4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2018-D-3631]

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing four public meetings to discuss "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry." The purpose of the public meetings is to discuss the draft guidance for compliance and implementation of the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" rule, which was issued under the FDA Food Safety Modernization Act.

DATES: Submit either electronic or written comments on the notice by April 22, 2019. See "How to Participate in the Public Meetings" in the SUPPLEMENTARY INFORMATION section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, and other information regarding meeting participation.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 22, 2019. The https://www.regulations.gov electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of April 22, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-3631 for "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry." Received comments, those filed in a timely manner (see ADDRESSES), 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: *For questions about registering for the meetings or to register by phone*: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington DC 20006, 240-393-2901, EventSupport@Sidemgroup.com.

For general questions about the public meetings or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

"The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" rule (the produce safety rule, published in the *Federal Register* of November 27, 2015 (80 FR 74354) (https://www.fda.gov/fsma)) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The rule is part of the Agency's ongoing efforts to implement the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). FSMA also

requires FDA to issue guidance for the safe production and harvesting of fresh produce (section 419(e)(1) of the FD&C Act (21 U.S.C. 350h(e)(1))) and to also conduct at least three public meetings in diverse geographical areas of the United States as part of an effort to conduct education and outreach regarding the guidance for interested stakeholders (section 419(e)(2) of the FD&C Act).

In the *Federal Register* of October 22, 2018 (83 FR 53196), we announced the availability of the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry" (https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf). The draft guidance provides information on and recommendations for compliance with the requirements of the produce safety rule, which produce and farms are covered by the rule, and whether certain produce or farms may be eligible for exemptions.

FDA is announcing a series of public meetings entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry" so that stakeholders can better evaluate and comment on the draft guidance. These meetings will be held during the formal comment period on the draft guidance.[1] All four public meetings will cover the same agenda items and are intended to facilitate and support the public's evaluation and commenting process.

While oral presentations[2] from specific individuals and organizations will be necessarily limited due to time constraints during the public meetings, stakeholders may submit electronic or

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[1] Under FDA's Good Guidance Practices regulation, anyone may comment on an FDA guidance document at any time (see 21 CFR 10.115(g)(5)).

[2] Requests to make oral presentations must be made in advance. Please see table 1 for deadlines to request making an oral presentation for each meeting.

written comments discussing any issues of concern to the administrative record (the docket) for the draft guidance (Docket No. FDA-2018-D-3631).

II. Purpose and Format of the Public Meetings

The purpose of the public meetings is to provide information and facilitate comment so that stakeholders can better evaluate and provide input on the draft guidance. We invite interested parties to provide information and offer comments related to the produce safety rule draft guidance. During the public meetings we will present information on the various chapters of the draft guidance: general provisions; personnel qualifications and training; health and hygiene; biological soil amendments of animal origin; domesticated and wild animals; growing, harvesting, packing, and holding activities on a farm; equipment, tools, buildings, and sanitation; records; and variances[3]. Stakeholder panels will provide discussion on the various issues. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. How to Participate in the Public Meetings

There will be a total of four public meetings held in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment on the draft guidance.

Table 1 provides information on participation in the public meetings.

[3] We have proposed to extend the compliance dates related to the requirements of subpart E of the produce safety rule, which addresses agricultural water, and have provided enforcement discretion until the finalization of that rulemaking (82 FR 42963, 42965; September 13, 2017). Accordingly, the draft guidance does not contain any recommendations related to subpart E, and agricultural water is not on the agenda for these public meetings. Also not on the agenda for these public meetings is the draft guidance issued in January 2017 entitled "Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations."

Table 1.--Information on Participating in the Public Meetings and on Submitting Comments to the Produce Safety Rule Draft Guidance Docket

Activity	Date	Electronic Address	Address	Other Information
First public meeting	November 27, 2018; 8:30 a.m.--5 p.m.		Hilton Portland Downtown, 921 SW Sixth Ave., Portland, OR 97204	
View webcast	November 27, 2018; 8:30 a.m.--5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm		The webcast will have closed captioning.
Advance registration	by November 16, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation	by November 9, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMetingsConferences/default.htm.	
Submitting either electronic or written comments	Submit comments by April 22, 2019	https://www.regulations.gov	Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability	by November 9, 2018		See FOR FURTHER INFORMATION CONTACT	

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Activity	Date	Electronic Address	Address	Other Information
Second Public Meeting	November 29, 2018; 8:30 a.m.--5 p.m.		DoubleTree Suites by Hilton Anaheim Resort-Convention Center, 2085 S. Harbor Blvd., Anaheim, CA 92802	
View webcast	November 29, 2018; 8:30 a.m.--5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm		The webcast will have closed captioning.
Advance registration	by November 16, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation	by November 9, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	
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Request special accommodations due to a disability	by November 9, 2018		See FOR FURTHER INFORMATION CONTACT	

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Activity	Date	Electronic Address	Address	Other Information
Third Public Meeting	December 11, 2018; 8:30 a.m.--5 p.m.		Hilton Albany, 40 Lodge St., Albany, NY 12207	
View webcast	December 11, 2018; 8:30 a.m.--5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm		The webcast will have closed captioning.
Advance registration	by November 23, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation	by November 16, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	
Submitting either electronic or written comments	Submit comments by April 22, 2019	https://www.regulations.gov	Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability	by November 16, 2018		See FOR FURTHER INFORMATION CONTACT	

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Activity	Date	Electronic Address	Address	Other Information
Fourth Public Meeting	December 13, 2018; 8:30 a.m.--5 p.m.		Embassy Suites Atlanta at Centennial Olympic Park, 267 Marietta St., Atlanta, GA 30313	
View webcast	December 13, 2018; 8:30 a.m.--5 p.m.	Individuals who wish to participate by webcast are asked to preregister at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm		The webcast will have closed captioning.
Advance registration	by November 23, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation	by November 16, 2018	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Requests to make oral presentations must be made in advance to https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	
Submitting either electronic or written comments	Submit comments by April 22, 2019	https://www.regulations.gov	Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852	See ADDRESSES for information on submitting comments.
Request special accommodations due to a disability	by November 16, 2018		See FOR FURTHER INFORMATION CONTACT	

[1.] You may also register via email, mail, or Fax. Please include your name, title, firm name, address, and phone and Fax numbers in your registration information and send to: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, 240-393-4496, Fax: 202-495-2901, EventSupport@Sidemgroup.com. Onsite registration will be available at all four meetings, however, please note that if we have reached capacity, we will not be able to accommodate those who have not pre-registered.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at https://www.regulations.gov. You may also view the transcript at the Dockets Management Staff (see ADDRESSES).

Dated: October 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-23868 Filed: 10/31/2018 8:45 am; Publication Date: 11/1/2018]