How To Join Audio

*You must enter your attendee ID # when you call into the teleconference to ‘raise your hand’, be unmuted, and participate in the discussion.
Produce Safety Educators
Monthly Meeting #9
May 5, 2014
2PM EDT
Instructions

• All participants are muted.
  – To ask a question or make a comment, please ‘raise your hand’ using the small button on the right hand panel
  – We may not get around to all comments/questions, BUT you may leave additional comments in the comment box to be compiled after the session

• This session is being recorded.
• Notes will be circulated after the meeting.
Agenda

• Discussion on Traceability
  – Questions

• PSA Update
  – Need info on training needs

• Agenda items to discuss for June meeting
  – See you at CPS?
FDA FSMA Section 204.
Product Tracing

Implementation Update

Sherri A. McGarry
Food & Drug Administration
Office of Foods & Vet. Medicine/OC
May 5, 2014
FSMA

• FSMA signed into law January 4, 2011

• Title II. Section 204. Enhancing tracking and tracing of food and record keeping
  – Opportunities to advance public health through more rapid traceback
  – Limitations exist
Key Requirements

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

• Collaboration with IFT
• At least 2 pilots required: Produce & Processed food
• IFT report to FDA posted on FDA FSMA website
• IFT report also contains additional information required to be gathered
• Solicited comment in Docket & request information
  – Comment period closed July 2013
Key Pilot findings

“The process of conducting a step-wise product tracing investigation was complicated and often times confusing. Inconsistencies in the terminology, numbering systems, formatting, legibility, and occasionally the language sometimes required IFT to contact the submitting firm to gain clarity, increasing the time required to capture data before any meaningful analysis could begin. However, the pilot participants appeared to have many of the tools and processes in place which are required to allow the capture and communication of critical track and trace information…”
IFT’s Recommendations

Selected recommendations from IFT’s report to FDA:

• From an overarching perspective, IFT recommends that FDA establish a **uniform set of recordkeeping requirements** (for all FDA-regulated foods)
  – require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of **Critical Tracking Events (CTEs)** and **Key Data Elements (KDEs)** as determined by FDA.
Selected recommendations:

- FDA should develop **standardized electronic mechanisms** for the reporting and acquiring of CTEs and KDEs during product tracing investigations.

- FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.
IFT Recommendations (cont.)

*Selected recommendations:*

- FDA should coordinate traceback investigations and develop response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes.

  - FDA should formalize the use of industry subject matter experts in product tracing investigations.
Public Comments on IFT Recommendations and FDA questions in docket

• Review suggests varied opinions on issues
  – Ranging from no need for new regulations to surpassing authority in sec 204

• Ideas suggested

• Inform FDA’s Report to Congress and rule making
Report to Congress
Report to Congress...work in progress

- FDA wanted comments on IFT pilot and other info to consider in drafting the Report to Congress
- Examples of Likely Content:
  - FDA’s Overall and Historical Efforts to improve Product Tracing
  - FSMA required Pilot: Findings
  - IFT Recommendations to FDA
  - FDA Recommendations Moving Forward
Designating High Risk Foods

Specific to sec 204 of FDA FSMA
High Risk Foods List

HRFs 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.
Designating High Risk Foods

• Based on specific factors mandated in sec 204

• Open docket for comment:
  – FDA’s draft approach to designating high risk foods comment period ends May 22
  – [link](http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0053-0003)

• Refine approach, peer review method
FDA Proposed Rule

• Product tracing requirement by January 4, 2013
  – FDA prioritizing the many rules required

• Information gathering stage

FUTURE:

• Publish proposed rule for record keeping requirements for high risk foods
  – Three public meetings/public comment
Summary Status

Implementing
Sec 204 FDA FSMA
Summary Status

- IFT Report to FDA on pilots studies published on FDA FSMA website, product tracing page
- Report to Congress under development
- Open docket for comments on FDA’s draft approach to designating high risk foods (specific to sec 204)
- FAQs updated on FDA FSMA website [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#ProductTracing](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#ProductTracing)
- Exploring ways to enhance FDA’s process
- Gathering information for proposed rule
What we’re aiming for:

• A rapid and interoperable product tracing system that reduces illness if we can identify source faster

• More uniform approach globally

• Advance preventive food safety policies from lessons learned in investigations
Questions?

Please ‘raise your hand’ to be unmuted or type your question into the chat box.
Input for Training Needs

• Survey questions were helpful, but many did not fill out the survey and we would like complete info.

• You may be receiving a call from us in the next two weeks to get a more accurate information about:
  – Train the trainer needs in your state
  – Grower training needs in your state
  – Industry organizations and groups that your growers depend on or have joined

• Callers name is Claire!
PSA Update

• Final curriculum review
• Plan to conduct train-the-trainer workshops as soon as we can
• Plan to train (and certify) growers as soon as we can
  – This means before the rule if final
  – Follow up with them if something is different
Other Topics

• Next meeting: Monday June 2\textsuperscript{nd} at 2PM EDT
• Send Gretchen (glw53@cornell.edu) additional agenda items
Contact Us

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