

viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, "Letter to Manufacturers, Distributors, or Importers of Bottled Water with an Update on Fluoride Added to Bottled Water" (April 27, 2015). Available at <https://www.fda.gov/food/guidanceregulation/guidance documents/regulatoryinformation/bottled water/carbonatedsoftdrinks/ucm444373.htm> (accessed March 29, 2022).
2. International Bottled Water Association Communication to H. Kim, FDA, Letter, 6/15/2018.
3. New Hampshire Department of Environmental Services, Environmental Fact Sheet: Fluoride in Drinking Water (2020). Available at <https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/2020-01/dwgb-3-5.pdf> (accessed March 29, 2022).
4. Centers for Disease Control and Prevention, "Community Water Fluoridation." Available at https://www.cdc.gov/fluoridation/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Ffluoridation%2Findex.htm (accessed March 29, 2022).
5. FDA, "Final Rule to Revise the Allowable Level of Fluoride in Bottled Water to which Fluoride Has Been Added, Economic Analysis of Impacts, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis." Available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (accessed March 29, 2022).

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

PART 165—BEVERAGES

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

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

- 2. Amend § 165.110 by revising paragraphs (b)(4)(ii)(C) and (D) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(C) Bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(D) Imported bottled water to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

* * * * *

Dated: April 8, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–08273 Filed 4–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0168]

Special Local Regulations; Conch Republic Navy Parade and Battle, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the Conch Republic Navy Parade and Battle in Key West, Florida. Our regulation for Recurring Marine Events in Seventh Coast Guard District identifies the regulated area for this event. During the enforcement period no person or vessel may enter into, transit through, anchor in, or remain within the regulated area without approval from the Captain of the Port Key West or a designated representative.

DATES: The regulations in 33 CFR 100.701 will be enforced for the location identified in paragraph (b) Item 2 of Table 1 to § 100.701, from 7 p.m. until 8 p.m. on April 22, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email SKWWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.701, Table 1 to § 100.701, paragraph (b), Item 2, from 7 p.m. until 8 p.m. on April 22, 2022 for the annual Conch Republic Navy Parade and Battle in Key West, Florida. This action is being taken to provide for the

safety of life on the navigable waters of the Key West Harbor during the simulated battle event. Our regulation for Recurring Marine Events within Seventh Coast Guard District, § 100.701, Table 1 to § 100.701, paragraph (b), Item 2, specifies the location of the regulated area for the reenactment of the battle within the Key West Harbor.

During the enforcement period, as reflected in § 100.701, no person or vessel may enter, transit through, anchor within, or remain within the established regulated areas without approval from the Captain of the Port Key West or 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 notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notice of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: April 12, 2022.

Adam A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2022–08423 Filed 4–19–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0233]

RIN 1625–AA00

Safety Zones; Cape Canaveral, Daytona, Tampa, Jacksonville, and Tallahassee, Florida

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing five temporary safety zones for the reentry of capsules launched by Space Exploration Technologies Corporation (Space X) in support of the Axiom and the National Aeronautics and Space Administration (NASA) Crew-3 capsule recovery missions. These five temporary safety zones are located within the Coast Guard District Seven area of responsibility offshore of Cape Canaveral, Daytona, Jacksonville, Tampa, and Tallahassee, Florida. The purpose of this rule is to ensure the safety of vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled

event. This action is necessary to provide for the safe recovery of these capsules and astronauts in our exclusive economic zone and implements a special activities provision of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. This rule prohibits U.S. flagged vessels from being in the safety zones unless authorized by the Commander of the Seventh Coast Guard District or a designated representative.

DATES: This rule is effective without actual notice from April 20, 2022 through May 15, 2022. For purposes of enforcement, actual notice will be used from April 17, 2022 until April 20, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0233 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Stephanie Miranda, District 7 Waterways Division (dpw), U.S. Coast Guard; telephone (305) 415–6748, email Stephanie.L.Miranda@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 EEZ Exclusive Economic Zone
 FR Federal Register
 NASA National Aeronautics and Space Administration
 NPRM Notice of proposed rulemaking
 § Section
 U.S.C. United States Code
 COTP Captain of the Port
 Space X Space Exploration Technologies Corporation

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 it is impracticable and contrary to the public interest. The U.S. company, Space

Exploration Technologies Corporation (Space X) Axiom-1 and the National Aeronautics and Space Administration (NASA) Crew-3 capsule recovery missions were approved and scheduled less than 30 days before the need for the five safety zones to be in place starting on April 17, 2022. Publishing an NPRM would be impracticable and contrary to the public interest since the missions would begin before completion of the rulemaking process, thereby inhibiting the Coast Guard’s ability to protect against the hazards associated with the recovery missions.

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 impracticable and contrary to the public interest because the temporary safety zones must be established on April 17, 2022, to mitigate safety concerns during the capsule recovery missions.

III. Legal Authority and Need for Rule

On January 1, 2021, the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) (Authorization Act) was enacted. Its section 8343 (134 Stat. 4710) calls for the Coast Guard to conduct a 2-year pilot program to establish and implement a process to establish safety zones to address special activities in the exclusive economic zone (EEZ).¹ These special activities include space activities carried out by United States citizens. The Seventh District Commander, Captain of the Port Jacksonville, and Captain of the Port St. Petersburg have determined that potential hazards associated with the Space X Axiom-1 and the NASA Crew-3 capsule recovery missions present a safety concern for anyone within the perimeter of the five safety zones. The safety zones will only be activated at a reasonable time before a recovery mission and deactivated once the area is no longer hazardous. The purpose of this rule is to ensure the safety of astronauts, vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled event. The Coast Guard is issuing this rule under authority of section 8343 of the Authorization Act and 46 U.S.C. 70034.

IV. Discussion of the Rule

The Coast Guard is establishing five temporary safety zones. The Space X Axiom-1 and Crew-3 recovery missions

may occur within one of the five following sites: Cape Canaveral, Daytona, Jacksonville, Tampa, and Tallahassee, Florida. Based on mission and environmental factors, Space X and NASA will determine which of the sites will be utilized approximately one day before capsule reentry and recovery. The appropriate safety zone will then be activated at a reasonable time before the recovery mission and deactivated once the area is no longer hazardous. Coast Guard District Eight may also establish temporary safety zones for recovery missions in its respective area of responsibility for these missions.

The five temporary safety zones are listed below and include all waters within the coordinates from surface to bottom. The coordinates are based on the projected reentry locations as determined from telemetry data and modeling by Space X.

(1) Cape Canaveral site:

Point 1	29°02'27" N	080°13'48" W
Point 2	28°51'00" N	080°00'46" W
Point 3	28°39'32" N	080°13'48" W
Point 4	28°51'00" N	080°26'49" W
Point 5	29°02'27" N	080°13'48" W

(2) Daytona site:

Point 1	29°59'27" N	080°35'59" W
Point 2	29°48'00" N	080°22'51" W
Point 3	29°36'32" N	080°35'59" W
Point 4	29°48'00" N	080°49'08" W
Point 5	29°59'27" N	080°35'59" W

(3) Jacksonville site:

Point 1	31°06'28" N	080°15'00" W
Point 2	30°55'01" N	080°01'40" W
Point 3	30°43'30" N	080°15'00" W
Point 4	30°55'01" N	080°28'19" W
Point 5	31°06'28" N	080°15'00" W

(4) Tampa site:

Point 1	28°17'27" N	083°54'00" W
Point 2	28°06'00" N	083°41'02" W
Point 3	27°54'32" N	083°54'00" W
Point 4	28°06'00" N	084°06'57" W
Point 5	28°17'27" N	083°54'00" W

(5) Tallahassee site:

Point 1	29°22'38" N	084°05'20" W
Point 2	29°16'59" N	083°58'55" W
Point 3	29°06'20" N	084°11'12" W
Point 4	29°22'38" N	084°05'20" W

When the safety zones are activated, the COTP or a designated representative will be able to restrict vessel movement including but not limited to transiting, anchoring, or mooring within the safety zone to protect vessels from hazards associated with rocket and capsule recovery missions. Active restrictions are based on mission specific recovery

¹ The Coast Guard defines the exclusive economic zone in 33 CFR 2.30.

exclusion areas provided by Space X and NASA, are temporary in nature, and would only be enacted and enforced at a reasonable time prior to and after a recovery. Since the safety zones fall in the EEZ, only United States flagged vessels are subject to safety zone enforcement. The determination of risk would be at the discretion of the COTP and informed by the mission specific recovery exclusion areas provided by Space X and NASA.

The COTP will inform the public of the activation or status of the safety zones by Local Notice to Mariners and Broadcast Notice to Mariners on VHF-FM channel 16.

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 protesters.

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).

This regulatory action determination is based on the size, location, duration, and scope of the safety zones. The safety zones are limited in size and location to only those areas where capsule re-entry is reasonably expected to occur. Of the five safety zones, only one may will be activated for approximately two hours and only at a reasonable time prior to re-entry, then deactivated once the area is no longer hazardous. The safety zones are limited in scope, as vessel traffic will be able to safely transit around the safety zones which will impact a small part of the United States exclusive economic zone (EEZ) within the Atlantic Ocean and Gulf of Mexico.

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.

The total time of the safety zone activation and thus restriction to the public is expected to be approximately two hours per capsule recovery, of which two instances are projected during prior to the expiration of this rule. Vessels would be able to transit around the activated safety zone location during these recoveries. We do not anticipate any significant economic impact resulting from activation of the safety zones.

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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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 the establishing of five temporary safety zones, one of which may be activated on two occasions for approximately two hours between April 17, 2022 and May 15, 2022 for a Space X and NASA mission. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

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. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T07–0233 to read as follows:

§ 165.T07–0233 Safety Zones; Cape Canaveral, Daytona, Tampa, Jacksonville, and Tallahassee, Florida.

(a) *Location.* The following areas are safety zones:

(1) *Cape Canaveral site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, thence to Point 3, thence to Point 4, connecting back to Point 5:

Point 1	29°02'27" N	080°13'48" W
Point 2	28°51'00" N	080°00'46" W
Point 3	28°39'32" N	080°13'48" W
Point 4	28°51'00" N	080°26'49" W
Point 5	29°02'27" N	080°13'48" W

(2) *Daytona site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, thence to Point 3, thence to Point 4, connecting back to Point 5:

Point 1	29°59'27" N	080°35'59" W
Point 2	29°48'00" N	080°22'51" W
Point 3	29°36'32" N	080°35'59" W
Point 4	29°48'00" N	080°49'08" W
Point 5	29°59'27" N	080°35'59" W

(3) *Jacksonville site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, thence to Point 3, thence to Point 4, connecting back to Point 5:

Point 1	31°06'28" N	080°15'00" W
Point 2	30°55'01" N	080°01'40" W
Point 3	30°43'30" N	080°15'00" W
Point 4	30°55'01" N	080°28'19" W
Point 5	31°06'28" N	080°15'00" W

(4) *Tampa site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2,

thence to Point 3, thence to Point 4, connecting back to Point 5:

Point 1	28°17'27" N	083°54'00" W
Point 2	28°06'00" N	083°41'02" W
Point 3	27°54'32" N	083°54'00" W
Point 4	28°06'00" N	084°06'57" W
Point 5	28°17'27" N	083°54'00" W

(5) *Tallahassee site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, thence to Point 3, connecting back to Point 4:

Point 1	29°22'38" N	084°05'20" W
Point 2	29°16'59" N	083°58'55" W
Point 3	29°06'20" N	084°11'12" W
Point 4	29°22'38" N	084°05'20" W

(b) *Definitions.* As used in this section—

Designated representative means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, Coast Guard Representatives in the Merrill Operations Center, and Federal, state, and local officers designated by or assisting the Captain of the Port (COTP) Jacksonville and COTP St. Petersburg in the enforcement of the safety zones.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C 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) The COTP Jacksonville and COTP St. Petersburg or a designated representative may restrict vessel movement including but not limited to transiting, anchoring, or mooring within these safety zones to protect vessels from hazards associated with rocket recoveries. These restrictions are temporary in nature and will only be enacted and enforced prior to and just after the recovery missions.

(3) Due to the safety zones falling within the United States exclusive economic zone, only United States flagged vessels are subject to safety zone enforcement. Other vessels are encouraged to remain outside the safety zone.

(4) Activation of a safety zone will be based on the risk assessment of the COTP Jacksonville and COTP St. Petersburg and informed by the mission specific recovery exclusion areas provided by the Space Exploration Technologies Corporation and the National Aeronautics and Space Administration to account for the specific risks posed by individual recoveries.

(d) *Enforcement periods.* This rule will be enforced from a reasonable time before a recovery mission and deactivated once the area is no longer hazardous between April 17, 2022 and May 15, 2022. The COTP will inform the public of which safety zone will be activated by Broadcast Notice to Mariners on VHF–FM channel 16.

Dated: April 12, 2022.

Brendan C. McPherson,

Rear Admiral Commander, Seventh Coast Guard District.

[FR Doc. 2022–08425 Filed 4–18–22; 11:15 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–0270]

Safety Zones; Annual Events in the Captain of the Port Buffalo Zone—Cleveland National Air Show

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Cleveland National Airshow from September 1 through September 5, 2022, to provide for the safety of life and property on navigable waters during this event. Our regulation for annual events in the Captain of the Port Buffalo Zone identifies the regulated area for this event in Cleveland, OH. During the enforcement period, no person or vessel may enter the safety zone without the permission of the Captain of the Port Buffalo.

DATES: The regulations in 33 CFR 165.939 will be enforced for the Cleveland National Airshow safety zone listed in item d.2 in the Table to § 165.939 from 9 a.m. through 6 p.m., each day from September 1, 2022 through September 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Jared Stevens, Waterways Management Division, Marine Safety Unit Cleveland, U.S. Coast Guard; telephone 216–937–0124, email D09-SMB-MSUCLEVELAND-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone listed in 33 CFR 165.939 for the Cleveland National Airshow daily from 9 a.m. through 6 p.m. on September 1 through September 5, 2022. This action is being taken to provide for the safety of life on