Overview
Enhancing Tracking and Tracing
Sec. 204

FDA Food Safety
Modernization Act

FDA

FDA FOOD SAFETY
MODERNIZATION ACT

Before FSMA:

- Priority for the Administration
  - President's FSWG
- Reportable Food Registry – Sept, 2009
- 2 IFT Reports released in Dec, 2009. Industry "best practices" and tomato traceback exercise

Before FSMA:

- 2008 - Two Public Meetings - PRODUCE

- 2009 – joint Public Meeting by FDA and USDA

  ALL FOODS

  – Purpose to stimulate and focus efforts on mechanisms to enhance product tracing

  – Substantive comments from speaker panels and public comment

FSMA

- FSMA signed into law January 4, 2011

- Title II. Section 204. Enhancing tracking and tracing of food and record keeping

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The Public Health Imperative

- Foodborne illness is a significant burden
  - About 48 million (1 in 6 Americans) get sick each year
  - 128,000 are hospitalized
  - 3,000 die
- Immune-compromised individuals more susceptible
  - Infants and children, pregnant women, older individuals, those on chemotherapy
- Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
  - Arthritis, kidney failure

FSMA Sec 204. Key Requirements

- Pilot Projects
- Report to Congress
- Designation of High Risk Foods
- Proposed Rule
- Public meetings
- Final Rule
- Guidance

Pilot Projects

- Collaboration with IFT
- At least 2 pilots required: Produce & Processed food
- Stakeholder input critical
- IFT report to FDA posted on FDA FSMA website
- IFT report also contains additional information required to be gathered.
- Docket opened, request for information
  - Docket No. FDA-2012-N-1153 ; www.regulations.gov

Federal Register Notice, Request for information

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.**

Request for Information cont. (Docket No. FDA-2012-N-1153)

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?**

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FDA Report to Congress

- Provide findings and recommendations from pilots
- Consider comments submitted in the Docket
- Provide FDA's recommendations, based on long history of efforts in this area, as we move forward in proposed rule making

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High Risk Foods List

HRFL designation shall be based on--

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

High Risk Foods List cont.

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

Rulemaking Process

- Rulemaking is open and public.
- Time is allowed for public comment; FDA will consider significant comments during the rulemaking process.
- FSMA required proposed rule by January 4, 2013
  - FDA prioritizing the many rules required

- Record keeping requirements for high risk foods
  - 3 Public Meetings in diverse geographic settings

Current Activities

- IFT Report to FDA on pilots studies published on FDA FSMA website, product tracing page
- Docket opened for public comments on pilot study's recommendations with specific request for information.
- Review comments from the docket (open) to inform FDA's Report to Congress and rulemaking process
- Gathering information for proposed rule

For more information

Consumer Health Information

Food Bill Aims to Improve Safety

Recent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The reasoning is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

Under the provisions of FSMA, companies will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected

- Product tracing page on FDA Web site is at http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov

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Thank You!

Remember to submit comments

to the Docket