

must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Blakely Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of March 2, 2018 (83 FR 8953), we published a document announcing the availability of a draft guidance for industry entitled “The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry.” The draft guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol “†” immediately after the added sugars percent Daily Value information on certain foods. The symbol would lead the reader to truthful and non-misleading statements outside the Nutrition Facts label to provide additional information regarding the added sugars present in particular foods. The draft guidance explains that we intend to consider exercising enforcement discretion for the use of this symbol on single ingredient packages and/or containers of pure honey or pure maple syrup, and certain dried cranberry and cranberry juice products that are sweetened with added sugars, and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars. We provided a 60-day comment period that was scheduled to close on May 1, 2018.

We have received requests to extend the comment period for the draft guidance (Refs. 1 and 2). The requests conveyed concern that the current 60-

day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the draft guidance.

We have considered the requests and are extending the comment period for the draft guidance for 45 additional days, until June 15, 2018. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

### II. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Letter from Margaret Lombard, Chief Executive Officer, National Honey Board, to FDA Dockets Management Staff (April 3, 2018).
2. Letter from Ray Bonenberg, President, International Maple Syrup Institute, to Dr. Scott Gottlieb, Commissioner of Food and Drugs, FDA (April 4, 2018).

Dated: April 19, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-08603 Filed 4-24-18; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2018-0078]

RIN 1625-AA00

#### **Safety Zone; Officer Lehner Memorial Vintage Regatta; Buffalo Outer Harbor, Buffalo, NY**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a temporary safety zone for certain waters of the Buffalo Outer Harbor during the Officer Lehner Memorial Vintage Regatta. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Buffalo 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 May 25, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2018-0078 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 LT Michael Collet, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716-843-9322, email [D09-SMB-SECBuffalo-WWM@uscg.mil](mailto:D09-SMB-SECBuffalo-WWM@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

On December 27, 2017, the Buffalo Vintage Boat Racing Association and BR Guest Inc., notified the Coast Guard that it will be conducting a boat race from 10:00 a.m. to 4:00 p.m. on July 1, 2018, on the Buffalo Outer Harbor. Hazards from the boat regatta include high speed vessels. The Captain of the Port Buffalo (COTP) has determined that potential hazards associated with the Officer Lehner Memorial Vintage Regatta would be a safety concern for anyone within the designated course encompassed by all waters inside of the Outer Harbor, Buffalo, NY starting at position 42° 52’04” N, 078° 53’03” W then South to 42° 51’07” N, 078° 52’09” W (NAD 83). The course will extend a minimum of 100 yards from the shore and the breakwall.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the above stated points before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

#### III. Discussion of Proposed Rule

The COTP proposes to establish a temporary safety zone, enforced intermittently, from 9:45 a.m. to 4:15 p.m. on July 1, 2018. The safety zone will encompass all waters inside of the Outer Harbor, Buffalo, NY starting at position 42° 52’04” N, 078° 53’03” W then South to 42° 51’07” N, 078° 52’09” W (NAD 83). The course will extend a minimum of 100 yards from the shore and the breakwall. The duration of the

zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 10:00 a.m. to 4:00 p.m. boat races. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. 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 safety zone. Vessel traffic would be able to safely transit around this safety zone, which would impact a small designated area of the Buffalo Outer Harbor, by transiting a short distance in Lake Erie. The safety zone would also have built in times where vessels will be able to transit through between race heats. 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 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.

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 (Public Law 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 an intermittently enforced safety zone lasting 6.5 hours that would prohibit entry into all waters inside of the Outer Harbor, Buffalo, NY starting at position 42° 52′04″ N, 078° 53′03″ W then South to 42° 51′07″ N, 078° 52′09″ W (NAD 83). The course will extend a minimum of 100 yards from the shore and the breakwall. Normally such actions are categorically excluded from further review under paragraph L[61] 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, 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 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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:** Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0078 to read as follows:

**§ 165.T09–0078 Safety Zone; Officer Lehner Memorial Vintage Regatta; Buffalo Outer Harbor, Buffalo, NY.**

(a) *Location.* The safety zone will encompass all waters inside of the Outer Harbor, Buffalo, NY, starting at position

42° 52'04" N, 078° 53'03" W then South to 42° 51'07" N, 078° 52'09" W (NAD 83). The course will extend a minimum of 100 yards from the shore and the breakwall.

(b) *Enforcement Period.* This rule is effective from 9:45 a.m. until 4:15 p.m. on July 1, 2018.

#### (c) Regulations.

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: March 21, 2018.

**J.S. DuFresne,**

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

[FR Doc. 2018–08626 Filed 4–24–18; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R06–OAR–2017–0056; FRL–9976–75–Region 6]

### Approval and Promulgation of Implementation Plans; Texas; Reasonable Further Progress Plan for the Houston-Galveston-Brazoria Ozone Nonattainment Area

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA)

is proposing to approve a revision to the Texas State Implementation Plan (SIP) to meet the Reasonable Further Progress (RFP) requirements for the Houston-Galveston-Brazoria (HGB) moderate 2008 8-hour ozone nonattainment area (HGB area). Specifically, EPA is proposing to approve the RFP demonstration, contingency measures, motor vehicle emissions budgets (MVEBs) and an updated 2011 base year emissions inventory.

**DATES:** Written comments must be received on or before May 25, 2018.

**ADDRESSES:** Submit your comments, identified by Docket No. EPA–R06–OAR–2017–0056, at <http://www.regulations.gov> or via email to [jacques.wendy@epa.gov](mailto:jacques.wendy@epa.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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 Ms. Wendy Jacques, (214) 665–7395, [jacques.wendy@epa.gov](mailto:jacques.wendy@epa.gov). For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**Docket:** The index to the docket for this action is available electronically at [www.regulations.gov](http://www.regulations.gov) and in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material), and some may not be publicly available at either location (*e.g.*, CBI).

**FOR FURTHER INFORMATION CONTACT:** Ms. Wendy Jacques, 214–665–7395, [jacques.wendy@epa.gov](mailto:jacques.wendy@epa.gov). To inspect the hard copy materials, please schedule an appointment with Ms. Wendy Jacques or Mr. Bill Deese at 214–665–7253.

**SUPPLEMENTARY INFORMATION:** Throughout this document wherever