements for the 2012 annual PM_{2.5} NAAQS. The reasons for that action are given in the NFRM and are not restated here. See 87 FR 32316.

In this action, EPA is approving Rhode Island's SIP for the PSD-related infrastructure SIP requirements of section 110(a)(2)(C), (D)(i)(II), and (J) for the 2012 annual PM_{2.5} NAAQS. To

¹ PM_{2.5} refers to particulate matter of 2.5 microns or less in diameter, often referred to as “fine” particles.

² In particular, EPA noted that Rhode Island's SIP did not yet incorporate: (1) a requirement to identify NO_x as a precursor to ozone in the definition of “major stationary source” from EPA's “Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2; Final Rule to Implement Certain Aspects of the 1990 Amendments Relating to New Source Review and Prevention of Significant Deterioration as They Apply in Carbon Monoxide, Particulate Matter, and Ozone NAAQS; Final Rule for Reformulated Gasoline,” 70 FR 71612 (November 29, 2005); and (2) definitional changes required under an EPA Rule entitled “Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5})—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration”, 75 FR 64864 (October 20, 2010); see 84 FR 1025 at 1027–28 (February 1, 2019). EPA had previously found, in the context of infrastructure SIP actions on other criteria pollutants, that Rhode Island's SIP did not incorporate these requirements. See, e.g., 81 FR 58849 (August 26, 2016); 81 FR 23175 (April 20, 2016).