

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 101 and 102

[Docket No. FDA-2019-D-0892]

#### The Use of an Alternate Name for Potassium Chloride in Food Labeling; Draft Guidance for Industry; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling,” which was announced in the **Federal Register** of May 20, 2019. In the notification, FDA requested comments on the use of “potassium chloride salt” as an alternate common or usual name for potassium chloride. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the draft guidance published May 20, 2019 (84 FR 22749). Submit either electronic or written comments by September 17, 2019, to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2019-D-0892 for “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you 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:** Andrea Krause, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 20, 2019, FDA published a notification announcing the availability of a draft guidance entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling; Draft Guidance for Industry” with a 60-day comment period to request comments on the use of “potassium chloride salt” as an alternate common or usual name for potassium chloride. The draft guidance is intended to explain to food manufacturers our intent to exercise enforcement discretion for the declaration of the name “potassium chloride salt” in the ingredient statement on food labels as an alternative to the common or usual name “potassium chloride.”

We have received requests for a 60-day extension of the comment period for the draft guidance. The requests conveyed concern that the current 60-day comment period does not allow

sufficient time to develop a meaningful or thoughtful response to the draft guidance.

We have considered the requests and are extending the comment period for the draft guidance for 60 additional days, until September 17, 2019. We believe that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: July 3, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-14666 Filed 7-9-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG-2019-0300]

RIN 1625-AA08

#### Special Local Regulations; Festival of Sail Duluth 2019, Lake Superior, Duluth, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary special local regulation for a designated area of the Duluth Harbor entrance to Superior Bay on Lake Superior during the Festival of Sail 2019 event in Duluth, MN. This action is necessary to provide for the safety of life on these navigable waters around the port of Duluth, MN during a sail festival with tall ships beginning on August 11, 2019 and ending the afternoon of August 13, 2019. This proposed rulemaking would prohibit persons and vessels from being in the designated region unless authorized by the Captain of the Port Duluth or a designated representative. We invite the public to comment on this supplemental notice of proposed rulemaking, specifically on the extended time of the special local regulation.

**DATES:** Comments and related material must be received by the Coast Guard on or before July 17, 2019.

**ADDRESSES:** You may submit comments identified by docket number USCG-2019-0300 using the Federal eRulemaking Portal at <https://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 Lieutenant Abbie Lyons, Waterways Management, MSU Duluth, U.S. Coast Guard; telephone 218-725-3818, email [Abbie.E.Lyons@uscg.mil](mailto:Abbie.E.Lyons@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 11, 2018, Draw Events LLC notified the Coast Guard that it will be conducting a Festival of Sail event in Duluth, MN from August 11 through August 13, 2019. The Coast Guard published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on May 8, 2019. A public comment period was held from May 8, 2019 to July 7, 2019 with no comments received; however, concerns were raised by local law enforcement and public safety of the initial proposed temporary special local regulation only covering the parade of sail on August 11, 2019 from 7:00 a.m. to 1:00 p.m. Due to the influx of spectator vessel traffic during this event, we are proposing to extend the special local regulation to include the entire Festival of Sail, from August 11, 2019 at 7:00 a.m. to August 13, 2019 at 1:00 p.m. This special local regulation will be enforced from 7:00 a.m. through 1:00 p.m. on August 11, 2019 during the Parade of Sail event. It will be enforced at other times during the effective period as deemed necessary by the Captain of the Port Duluth (COTP) or her on-scene representatives. Notice of enforcement of the special local regulation will be provided by Broadcast Notice to Mariners and by the COTP's on-scene representatives. The purpose of this supplemental notice of proposed rulemaking is to solicit comments on the extended effective time period of the regulation.

The legal basis for this proposed rule is the Coast Guard's authority under 46 U.S.C. 70041; 33 CFR 1.05-1.

##### **III. Discussion of Proposed Rule**

The COTP is proposing to establish a special local regulation from 7 a.m. on August 11, 2019 to 1 p.m. on August 13, 2019. The special local regulation would cover designated navigable waters in the vicinity of Duluth Harbor.

The duration of the zone is intended to protect the safety of vessels and these

navigable waters before, during, and immediately after the scheduled Festival of Sail. Only the designated sailing vessels associated with the event are permitted within the zone while it is being enforced. No other vessels or persons will be permitted to enter the zone without obtaining permission from the COTP or a designated representative. The COTP or a designated representative may be contacted via VHF Channel 16 or by telephone at (218) 428-9357. The regulatory text proposed 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 SNPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the SNPRM 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 availability of the Superior Harbor entrance as an alternate entry into Superior Bay, the short time frame of the special local regulation, and the estimated number of spectator vessels around the Duluth Harbor entrance for the event. We anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The Coast Guard will 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