

FDA Progress Report on Implementing the Food Safety Modernization Act: January – March 2013

The FDA provides regular updates to inform the public and Congress on its progress in implementing the FDA Food Safety Modernization Act (FSMA). This summary does not reference all actions taken by FDA.

January 2013

FDA Announces Two Proposed Rules for Public Comment

On January 4, FDA announced and on January 16 published for public comment a proposed rule on preventive controls for human food and a proposed rule on standards for produce safety.

FSMA Proposed Rule on Preventive Controls for Human Food

[http://www.regulations.gov/ - !docketDetail;D=FDA-2011-N-0920](http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920)

FSMA Proposed Rule for Produce Safety

[http://www.regulations.gov/ - !docketDetail;D=FDA-2011-N-0921](http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921)

The following resources were published relating to the two proposed rules:

Overview of FSMA Proposed Rules on Produce Safety Standards and Preventive Controls for Human Food

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334120.htm>

Fact Sheet on FSMA Proposed Rule for Produce

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm>

Fact Sheet on Subparts of FSMA Proposed Rule for Produce Safety

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334552.htm>

Fact Sheet on FSMA Proposed Rule for Preventive Controls for Human Food

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334115.htm>

Power Point Presentation (with notes)

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm265429.htm>

Video Tutorial on The Rule-Making Process

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm249243.htm>

Video Primer on FSMA

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm249243.htm> - primer

Blog Post from Commissioner Hamburg on Basing Food Safety Standards on Science and Prevention

<http://blogs.fda.gov/fdavoices/index.php/2013/01/basing-food-safety-standards-on-science-and-prevention/>

FDA Issues New FAQs Concerning Food Facility Registration Renewal

On January 18, FDA added two new FAQs concerning the renewal process for food facility registration. The questions pertain to accessing the system and retaining access to historical information.

New FAQs on Renewal Process

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm314178.htm>

FDA Announces Public Meetings on Proposed FSMA Rules

On January 30, FDA announced a series of three public meetings concerning the FSMA Proposed Rules for Produce Safety Standards and Preventive Controls for Human Food.

Public Meeting in Washington, D.C.

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm336329.htm>

Public Meeting in Chicago

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm339097.htm>

Public Meeting in Portland

<http://www.fda.gov/Food/guidanceregulation/FSMA/ucm339096.htm>

February 2013

FDA Announces Final Rule on Administrative Detention of Food

On February 4, FDA announced a final rule amending the criteria for administrative detention to prevent potentially unsafe food from reaching the marketplace. This action makes the criteria consistent with changes to the Federal Food, Drug, and Cosmetic Act under FSMA. The final rule adopts the interim final rule, "Criteria Used to

Order Administrative Detention of Food for Human or Animal Consumption,” published in May 2011, without change.

Final Rule: Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption

<https://www.federalregister.gov/articles/2013/02/05/2013-02497/criteria-used-to-order-administrative-detention-of-food-for-human-or-animal-consumption>

FDA Issues Reminder on Comment Period Deadline for Draft Qualitative Risk Assessment under Proposed Rule on Preventive Controls for Human Food

On February 13, FDA issued a reminder about the February 15 deadline for comments on “Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.” The purpose of the draft risk assessment is to provide a science-based risk analysis of those activity/food combinations that could be considered low risk.

Draft Risk Assessment

<http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1258-0001>

FDA Extends Comment Period for Information Collection Provisions of Two Proposed FSMA Rules

On February 15, FDA announced the extension of the comment period to May 16 for the information collection provisions associated with the proposed FSMA rules on produce safety standards and preventive controls for human food.

Information on Comment Period Extension

<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm339908.htm>

FDA Releases International Capacity-Building Plan

On February 28, FDA released a plan, which outlines goals, objectives, and key actions that will provide a strategic framework for the FDA in setting priorities and managing international food safety capacity-building programs.

International Capacity-Building Plan

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm301708.htm>

FDA Holds First Public Meeting on FSMA Proposed Rules

On February 28 and March 1 in Washington, D.C., FDA held the first of three public meetings on the proposed rule for preventive controls for human food and the proposed rule for produce safety standards.

The materials from that meeting are available online at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm>

March 2013

FDA Seeking Input on Product Tracing Pilot Report

On March 4, FDA called for public comment on a report from the Institute of Food Technologists (IFT) entitled "Pilot Projects for Improving Product Tracing along the Food Supply System." The comments are to be considered by FDA in the development of recommendations in a report to Congress.

Information on Comment Period for Product Tracing Report

<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm342068.htm>

FDA Releases Guidance For Industry on Administrative Detention

On March 7, FDA released revised guidance on administrative detention entitled "Guidance for Industry: What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide."

Guidance for Industry on Administrative Detention

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm342588.htm>

FDA Holds Second Public Meeting on FSMA Proposed Rules

On March 11 and 12, in Chicago, Illinois, FDA held the second of three public meetings to receive comment on the proposed rule for preventive controls in human food and the proposed rule for produce safety standards.

Materials related to that meeting are available at

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339097.htm>

Comment Period Extended for Draft Risk Assessment

On March 12, FDA reopened the comment period for a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm." Based on three requests for a deadline extension, FDA reopened the comment period until May 16, 2013.

Federal Register Notice

<https://www.federalregister.gov/articles/2013/03/13/2013-05730/draft-qualitative-risk-assessment-of-risk-of-activityfood-combinations-for-activities-outside-the>

Corrections to Proposed Rules

On March 19, FDA corrected technical errors to the proposed rules for Preventive Controls for Human Food and Standards for Produce Safety, originally published on January 16, 2013.

Federal Register Notice of Corrections to the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule

<https://www.federalregister.gov/articles/2013/03/20/2013-06356/current-good-manufacturing-practice-and-hazard-analysis-and-risk-based-preventive-controls-for-human>

Federal Register Notice of Corrections to the Standards for Growing, Harvesting, and Holding of Produce for Human Consumption Proposed Rule

<https://www.federalregister.gov/articles/2013/03/20/2013-06357/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-correction>

Frequently Asked Questions Concerning the Proposed Rules for Preventive Controls and Produce Safety

On March 26, FDA released an expanded list of questions and answers on the Preventive Controls Proposed Rule and the Produce Safety Proposed Rule.

Questions & Answers on the Preventive Controls Proposed Rule

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

Questions & Answers on the Produce Safety Proposed Rule

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

FDA Holds Final Public Meeting on FSMA Proposed Rules

On March 27 and 28, in Portland, Oregon, FDA held the third in a series of public meetings to receive comment on the proposed rule for preventive controls for human food and the proposed rule for produce safety.

Materials related to the public meeting are available at

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339096.htm>