FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic.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.

We intend to conduct four public meetings in diverse regions of the United States to discuss the draft guidance, and we will provide details about these public meetings in a notice published in the **Federal Register**.

The Produce Safety Rule (80 FR 74353) established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. Requirements of the rule focus on major routes of contamination, including health and hygiene; biological soil amendments of animal origin; domesticated and wild animals; and equipment, tools, and buildings.

This draft guidance provides recommendations, examples, and information related to compliance and implementation of the following subparts of the Produce Safety Rule:

Subpart A—General Provisions

Subpart C—Personnel Qualifications and Training

Subpart D—Health and Hygiene

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

Subpart I—Domesticated and Wild Animals

Subpart K—Growing, Harvesting, Packing, and Holding Activities

Subpart L—Equipment, Tools, Buildings, and Sanitation

Subpart O—Records

Subpart P—Variances

This draft guidance is based on FDA's current thinking and we believe that additional information would assist us in developing the final guidance. While we invite comments on all aspects of the draft guidance, we seek specific comments, information, and data on the following:

For equipment and tools intended to or likely to contact covered produce:

- When acquiring equipment and tools, how do you engage with equipment and tool suppliers about the size, design, and construction of your buildings so that they can accommodate the equipment and tools?
- What information or data can you provide about cleaning, sanitizing, and maintenance practices and procedures for equipment and tools that have wood, foam, or other porous or absorbent materials?

For domesticated and wild animals:

- What data or information can you provide about factors or conditions that would affect the likelihood of contamination of covered produce by animals? Such factors include, for example, historical information and conditions on or near farms that influence animal habitats.

II. 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 21 CFR part 112 have been approved under OMB control number 0910–0816.

III. 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: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23006 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2018–D–3583]

Guide To Minimize Food Safety Hazards of Fresh-Cut Produce: Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Guide to Minimize Food Safety Hazards of Fresh-cut Produce.'' The draft guidance, when finalized, will supersede a previous guidance, entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,'' that we issued in 2008. The draft guidance is intended to explain our current thinking on how to comply with recently modernized requirements for current good manufacturing practice (CGMP) and with new requirements for hazard analysis and risk-based preventive controls under our regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' during the production of fresh-cut produce.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 to ensure that the Agency considers your comment on the draft guidance before it begins 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–2018–D–3583 for ''Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Food Safety, Division of Produce Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Insook Son, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1648.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Guide to Minimize Food Safety Hazards of Fresh-cut Produce.'' 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.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d).

In 2008, we issued a guidance for industry entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables.'' Fresh-cut fruits and vegetables mean any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (*e.g.,* by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking). That guidance was intended for all fresh-cut produce processing firms to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. It explained our thinking on how to comply with CGMP requirements that then were established in a regulation entitled ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food'' (21 CFR part 110).

In the **Federal Register** of September 17, 2015 (80 FR 55908), we published a final rule that, among other things, modernized the CGMP requirements and established them in new 21 CFR part 117 (part 117), entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' Part 117 also includes new requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities. The draft guidance that we are making available for public comment is intended to explain our current thinking on how all food establishments that produce fresh-cut produce can comply with the modernized CGMP requirements in part 117. The draft guidance also is intended to explain our current thinking on how fresh-cut produce food facilities that are subject to the new requirements for hazard analysis and risk-based preventive controls can comply with those requirements.

II. 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.

III. 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: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23005 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0948]

RIN 1625–AA00

Safety Zone; Delaware River; Camden, NJ; Fireworks Display

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on a portion of the Delaware River in Camden, NJ. This action is necessary to protect the surrounding public and vessels on these navigable waters adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ, during a fireworks display on November 14, 2018. This proposed rulemaking would prohibit persons and vessels from entering, transiting, or remaining within the safety zone unless authorized by the Captain of the Port Delaware Bay 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 November 6, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0948 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 Thomas Welker, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division; telephone 215–271–4814, email *Thomas.j.welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
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 September 14, 2018, Rexel, Inc notified the Coast Guard that it will be conducting a fireworks display from 8:35 p.m. to 8:55 p.m. on November 14, 2018. The fireworks are to be launched from a barge in the Delaware River adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Delaware Bay (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 600-foot radius of the barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 600-foot radius of the fireworks barge 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 is proposing to establish a safety zone from approximately 8:15 p.m. through 9:15 p.m. on November 14, 2018. The safety zone would cover all navigable waters within 600 feet of a fireworks barge in the Delaware River adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ. The barge will be anchored in approximate position 39°56′20″ N Latitude, 075°08′08″ W Longitude. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 8:35 p.m. to 8:55 p.m. fireworks display. No vessel or person would be permitted to enter, transit, or remain within 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 Delaware River for one hour during the evening when vessel traffic is normally low. 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.