Produce Safety Educator’s Monthly Call #9
May 5, 2014
2 PM EST
Meeting Summary

Total Attendance (Web & Call In): 40
Meeting recording available at:
https://cornell.webex.com/cornell/lsr.php?RCID=f59ac9c38b74f18031308e825a6757d2

Agenda

• Questions on Traceability
  o Sherri McGarry, FDA, Senior Advisor, Office of Foods and Veterinary Medicine
• Input for national need of Train-the-Trainer and Grower Trainings
• PSA Update

Discussion

I. Traceability

• The proposed rule has not been issued yet for this section of FSMA (Section 204 – Enhanced Tracking and Tracing of Food and Recordkeeping)
  o General Web Information on FDA Product Tracing: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm270851.htm#producttracing
• Data is kept in records to track and manage movement of food through the food system. FDA is working on identifying what key data elements are needed to improve the system.
• Product tracing helps get to the source of where a food came from that is causing a foodborne illness outbreak to prevent more people from getting sick or if contaminated product is identified through testing remove it from the market.

• Key Requirements in Section 204
  o Pilot project reports – completed, partnered with IFT
    ▪ Two pilots completed: one on produce, one on process food
    ▪ IFT report also contains what information is still needed
    ▪ Solicited comment in the docket and request for specific information which closed in July 2013
    ▪ A few recommendations from the IFT Report:
      – Need uniform set of requirements (for all FDA regulated foods)
      – Require firms that manufacture, process, pack, transport, process, distribute, receive, hold, or import food to identify and maintain records of critical tracking events (CTEs) and key data elements (KDEs)
      – Should develop a standardized electronic mechanism for reporting and product tracing
– FDA should clearly and consistently articulate and communicate to industry the info it needs to conduct a product tracing investigation
– FDA should coordinate traceback investigations and protocols with state and local authorities and improve existing commissioning and credentialing processes
– Formalize the use of industry subject matter experts in traceback investigations


○ Report to Congress
   FDA is working on this currently. The IFT pilot reports helped inform the report to Congress.
   Report will include FDA’s overall and historic efforts to improve product tracing, the FSMA required pilot findings, IFT’s recommendation to FDA, and FDA’s recommendation moving forward

○ Designation of High Risk Foods
   FSMA requires designation of high risk foods, these are based on:
    1.) Known safety risks of a particular food, including outbreak history and severity
    2.) Likelihood that a particular food has a high 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 it
    3.) The point in the manufacturing process of the food where contamination is likely to occur
    4.) Likelihood of contamination and steps taken during the manufacturing process to reduce possibility of contamination
    5.) Likelihood of consuming a particular food will result in a foodborne illness due to contamination
    6.) The likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food

 There is opportunity to provide broader guidance, not just on high risk foods, but to better protect public health. FDA plans to partner with industry for solutions.
   You may comment electronically on http://www.regulations.gov. Comment Now!
   Comment period ends May 22, 2014!
   Submit written submissions to:
    Division of Dockets Management (HFA-305)
    Food and Drug Administration
    5630 Fishers Lane, Rm. 1061
    Rockville, MD 20852.
  *All submissions received must include the agency name and docket # FDA-2014-N-0053.

○ Enhancing the FDA process
   Need to create a more efficient and effective process for tracing food products.
o Issue a proposed rule
o Host public meetings (3)
o Issue a final rule
o Provide guidance
• What the FDA is aiming for:
o Rapid and interoperable product tracing system that reduces illness if we can identify the source faster
o Uniform global approach
o Advance preventive food safety policies from lessons learned in investigations
• Questions
o We know when there are outbreaks, the ‘teachable moments’ sometimes are not shared right away because of the legal issues. Has there been any discussion to get the ‘teachable moments’ out quicker so that we can know more about what caused the outbreak?
  ▪ Yes, but in small steps. The FDA Post-response unit in CORE is better able to capture these events and share this information. Also we hold calls with state partners on findings, within the realm of what they can share. More information has been going out in memos to the industry on outbreak investigations. FDA is definitely moving in this direction to improve sharing of information.
  ▪ FDA is making every effort to put more reports on the web – findings, environmental investigations, and letters to industry if a trend is noticed.
o What is the FDA looking at in terms of an electronic mechanism for product tracing? (Barcodes, other systems)
  ▪ FDA has not proposed the rule yet, so it is an open slate. They do not want to dictate the type of technology because there may be many options. They recognize that not all individuals use electronic systems.
  ▪ For example, barcodes are being used widely in the produce industry, but they have their limitations. In short shelf life products, such as produce, the actual barcode may not be useful because the product has already been eaten, but the data and records kept within the chain are more useful.
o When do you think the proposed rule will be published?
  ▪ There are too many variables. FDA is making solid progress and have finished the pilots and working diligently on the report to Congress. Still need to release high priority rules though (e.g. Produce Rule, Preventive Controls Rule).

II. Input for Train Needs
• Surveys from last month’s meeting on training needs were very helpful, but not complete.
• Expect a call from a graduate student named Claire in the next week or so to ask:
  i. Train the Trainer needs in your state
  ii. Grower training needs in your state
  iii. Industry organizations and groups your growers are affiliated with
Even an estimated number is helpful. We are looking for how many trainings are needed to satisfy the FSMA training requirement for growers or how many you think you will have demand for even if the growers are not required to attend. Claire will record the information and note the differences, so please just let her know so she can make a note.

III. PSA Update

- Final curriculum is scheduled to be released in the next few days for a final review
- Train-the-Trainers to be launched as soon as possible
- We will be training BEFORE the rule is final and following up with growers if something changes in the final regulation
- Question: Who will be paying for what – e.g. Train-the-Trainer programs?
  - Short answer: the initial budget had funding to go to the top eight production states. This will be the initial focus of our efforts. We have received letters of support to go to places where we initially did not have funding to go. We are hoping to receive additional funding to go to more states. We will try our best to conduct Train-the-Trainers in regional locations that would support other people coming from neighboring states.
  - Grower trainings: many people are putting in for Specialty Crop Block Grants and state support

IV. Other news

- **Special Session at IAFP – Mark Your Calendars**: August 4th from 5:15pm-6:45pm for an update on the Produce Safety Alliance. More info will be sent out soon.

Call Wrap Up:

- **Future Produce Safety Educator Meeting Agendas**: Let us know what you would like to talk about! Send us your ideas, concerns, comments and we will add it to the next monthly meeting.
  - **Next meeting: Monday June 2nd, 2014 at 2PM EST**
  - Happy Cinco de Mayo!