published at *https://www.faa.gov/training_testing/testing/acs/.*

Comments Invited

The FAA invites interested persons to join in this notice and comment process by filing written comments, data, or views. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments or, if comments are filed electronically, commenters should submit only one time. More information on submitting comments can be found in the **ADDRESSES** section of this document.

The FAA will review all comments it receives on or before the closing date for the comment period. The FAA will consider comments submitted after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may make changes based on the comments it receives.

Issued in Washington, DC, on October 16, 2018.

Lirio Liu,

Executive Director, Office of Rulemaking, Federal Aviation Administration.

[FR Doc. 2018–23013 Filed 10–19–18; 8:45 am]

BILLING CODE 4910–13–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Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' The draft guidance, when finalized, will provide FDA's current thinking and recommendations to help covered farms comply with the final regulation entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (Produce Safety Rule), which established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.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–3631 for ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; 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 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: 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