



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Extension of comment period for the Environmental Impact Statement for the proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the "Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" that appeared in the Federal Register of August 19, 2013. We are taking this action to allow interested persons an opportunity to provide comment on the scope of issues the Agency should include in the Environmental Impact Statement (EIS), including their significance, as part of the scoping process for the EIS.

DATES: The date(s) and location(s) of any scoping meetings, if determined to be necessary, will be announced at least 15 days in advance through FDA Web site's at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>. Comments on the scope of issues the Agency should include in the EIS may be submitted in writing until March 15, 2014.

ADDRESSES: You may submit comments on the scope of issues the Agency should include in the EIS, identified by Docket No. FDA-2011-N-0921 and/or Regulatory Information Number (RIN) 0910-AG35, 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 or CD-ROM submissions): 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 Agency name and Docket No. FDA-2011-N-0921, and RIN 0910-AG35 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

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.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 19, 2013 (78 FR 50358), we published a notice of intent entitled "Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" with a comment period extending through November 15, 2013, to announce the beginning of the scoping process. We solicited public comments and requested public input to identify issues to be analyzed in an EIS.

The purpose of the public scoping process for the EIS is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS. Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the produce safety rule are invited to participate in the scoping process. FDA has previously sought comment on potential environmental effects as part of the public comment period for the proposed rule, including specific questions regarding agricultural water, biological soil amendments of animal origin, and wildlife (78 FR 3504 at 3616, 3619-3620; January 16, 2013). FDA believes that these questions are still relevant to the environmental analysis and will consider comments received.

FDA is granting an extension of the public scoping period to allow the public additional time to provide comment and for FDA to hold, as appropriate, one or more public scoping

meetings during this time period. As part of the scoping process, the Agency will determine the range of actions, alternatives, and impacts to be considered in the EIS. This notice does not extend the comment period on the produce safety proposed rule published on January 16, 2013 (78 FR 3504). As previously announced (78 FR 48637, August 9, 2013), the comment period on the produce safety proposed rule closes on November 15, 2013.

II. Request for Comments

Interested persons may submit either electronic comments regarding the issues to be included in the EIS for the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.