# Proposed Rules

Federal Register
Vol. 80, No. 9
Wednesday, January 14, 2015

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 Part 112

**[Docket No. FDA–2014–N–2244]**

**RIN 0910–AG35**

## Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

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

**ACTION:** Notification of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA or we) has made available for public review and comment the Draft Environmental Impact Statement (EIS) for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption. The document is available in Docket No. FDA–2014–N–2244. FDA is also announcing a public meeting to discuss the Draft EIS. The purpose of the public meeting is to inform the public of the findings in the Draft EIS, to provide information about the EIS process (including how to submit comments, data, and other information to the docket), to solicit oral stakeholder and public comments on the Draft EIS, and to provide clarification, as needed, about the contents of the Draft EIS.

**DATES:** See section II, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments on the Draft EIS.

**ADDRESSES:** You may submit comments by any of the following methods.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Docket No. FDA–2014–N–2244. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Public Meeting:* See section II, ''How to Participate in the Public Meeting'' in **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For questions about the Draft Environmental Impact Statement, or submitting comments contact:* Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1057.

*For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX, or email, contact:* Rick Williams, c/o FDA EIS, 72 Loveton Circle, Sparks, MD 21152; telephone: 410–316–2377; FAX: 410–472–3289; email: *RWilliams@jmt.com.*

*For general questions about the meeting, to request an opportunity to make an oral presentation at the public meeting, to submit the full text, comprehensive outline, or summary of an oral presentation, or for special accommodations due to a disability, contact:* Cynthia Wise, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, telephone: 240–402–1357, email: *cynthia.wise@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. As part of our implementation of FSMA, we published the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as ''the 2013 proposed rule'') to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce (78 FR 3504, January 16, 2013). On September 29, 2014, FDA issued a supplemental notice of proposed rulemaking (''the supplemental proposed rule''), amending certain specific provisions of the 2013 proposed rule (79 FR 58434). Taken together, these publications constitute FDA's proposed standards for the growing, harvesting, packing, and holding of produce for human consumption (''the Produce Safety Proposed Rule'').

FDA announced a ''Notice of Intent'' (NOI) to prepare an EIS to evaluate the potential environmental effects of the Produce Safety Proposed Rule in the **Federal Register** on August 19, 2013 (78 FR 50358). In the NOI, FDA also announced the beginning of the scoping process and solicited public comments to identify issues to be analyzed in an EIS. The NOI asked for public comment by November 15, 2013, and FDA later extended the deadline for the comment period to April 18, 2014 (79 FR 13593; March 11, 2014). A public scoping meeting was held on April 4, 2014, in College Park, MD.

In the Produce Safety Proposed Rule, FDA proposed science-based minimum standards for the safe production and harvesting of produce. As discussed in the Draft EIS (Ref. 1), out of these standards, we identified four provisions that could potentially significantly affect the quality of the human

environment, if finalized (hereinafter referred to as ''potentially significant provisions''). For each of the potentially significant provisions, FDA then identified alternative provisions to consider. The potentially significant provisions are: (1) Standards directed to agricultural water, (2) standards directed to biological soil amendments (BSA) of animal origin, (3) standards directed to domesticated and wild animals, and (4) general provisions (*i.e.,* cumulative impacts). Additionally, an overarching ''No Action'' Alternative was considered for the purpose of evaluating conditions in the absence of any final rule.

For standards directed to agricultural water, we considered the following alternatives: (1) As proposed by FDA, *i.e.,* a statistical threshold value (STV) not exceeding 410 colony forming units (CFU) of generic *Escherichia coli* per 100 ml of water and a geometric mean (GM) not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing (proposed 21 CFR 112.44(c)); (2) a microbial quality standard of no more than 235 CFU (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as was proposed in the 2013 proposed rule; (3) as proposed (*i.e.,* Alternative 1), but with an additional criterion establishing a maximum generic *E. coli* threshold ; and (4) for each of the alternatives above, consider the environmental impacts of two different interpretations of the definition of ''direct water application method'' in proposed § 112.3(c): (a) To include root crops that are drip irrigated and (b) to exclude root crops that are drip irrigated.

For standards directed to BSAs of animal origin, FDA considered standards for both untreated and treated BSAs. For untreated BSAs of animal origin, the alternatives considered included a range of minimal application intervals (the time between application and harvest) when the BSA is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. The alternative application intervals evaluated were: (1) 9 months, (2) 0 months, (3) 90 and 120 days, consistent with the National Organic Programs' regulations in 7 CFR 205.203(c)(1), (4) 6 months, and (5) 12 months. For standards directed to treated BSAs, the alternatives considered included a range of application intervals when the BSA is composted in accordance with the requirements proposed in § 112.54(c) and applied in a manner that minimizes the potential for contact with covered produce during and after application. The application intervals evaluated were: (1) As proposed by FDA, 0 days (proposed § 112.56(a)(4)(i)), (2) 45 days, and (3) 90 days.

For standards directed at domesticated animals, we considered alternatives under which, if working animals are used in a growing area where a crop has been planted, measures would be required to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce with the waiting period between grazing and harvesting varying by alternative. The following alternatives were evaluated: (1) As proposed by FDA, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop (proposed § 112.82(a)); (2) a minimum waiting period of 9 months; and (3) a minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (applying the timeframes for raw manure set forth in the National Organic Programs' regulations in 7 CFR 205.203(c)(1)). For standards directed to wild animals, we considered alternatives to the proposed requirement that under circumstances when there is a reasonable probability that animal intrusion will contaminate covered produce, the grower would be required to monitor those areas that are used for a covered activity for evidence of animal intrusion: (1) As needed during the growing season based on (i) the grower's covered produce and (ii) the grower's observations and experience; and (2) immediately prior to harvest. The alternatives evaluated were: (1) As proposed by FDA, if animal intrusion occurs—as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing—the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112 (proposed § 112.83(a) and (b)) and (2) if animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

The cumulative impacts of the proposed rule were considered using a range of alternatives to the general provision in proposed § 112.4, which would specify the farms that would be covered under the rule based on the farm's annual sales of produce. The alternatives evaluated were to cover those farms that have: (1) As proposed by FDA, an average annual monetary value of produce sold during the previous 3-year period of more than $25,000 (on a rolling basis) (proposed § 112.4); (2) an average annual monetary value of food sold during the previous 3-year period of more than $50,000 (on a rolling basis); (3) an average annual monetary value of food sold during the previous 3-year period of more than $100,000 (on a rolling basis); and (4) an average annual monetary value of covered produce sold during the previous 3-year period of more than $25,000 (on a rolling basis).

FDA has made this Draft EIS available for public review and comment in Docket No. FDA–2014–N–2244 (See Ref. 1).

## II. How To Participate in the Public Meeting

FDA is holding the public meeting on February 10, 2015, from 1 p.m. until 4 p.m., at Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740, to discuss the Draft EIS for the proposed rule to establish standards for growing, harvesting, packing and holding of produce for human consumption. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register early and in advance of the meeting. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request in advance and to provide information about the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comments and the limited time available, FDA is allocating 4 minutes to each speaker to make an oral presentation. FDA will provide opportunities to submit written comments at the meeting; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations

that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (*i.e.,* 4-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket). All relevant data and documentation should be submitted with the comments to Docket No. FDA–2014–N–2244.

Table 1 provides information on participation in the public meeting:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET

| | Date | Electronic address | Address | Other information |
|---|---|---|---|---|
| College Park, MD Public Meeting. | February 10, 2015, 1 p.m. to 4 p.m. | *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*. | Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740. | |
| Deadline for Registration ... | February 3, 2015 ..... | *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm,* Docket No. FDA–2014–N–2244 | 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. |
| Request to Make a Public Comment. | February 3, 2015 ..... | *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*[2] | ..... | Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided. |
| Request Special Accommodations Due to a Disability. | February 3. 2015 ..... | Cynthia Wise email: *cynthia.wise@fda.hhs.gov*. | See **FOR FURTHER INFORMATION CONTACT**. | |
| Closing Date for Written Comments. | March 13, 2015. | | | |

[1] For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, Fax, or email, contact: Rick Williams, c/o FDA EIS, 72 Loveton Circle, Sparks, MD 21152; telephone: 410–316–2377; FAX: 410–472–3289; email: *RWilliams@jmt.com.*

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Cynthia Wise, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, telephone: 240–402–1357, email: *cynthia.wise@fda.hhs.gov.*

## III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record. Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and at FDA's FSMA Web site at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be live webcasting and recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.*

## IV. Reference

1. Draft Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

Dated: January 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–00564 Filed 1–12–15; 4:15 pm]

**BILLING CODE 4164–01–P**