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#### SUPPLEMENTARY INFORMATION:

### I. Background

We are announcing the availability of a draft guidance for industry entitled “Determining the Number of Employees for Purposes of the ‘Small Business’ Definition in Parts 117 and 507: Guidance for Industry.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

This draft guidance concerns two regulations that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (Pub. L. 111-353). These two regulations are 21 CFR part 117 (part 117) (published in the **Federal Register** on September 17, 2015, 80 FR 55907) and 21 CFR part 507 (part 507) (published in the **Federal Register** on September 17, 2015, 80 FR 56170). Under parts 117 and 507, whether a business is a “small business” has two main implications. First, certain small businesses are exempt from the human food preventive controls requirements and the animal food preventive controls requirements if they are engaged only in specified low-risk activity/food combinations. Second, small businesses have later compliance dates for parts 117 and 507 than larger businesses. This guidance will provide additional information to assist businesses in determining their status as a “small business.”

### II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-05705 Filed 3-19-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 147

[Docket Number USCG-2017-0446]

RIN 1625-AA00

### Safety Zone; Appomattox FPS, Mississippi Canyon 437, Outer Continental Shelf on the Gulf of Mexico

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a safety zone around the Appomattox Floating Production System (FPS) facility located in Mississippi Canyon Block 437 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility will significantly reduce the threat of allisions, collisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before April 19, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2017-0446 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Ms. Laura Knoll, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504-671-2139, [laura.b.knoll@uscg.mil](mailto:laura.b.knoll@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

#### I. Table of Abbreviations

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FPS Floating production system  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 OCS Outer Continental Shelf  
 § Section  
 U.S.C. United States Code

### II. Background, Purpose, and Legal Basis

Under the authority provided in 14 U.S.C. 85, 43 U.S.C. 1333, and Department of Homeland Security Delegation No. 0170.1(90), Title 33, CFR 147.1, 147.5, and 147.10 permit the establishment of safety zones for facilities located on the Outer Continental Shelf (OCS) for the purpose of protecting life and property on the facilities, their appurtenances and attending vessels, and on the adjacent waters within the safety zones.

The safety zone proposed by this rulemaking is on the OCS in the deepwater area of the Gulf of Mexico at Mississippi Canyon Block 437. The area for the safety zone would be 500 meters (1640.4 feet) from each point on the facility, which is located at 28°34'25.47" N, 87°56'03.11" W. The deepwater area would be considered to be waters of 304.8 meters (1,000 feet) or greater depth extending to the limits of the Exclusive Economic Zone (EEZ) contiguous to the territorial sea of the United States and extending to a distance up to 200 nautical miles from the baseline from which the breadth of the sea is measured. The deepwater area would also include an extensive system of fairways. Navigation in the vicinity of the safety zone consists of large commercial shipping vessels, fishing vessels, cruise ships, tugs with tows and the occasional recreational vessels. The establishment of this safety zone will not interfere with these vessels' navigation in the area.

### III. Discussion of Proposed Rule

Shell Exploration and Production Co. requested that an OCS safety zone extending 500 meters from each point on the Appomattox Floating Production System (FPS) facility structure's outermost edge be established. There are safety concerns for both the personnel aboard the facility and the environment. The District Commander has determined that it was highly likely that any allision with the facility would result in a catastrophic event. Placing a safety zone around the facility will significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the living marine resources.

In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including but not limited to (1) the level of the existing and foreseeable shipping activity, the presence of unusually harmful or hazardous substances and obstructions within 500 meters of the

facility, (2) safety concerns for personnel aboard the facility, (3) concerns for the environment, (4) the likelihood that an allision would result in a catastrophic event based on the proximity to shipping fairways, offloading operations, production levels, and size of the crew, (5) the volume of traffic in the vicinity of the proposed safety zone, (6) the types of vessels navigating in the vicinity of the proposed area, and (7) the structural configuration of the facility.

Results from a thorough and comprehensive examination of the criteria, International Maritime Organization (IMO)'s guidelines, and existing regulations, warrant the establishment of a safety zone of 500 meters around the facility. The proposed safety zone would significantly reduce the threat of allisions, oil spills, and releases of natural gas, and increase the safety of life, property, and the environment in the Gulf of Mexico by prohibiting entry into the zone. Only vessels measuring less than 100 feet in length overall and not engaged in towing, attending vessels as defined in 33 CFR 147.20, or those vessels specifically authorized by the Eighth Coast Guard District Commander or a designated representative would be permitted to enter the proposed safety zone.

#### IV. Regulatory Analyses

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

##### 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM 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 13771.

This regulatory action determination is based on the safety zone's location and its distance from both land and safety fairways. This proposed rule is not a significant regulatory action due to

the location of the Appomattox FPS, on the Outer Continental Shelf, and its distance from both land and safety fairways. Vessels traversing waters near the proposed safety zone would be able to safely travel around the zone using alternate routes. Exceptions to this proposed rule would include vessels measuring less than 100 feet in length overall and not engaged in towing. The Eighth Coast Guard District Commander, or a designated representative, would consider requests to transit through the proposed safety zone on a case-by-case basis.

##### 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 proposed rule would 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 IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator. This proposed safety zone would not have a significant economic impact or a substantial number of small entities for the following reasons. Vessel traffic can pass safely around the safety zone using alternate routes. Based on the limited scope of the safety zone, any delay resulting from using an alternate route is expected to be minimal depending on vessel traffic and speed in the area. Additionally, exceptions to this proposed rule would include vessels measuring less than 100 feet in length overall and not engaged in towing, as well as any attending vessel, as defined in 33 CFR 147.20. Entry into and transit through the proposed safety zone could be requested. Such requests would be considered on a case-by-case basis and may be authorized by the Eighth Coast Guard District Commander or a designated representative.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it

qualifies and how and to what degree this rule would economically affect it.

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 proposed 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

##### C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

##### 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

proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have made a preliminary determination 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 proposed rule involves establishing a safety zone around an offshore deepwater facility. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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.

#### V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

#### List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 147 as follows:

#### PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

**Authority:** 14 U.S.C. 85; 43 U.S.C. 1333; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.869 to read as follows:

#### § 147.869 Safety Zone; Appomattox FPS Facility, Outer Continental Shelf on the Gulf of Mexico

(a) *Description.* The Appomattox Floating Production System (FPS) system is in the deepwater area of the Gulf of Mexico at Mississippi Canyon Block 437. The facility is located at 28°34'25.47" N, 87°56'03.11" W (NAD 83), and the area within 500 meters (1640.4 feet) from each point on the facility structure's outer edge is a safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

- (1) An attending vessel, as defined by 33 CFR 147.20;
- (2) A vessel under 100 feet in length overall not engaged in towing; or
- (3) A vessel authorized by the Eighth Coast Guard District Commander.

Dated: March 9, 2018.

**Paul F. Thomas,**

*Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.*

[FR Doc. 2018-05605 Filed 3-19-18; 8:45 am]

**BILLING CODE 9110-04-P**