Food Safety, What’s Next

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FSIS Initiatives

- FSIS continues to issues policies and proposed rules that have been on “hold” for a period of time
- FSIS is not looking to “change” the implementing Acts, but are looking to increasingly become more proactive and preventive in conducting their verification activities

PHIS

- Comprehensive data analytics system
- Collect, consolidate, and analyze data
  - Support for the preventive system
- Domestic inspection, import activities, export activities and predictive analytics
- PHIS empowers FSIS with the tools to stay ahead of food safety threats by more rapidly and accurately identifying emerging trends, patterns and anomalies in data

FSIS Current Initiatives

- Public Health Inspection System (PHIS)
- Validation
- Salmonella Initiatives
- Poultry Slaughter Modernization
- STEC Initiatives
- Residues

Validation

- Will the HACCP work in theory?
- Does the plan work in practice?
  - FSIS issued draft Compliance Guidance for Industry
    - Comment period
    - Received feedback from National Advisory Committee for Meat and Poultry Inspection
    - Public Meeting (June 25, 2013)
      - FSIS working towards best understanding for all to ensure validated HACCP programs
Salmonella (raw beef)

- FSIS conducts on-going performance standard testing for Salmonella in beef
- However, if at any point FSIS determines there is specific product in commerce making people sick... They WILL ask for a voluntary recall of that specific production of product.

Salmonella

2009

- 3 recalls for raw beef and Salmonella
  - As a result of an ongoing investigation into illnesses from Salmonella Newport associated with ground beef products, the Arizona Department of Health Services (ADHS) notified FSIS of the situation. Epidemiological and traceback investigations conducted by FSIS and ADHS determined that there is an association between the fresh ground beef products and two (2) illnesses reported in Arizona. The Salmonella Newport strain was isolated both from the patients and from ground beef produced by Est ABC

Salmonella

- Prevalence and Characterization of Salmonella in Bovine Lymph Nodes Potentially Destined for Use in Ground Beef
  - ARTHUR,* BRICHTA-HARHAY, BOSILEVAC, ET AL
- “A potential source of pathogenic bacteria in ground beef is the lymphatic system, specifically the lymph nodes.”

Salmonella

- FSIS has received a petition to make certain serotypes adulterants in raw beef (Newport and Typhimurium)
- FSIS will have to respond to petition
- FSIS continues to take samples in ground beef as “process control” samples
  - FSIS will have to become more aggressive in light of the petition and the lack of progress in meeting Healthy People goals

Salmonella

- ... not emerging as a pathogen but as a “focus for regulators”
  - CDC reported—“The incidence of infections with specific Salmonella serotypes in 2012, compared with 2006–2008, was lower for Typhimurium (19% decrease; CI: 10%–28%), higher for Newport (23% increase; CI: 1%–50%), and unchanged for Enteritidis. Compared with 1996–1998, the incidence of infection was significantly higher for Enteritidis and Newport, and lower for Typhimurium.

Poultry Slaughter Modernization
Poultry Slaughter Modernization

- FSIS has issued a proposed rule to modernize poultry slaughter inspection
- Relies on industry conducting *Salmonella* testing as a component of the verification process
- Industry “pre-sorts” birds for FSIS inspection
- Once finalized could lead to FSIS looking at other species and changes to modernize inspection process

Non-O157 STEC

Agency Current Actions for STEC

- FSIS has been collecting beef trim samples
- FSIS now responds to a positive similar to an O157 positive
  - FSIS takes follow-up samples (16 samples at large establishments; 8 at small)
  - FSIS conducts “for cause” food safety assessments
- FSIS to verify that controls are effective for STEC

FSIS Actions and Expectations

- Specifically, during FSA, FSIS verifies that:
  - Establishments have reassessed their HACCP plans, as part of 9 CFR 417.3(b) corrective actions.
  - Establishments can provide scientific support that their existing controls for *E. coli* O157:H7 effectively control the non-O157 STEC
    - Establishment has data to demonstrate the implementation of the controls according to this support.

STEC Policy Expanded – What’s Next

- FSIS is sending sample enrichment broths that are positive for the stx and eae genes but negative for all of the six non-O157 STEC and *E. coli* O157:H7 to USDA, ARS for further analysis. Data will be used to determine next steps.
  - Ground beef testing
  - Component testing
    - FSIS will publish Federal Register prior to initiating further testing.

FSIS National Residue Program

- FSIS works in partnership with FDA and EPA to implement the regulatory “National Residue Program”
- FDA and EPA set tolerances for the compounds used
- FDA does on-farm investigations and “takes action” at producer level
- FSIS conducts testing at slaughter establishments
  - Tier 1 – random surveillance testing of healthy animals
  - Tier 2 – targeting testing of suspect animals selected and screened by in-plant veterinarians
  - Tier 3 – special projects and follow-up if FSIS suspects a herd situation (e.g., dioxin in environment on a farm)
Tier 1

- FSIS uses a multi-residue method analyzes for:
  - Fluoroquinolones
  - Hormones
  - Macrolides/Lincosamides
  - Analgesics/Anti-inflammatories
  - Tetracyclines
  - Phenicols
  - Sulfonamides
  - β-agonist
  - β-Lactam/Cephalosporin

Tier 2

- In-plant directed sampling
  - FSIS public health veterinarians will select animals based on disease conditions (itis and emias) and run an in-plant KIS™ test on kidneys
    - If in-plant “positive” on the KIS™, then samples (kidney, muscle and liver) are sent to FSIS laboratory for confirmation
      - Initially using the multi-residue methods described above, then using the FDA confirmatory method for any specific residue identified on the MRM

What Actions is FSIS Looking For?

- “Best Practices”!
  - Identification of all animals received at slaughter (traceback to producers)
  - Provide traceback information to FSIS at the time testing is conducted
  - Establishment contacting producers when there is a violation to educate them and expressing concern regarding violations
    - Notification to producer that establishment will not continue to purchase animals from repeat violators

Food and Drug Administration

Expectations for 2013

Prevention as the “Cornerstone”

- Food Safety Modernization Act (FSMA)
  - Comprehensive preventive controls for food facilities
  - Produce safety standards
  - Foreign supplier verification program
  - Comprehensive preventive controls for animal feed
  - Third party certification

Residues

- FSIS issued a Compliance Guidance for Preventing Residues – May 2013
  - Reinforces these “Best Practices”
  - Highlights times FSIS will increase sampling
  - Describes FSIS repeat residue violator list
Inspection, Compliance, and Response

- FDA is mandating inspection frequencies
- Introducing new tools
  - Mandatory recall
  - Expanded records access
  - Expanded administrative detention
  - Re-registration of facilities
    - Ability to suspend registration of facilities
  - Enhanced product tracing

Partnerships = key to success

- FDA will rely on inspection by other Agencies as part of standards being met
- State/local and international capacity building
- Consortium of laboratory networks
- National agriculture and food defense strategy

Most Significant New Change: Import Safety

- Importers responsible to have preventive controls in place
- FDA may use third parties to certify foreign food facilities meet US requirements
- FDA can deny entry if access for inspection is denied
- FDA can require mandatory certification for high-risk foods

Preventive Controls for Human Food

Proposed Rule

Food Safety Plan

- Covered facilities must have a written food safety plan
  - Unless no hazards reasonably likely to occur
  - “Qualified individual” must prepare, or oversee preparation of, the plan
  - Owner, operator, or agent in charge of facility must sign and date plan

Written Food Safety Plan

- Required elements:
  - hazard analysis;
  - preventive controls;
  - monitoring procedures;
  - corrective action procedures;
  - verification procedures (including frequency of calibration of instruments); and
  - recall plan
Written Food Safety Plan

• Hazards include:
  ➢ Biological (e.g., bacteria, viruses, parasites)
  ➢ Chemical (e.g., heavy metals, pesticides, drug residues, natural toxins, unapproved food and color additives, major food allergens, decomposition resulting in toxin production)
  ➢ Physical (e.g., metal, glass, plastic)
  ➢ Radiological (e.g., strontium-90, cesium-137, radium-226)

Preventive Controls

• “Preventive control”
  ➢ Reasonably appropriate procedures, practices, and processes that a knowledgeable person would employ to reduce hazards reasonably likely to occur to an acceptable level

Preventive Controls

• Preventive controls must include, as appropriate:
  ➢ Sanitation controls (e.g., procedures for cleaning and sanitizing food-contact surfaces)
  ➢ Process controls (e.g., cooking, cooling, acidifying)
  ➢ Food allergen controls (e.g., production sequencing, physical barriers, control of dusts and aerosols)
  ➢ Any other necessary controls (e.g., temperature control during transportation)

Dual Jurisdiction Plants

• Plants running both FSIS and FDA products
  ➢ Cautiously optimistic that the Agencies will reach agreement that written plans could meet requirements for both Agencies
    ✧ FDA proposal requires documentation for pre-requisite programs

Animal Feed Preventive Controls

• Very similar to human preventive controls
  ➢ Will also be issued as a new section to the CFR (proposed rule)
    ✧ Do not anticipate to require including allergens as a hazard

Animal Feed Preventive Controls

Expect Proposal Soon
Animal Preventive Controls

- Current cGMPs
  - Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution

Standards for Produce Safety

Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Agricultural water
- Growing, harvesting, packing and holding activities
- Biological soil amendments of animal origin
- Specific requirements for sprouts

Implementation

- FDA will continue to issue proposed rules to meet the entirety of the Food Modernization Act...
- FDA will publish a guidance document that provides the requirements to assist in complying with the hazard analysis and preventive controls requirements
- FDA has established a Food Safety Preventive Controls Alliance to develop a core training curriculum and to disseminate information on hazards and controls to help industry in meeting the requirements

Produce Safety

Proposed Rule

- FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables.
- Standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.

Summary

- Food safety remains a priority of the Administration
- Both FSIS and FDA working towards a preventive food safety system
  - Prevention; Compliance; Enforcement
- The Agencies are working together to protect public health
- We are a key component to the success!
Questions