

In the **Federal Register** of August 24, 2016 (81 FR 57816), we announced the availability of several chapters (Chapters 1–5) of a multichapter draft guidance for industry entitled “Hazard Analysis and Risk-Based Preventive Controls for Human Food.” In the **Federal Register** of August 31, 2017 (82 FR 41364), we announced the availability of an additional chapter (Chapter 6). We now are announcing the availability of an additional draft chapter of this multichapter guidance for industry.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Hazard Analysis and Risk-Based Preventive Controls for Human Food”. 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.

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. The chapter that we are announcing in this document is entitled “Chapter 15—Supply-Chain Program for Human Food Products.”

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751.

## IV. 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Persons with access to the internet may obtain the draft guidance at either 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: January 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

[Docket Number USCG–2017–0993]

RIN 1625–AA00

### Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a recurring special local regulation for navigable waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet. This action is necessary to ensure the safety of the general public, spectators, vessels, and the marine environment from potential hazards during aerobatic maneuvers conducted by high-speed, low-flying airplanes and any high speed vessels performing inside of the regulated area during the Fort Lauderdale Air Show. This proposed rulemaking would prohibit persons and non-participant vessels from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before February 26, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG–2017–0993 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 Petty Officer Mara J. Brown, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email [Mara.J.Brown@uscg.mil](mailto:Mara.J.Brown@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, Purpose, and Legal Basis

The City of Fort Lauderdale notified the Coast Guard that it will be hosting the Fort Lauderdale Air Show annually on one weekend (Saturday and Sunday) during the month of May. The regulated area would cover all navigable waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and continues north for approximately six miles. The regulated area is intended to protect personnel, vessels, and the marine environment from potential hazards during aerobatic maneuvers by high speed, low flying airplanes and high speed vessels during the air show. Over the years, there have been unfortunate instances of aircraft mishaps during performances at various air shows around the world. Occasionally, these incidents result in a wide area of scattered debris in the water that can damage property or cause significant injury or death to the public observing the air shows. The Captain of the Port Miami has determined that a special local regulation is necessary to protect the general public from hazards associated with aerial flight demonstrations.

The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

## III. Discussion of Proposed Rule

This rule establishes a special local regulation on the waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and continuing north for approximately six miles. The duration of the regulated area is intended to ensure the safety of the public during the aerial flight demonstrations and high speed boat races. Non participant vessels are not permitted to enter, transit through, anchor in, or remain within the regulated area without obtaining permission from the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives. The regulatory text we are proposing appears at the end of this document.

#### IV. Regulatory Analyses

We developed this proposed 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. 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 size, location, duration, and time-of-day of the special local regulation. Vessel traffic would be able to safely transit around this special local regulation which would impact a small designated area of the Atlantic Ocean. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow 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 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 special local regulation 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.

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 Directive 023–01, which guides 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 a regulated area that would prohibit persons and vessels from transiting the regulated area during the air and sea show. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination will be available once we receive public comment for this rule and will be located in the docket 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, visit <http://www.regulations.gov/privacyNotice>.

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 100

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

#### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.726 to read as follows:

#### § 100.726 Special Local Regulation; Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL.

(a) *Regulated area.* The following area is a regulated area located on the Atlantic Ocean in Fort Lauderdale, FL. All waters of the Atlantic Ocean encompassed within an imaginary line connecting the following points: Starting at Point 1 in position 26°11'01" N, 080°05'42" W; thence due east to Point 2 in position 26°11'01" N, 080°05'00" W; thence south west to Point 3 in position 26°05'42" N, 080°05'35" W; thence west to Point 4 in position 26°05'42" N, 080°06'17" W; thence following the shoreline north back to the point of origin. These coordinates are based on North American Datum 1983.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.*

(1) All non participant vessels or persons are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area

unless authorized by the Captain of the Port Miami or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Miami by telephone at (305) 535–4472, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(d) *Enforcement period.* This rule will be enforced annually on one weekend (Saturday and Sunday) during the month of May. The exact dates and times will be published annually in the **Federal Register** through a Notice of Enforcement. Also, the Coast Guard may use Broadcast Notice to Mariners via VHF–FM channel 16 or on-scene oral notice to notify the public of the exact dates and time of enforcement.

Dated: January 4, 2018.

**M.M. Dean,**

*Captain, U.S. Coast Guard, Captain of the Port Miami.*

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