4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1153]

Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA to Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and information.

SUMMARY: In September 2011, the Food and Drug Administration (FDA or the Agency) asked the Institute of Food Technologists (IFT) to execute product tracing pilot projects as described in the FDA Food Safety Modernization Act (FSMA). FDA recently released a report from IFT on these pilot projects, entitled "Pilot Projects for Improving Product Tracing along the Food Supply System." FDA is announcing the opening of a docket to provide stakeholders and other interested parties an opportunity to submit comments and information that will help the Agency as it forms its own recommendations, to be contained in the Agency's report to Congress, and as it implements the FSMA provisions relating to the tracking and tracing of food.

DATES: Submit electronic or written comments and information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments and information, identified by Docket No.FDA-2012-N-2012-N-1153, by any of the following methods:

Electronic Submissions

Submit electronic comments and information in the following way:

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

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper, disk, 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-2012-N-1153 for this notice. All comments and information received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments and information, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments and information received, go to http://www.regulations.gov and insert the docket number(s), 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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sherri A. McGarry,

Office of Foods,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 1, rm. 1212,

Silver Spring, MD 20903,

301-796-3851.

SUPPLEMENTARY INFORMATION:

I. Background

A. FSMA Provisions Regarding Enhanced Tracking and Tracing of Food and Recordkeeping

On January 4, 2011, the President signed FSMA (Public Law 111-353) into law. Section 204 of FSMA, 21 U.S.C. 2223, relates to enhanced tracking and tracing of food and recordkeeping. As part of this provision, FDA must, among other things, complete the following:

1. Establish pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. FDA is required to submit a report to Congress on the findings of the pilot projects together with FDA's recommendations for improving tracking and tracing of food;
2. Assess the costs and benefits associated with the adoption and use of several product tracing technologies and the feasibility of such technologies for different sectors of the food industry (including small businesses);
3. To the extent practicable in assessing the costs, benefits, and feasibility of several product tracing technologies, evaluate domestic and international product tracing practices; consider international efforts and compatibility with global tracing systems, as appropriate; and consult with a diverse and broad range of experts and stakeholders;
4. Establish within FDA, as appropriate, a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food;
5. Publish a notice of proposed rulemaking to establish additional recordkeeping requirements for high risk foods;

6. Designate high-risk foods for which the additional recordkeeping requirements are appropriate and necessary to protect the public health. The list of high-risk foods is to be published on FDA's Internet Web site when the Agency issues the final rule establishing additional recordkeeping requirements for high-risk foods; and
7. Issue a small entity compliance guide within 6 months after the final rule is issued.

B. FSMA Provisions Directing FDA to Establish Pilot Projects to Explore and Evaluate Methods for Rapid and Effective Tracking and Tracing of Foods

Under section 204(a) of FSMA, in September 2011, FDA established pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. These product tracing pilots were executed through an existing contract with the IFT. IFT was required to:

1. Conduct two food product tracing pilot projects--one in coordination with the processed food sector and one in coordination with the produce sectors--working in consultation with the U.S. Department of Agriculture, State public health agencies, and nongovernmental organizations that represent the interests of consumers;
2. Conduct the pilot projects to reflect the diversity of the food supply and consider / address confounding factors, such as commingling and transshipment;
3. Include different types of FDA-regulated foods that were the subject of significant outbreaks between 2005 and 2010;
4. Use the selected foods to develop and demonstrate methods for rapid and effective tracking and tracing of foods that are practical for facilities of varying sizes, including small businesses;

5. Use the selected foods to demonstrate appropriate technologies that enhance the tracking and tracing of foods along the supply chain from source to points of service;
6. Demonstrate the tracking and tracing of: (a) A selected processed food and its key ingredients (minimum of two ingredients) and (b) a selected fruit and/or vegetable along the supply chain;
7. Assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients; and
8. Determine the feasibility of product tracing technologies for different sectors of the food industry, including small businesses.

FDA released the report containing the findings of the pilot projects, entitled "Pilot Projects for Improving Product Tracing along the Food Supply System" in March 2013. The report is available on FDA's Product Tracing Web page at http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm. This extensive report is being reviewed by FDA. After careful review of this report and information previously gathered, FDA will submit its report to Congress containing FDA recommendations for improving product tracing. This docket is being opened in order to request comments on the pilot project report's findings and recommendations to help inform FDA in preparing its recommendations in the Agency's report to Congress.

C. Request for Comments and Information

In addition to providing the findings of the pilot projects, the report contains IFT's recommendations for FDA on improving tracking and tracing of food. FDA released this report to make it available for stakeholders and to solicit input that may be helpful as FDA forms its own recommendations, to be contained in the Agency's report to Congress, and as FDA

implements other FSMA requirements related to product tracing. FDA invites comment on the findings and recommendations contained in the IFT report and the submission of information relevant to improving product tracing. In addition, FDA would like specific comment on the following:

1. The report contains specific recommendations regarding key data elements (KDEs) and critical tracking events (CTEs). How might this work for your industry segment? What would you keep the same or change in Table 2 in the Executive Brief of the report? Please include an explanation of why you would keep the same or change.
2. The report recommends that all foods be covered, not just high-risk foods. The rulemaking requirement in section 204(d) of FSMA only refers to high-risk foods. Should FDA pursue implementation of some or all of the report's recommendations with respect to all foods, not just high-risk foods? If so, what routes might the Agency use?
3. The report recommends that each member of the food supply chain should be required to develop, document, and exercise a product tracing plan. FDA is aware that industry often conducts and documents recall exercises, which are essentially traceforward exercises. Is it feasible to add a traceback to existing procedures and exercises? Should FDA include this IFT recommendation as one of its recommendations in the Agency's report to Congress? Please explain why the FDA should or should not include.
4. What additional information and data sources could be used to determine cost and benefits associated with implementing IFT's recommendations for KDEs and CTEs?
5. How might FDA more clearly and consistently articulate the information it needs to conduct product tracing investigations? Would posting information on FDA's Web site on how FDA typically conducts a traceback or traceforward be helpful?

6. The report recommends that FDA develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations. How would this work for your industry segment? How might it be achieved most expeditiously?
7. Is there anything else FDA should consider in preparing its recommendations for improving product tracing in the Agency's report to Congress?

II. Comments

Interested persons may submit either electronic comments regarding this document 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.

III. References

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov.

1. McEntire, Jennifer and Bhatt, Tejas, "Pilot Projects for Improving Product Tracing Along the Food Supply System–Final Report," Institute of Food Technologists, August 2012.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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