

States to consider and sign the updated standard MOU.

FDA is now extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that have not entered into a standard MOU with FDA until the effective date of a final rule regarding certain distributions of compounded human drug products under section 503A of the FD&C Act and publication of an updated standard MOU.¹

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2022-0870]

Special Local Regulations Northern California and Lake Tahoe Area Annual Marine Events; Sacramento Ironman Swim, Sacramento, CA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the annual Sacramento Ironman Triathlon marine event on October 23, 2022, to provide for the safety of life on navigable waterways in the Sacramento River during this event. Our regulation for marine events in Northern California identifies the regulated area for this event. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or loitering or anchoring in the regulated area, unless authorized by the designated Patrol Commander (PATCOM) or other Federal, State, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulations in 33 CFR 100.1103 will be enforced for the location listed in Table 1 to § 100.1103, Item number 5 from 6 a.m. to 10 a.m. on October 23, 2022.

¹ The Office of the Federal Register has published this document under the category "Rules and Regulations" pursuant to 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the legal content or intent of the document. See, 1 CFR 5.1(c).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony I. Solares, Sector San Francisco Waterways Management, U.S. Coast Guard; telephone 415-399-3585, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1103, Table 1 to § 100.1103, Item number 5 for the Sacramento Ironman Swim regulated area from 6 a.m. to 10 a.m. on October 23, 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 Northern California, § 100.1103, specifies the location of the regulated area for the Sacramento Ironman Swim which encompasses portions of the American River and Sacramento River. During the enforcement period, the regulated area will be in effect in the navigable waters of the American River and Sacramento River from Township 9 Park to North of Tower Bridge.

During the enforcement period, under the provisions of 33 CFR 100.1103(b), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander (PATCOM) or any other Official Patrol, defined as a Federal, State, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. During the enforcement period, if you are the operator of a vessel that participates in the marine event within the regulated area, you must follow the route established by the marine event sponsor, and comply with directions from the Patrol Commander or other Official Patrol. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: October 17, 2022.

Jordan M. Balduenza,

Captain, U.S. Coast Guard, Alternate Captain of the Port, San Francisco.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0853]

RIN 1625-AA11

Safety Zone; Oil Pipeline Repairs, San Pedro Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the oil pipeline repair operations in the vicinity of a damaged pipeline, off the coast of Orange County and near San Pedro Bay, CA. The safety zone is necessary to reduce significant hazards to vessels, the harbor, and the public during ongoing pipeline repair. Entry of persons or vessels into this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port Sector Los Angeles—Long Beach, or his designated representative.

DATES: This rule is effective without actual notice from October 21, 2022 through December 24, 2022. For the purposes of enforcement, actual notice will be used from October 10, 2022, until October 21, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0853 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357-1603, email Maria.C.Wiener@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision

authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because that is impracticable. It is impracticable to publish an NPRM, because we must establish this safety zone by October 10, 2022, to ensure the safety of response personnel and mariners during repairs of the damaged pipeline.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the pipeline repair operations for the damaged pipeline.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Los Angeles—Long Beach (COTP) has determined that potential hazards associated with the pipeline repair and potential oil recovery operations in the vicinity of the damaged pipeline will be a safety concern for anyone within a 750-yard radius from coordinates 33°38′51.072″ N, 118°06′43.146″ W. This rule is necessary to safeguard the public during repair operations; it would be impracticable for the Coast Guard to provide a public comment period on due to the updated repair schedule.

IV. Discussion of the Rule

This rule establishes a safety zone effective from October 10, 2022, to December 24, 2022. The safety zone will encompass all navigable waters from the surface to the sea floor in an area bound within a 750-yard radius from surface to sea bottom from 33°38′51.072″ N, 118°06′43.146″ W. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

To seek permission to enter, hail Coast Guard Sector Los Angeles—Long Beach on VHF—FM Channel 16 or call the 24-hour Command Center at (310) 521–3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.

The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate for the enforcement times and dates for the safety zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order.

This regulatory action determination is based on the size, location, and duration, and time-of-day of the safety zone. This safety zone will impact a 750-yard area of Newport Beach, CA for three months. The zone will be enforced 24 hours per day, but vessel traffic will be able to safely transit around the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have

determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone effective on October 10, 2022, until December 24, 2022, within a 750-yard radius from coordinates 33°38'51.072" N, 118°06'43.146" W. It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1. Revision No. 01.2.

■ 2. Add § 165. T11-113 to read as follows:

§ 165. T11-113 Safety Zone; Oil Pipeline Repairs, San Pedro Bay, CA.

(a) *Location.* The safety zone encompasses all navigable waters from the surface to the sea floor in a 750-yard radius from coordinates 33°38'51.072" N, 118°06'43.146" W.

(b) *Definitions.* For the purposes of this section:

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer designated by or assisting the Captain of the Port Sector Los Angeles—Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in § 165.23 of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail Coast Guard Sector Los Angeles—Long Beach on VHF-FM Channel 16 or call the 24-hour Command Center at (310) 521-3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is effective from October 10, 2022, through December 24, 2022. It will be enforced from midnight to midnight each day.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and dates for the safety zone.

Dated: October 7, 2022.

R.D. Manning,

Captain, U.S. Coast Guard, Captain of the Port Sector Los Angeles Long Beach.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA-HQ-OPPT-2018-0155; FRL-6004-02-OCSP]P]

RIN 2070-AK42

Parent Company Definition for Toxics Release Inventory (TRI) Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a rule to codify the definition of “parent company” for purposes of reporting to the Toxics Release Inventory (TRI) and to require the reporting of a foreign parent company when applicable. The existing regulation requires facilities reporting to TRI to identify their parent company in annual reporting forms. This rule adds a codified definition of this data element. Among the facilities reporting to TRI are those with complicated corporate ownership structures. As such, effort is required each year by reporting facilities and EPA to clarify how the parent company data element should be represented on the form. A codified definition of parent company will allow EPA to address various corporate ownership scenarios explicitly and will reduce the reporting burden caused by regulatory

uncertainty. This rule clarifies existing requirements to reporting facilities and adds a foreign parent company data element, while improving the Agency's data quality.

DATES: This final rule is effective on December 20, 2022.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPPT-2018-0155, is available online at <https://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC). Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Stephanie Griffin, Data Gathering and Analysis Division, (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: griffin.stephanie@epa.gov.

For general information contact: The Emergency Planning and Community Right-to-Know Information Center; telephone number: (800) 424-9346, TDD (800) 553-7672; website: <https://www.epa.gov/aboutepa/epa-hotlines#epcraic>.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if your facility submits annual reports under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. 11023, and section 6607 of the Pollution Prevention Act (PPA), 42 U.S.C. 13106, to EPA and States or Tribes of the facility's environmental releases or other waste management quantities of covered chemicals. (Pursuant to 40 CFR 372.30(a), facilities located in Indian country are required to report to the appropriate tribal government official and EPA instead of to the State and EPA. See April 19, 2012 (77 FR 23409) (FRL-9660-9)). To determine whether your facility is affected by this action, you should carefully examine the applicability criteria in 40 CFR part 372, subpart B. 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.