



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

Overview

- Notification of adulteration/misbranding (i.e., foreign material contamination/consumer complaints follow-up)
- Pathogen reduction performance standard verification: *Salmonella* and *Campylobacter*
- Worker safety attestation
- FSIS interaction with FDA on FSMA concerns in dual jurisdiction facilities
- Questions

Food Safety and Inspection Service:

9 CFR 418.2

- FSIS notification requirement is a preventive measure intended to reduce recalls by number or volume
 - Identify widespread distribution of associated product that may be contaminated, whether adulterated or misbranded
- District office (DO) notification is required by receiving and producing official establishments
 - Use FSIS Form 8140-1 when product moves between establishments

Food Safety and Inspection Service:

Foreign Material Contamination -- Recall Classification Considerations

- Recall classifications for foreign material are made on a case by case basis.
- Recall committee considers the likelihood of injury resulting in consumption of product
- Factors may include:
 - size
 - material (i.e., color, hardness)
 - intended customer (i.e. toddler food)

Food Safety and Inspection Service:

FSIS and FDA Comparison Regarding Recall Triggers

- The FDA foreign material guidance does NOT capture all incidents that could result in a recall
 - FDA has a limited size range (>7mm, <25mm)
 - Does not address soft objects
 - Does not address misbranding
 - Does not address chemical or biological

Food Safety and Inspection Service

Summary of Foreign Material Recalls

2005-December 1, 2016

	Class I	Class II	Class III	Total	<7 mm*	>7mm	unknown
Plastic	14	28	5	47	7	22	18
Metal	12	4	3	19	4	7	8
Rubber	1	1	0	2	0	0	2
Glass	4	0	0	4	0	2	2
Bone	2	0	0	2	2	0	0
Other single	2	1	1	4	0	2	2
Combination	4	5	2	11	0	6	5
TOTAL	39	39	11	89	13	39	37
Percent ⁺	44%	44%	12%	--	15%	44%	42%

* ALL particles <7mm, + Percentages add to greater than 100% due to rounding

Food Safety and Inspection Service:

FSIS Foreign Material/Consumer Complaint PHIS Questionnaire Results

- *Consumer Complaint Survey Questionnaire Results*
 - 2676 responses
 - 58% of the establishments have a process to gather and evaluate all consumer complaints regarding foreign material and maintain this information in a written document
 - 55% of the establishments have a written description of the actions it takes for all consumer complaints regarding foreign material, including when no action is taken
 - 56% of the establishments provide the written documents (items 1&2) to IPP for review upon request.

Food Safety and Inspection Service:

Voluntary “Consumer Complaint Best Practice” Suggested for Industry

- Develop a written plan to capture procedures for assessing and handling all foreign material contamination events, including how consumer complaints are tracked, supported, and resolved
- Inform FSIS that an event investigation is underway, especially if potentially food safety-related
- Make the written plan/status updates available for FSIS review

Food Safety and Inspection Service:

Pathogen Reduction Verification Status

- For *Salmonella* (through December 31, 2016):
 - For chicken carcasses, ~88 percent of establishments are passing the performance standard, with ~69 percent in Category 1; for turkey carcasses, ~100 percent of establishments are passing the performance standard, with ~97 percent in Category 1
 - For comminuted chicken, ~60 percent of establishments are passing the performance standard, with ~38 percent in Category 1; for comminuted turkey, ~68 percent of establishments are passing the performance standard, with ~47 percent in Category 1
 - For chicken parts, ~58 percent of establishments are passing the performance standard, with ~36 percent in Category 1
- For *Campylobacter*:
 - Performance is posted; however, FSIS is not focused on Category status at this time and is continuing to assess moving to a 30 ml performance standard due to relatively low numbers/frequency of contamination and tight performance criteria at the 1 ml performance standard
- Data continue to issue on ~20th of the month and is aggregated at this time

Food Safety and Inspection Service:

Worker Safety Attestation

- Applicable only to establishments operating under NPIS
- First annual submittal on work-related conditions due by end of February 2017
 - FSIS Directive 4791.16 (issued 10/6/16) outlines the procedures
 - IIC will collect the attestation on behalf of the management member of the local FSIS circuit safety committee
 - Policies to encourage early reporting of symptoms of work-related injuries and illness, and no policies to discourage reporting
 - Notification of the nature and early symptoms of occupational injuries and illnesses (including posting)
 - Monitoring on a regular basis of injury and illness logs, including workers compensation data
 - Must address the criteria requirements in 9 CFR 381.45
 - DO will be notified if attestation is not submitted
 - DO will submit the attestations to OSHA by end of March
- Appendix A: Workplace Safety and Health Criteria of the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols (Issued 4/15) is available to all establishments
 - Appendix A addresses engineering controls associated with chemical use in establishments (for example ventilation, shielding, shut off valves)

Food Safety and Inspection Service:

FSIS and FDA Dual Jurisdiction Establishments

- Dual Jurisdiction Establishments (DJE)
 - Establishments that operate under the jurisdiction of both FSIS and the Food and Drug Administration (FDA). Example:
 - DJE preparing spaghetti sauce with and without meat, or bone chips for edible gelatin (some rendering on-site)
 - FSIS inspection program personnel (IPP) follow instructions found in [FSIS Directive 5730.1, Responsibilities in Dual Jurisdiction Establishments](#), looking mostly to ensure that insanitary conditions are not created for the edible areas of the FSIS amenable products
 - FDA and FSIS maintain a partnership and collaborate. Examples:
 - Memorandum of Understanding regarding sharing information, including DJEs
 - Reporting on activities to reduce *Listeria monocytogenes* illnesses
 - Effectively implementing FDA's Food Safety Modernization Act (FSMA)
 - National Advisory Committee on Microbiological Criteria for Foods

Food Safety and Inspection Service:

FSIS and FDA Dual Jurisdiction Establishments: FSMA Impact

- FSMA includes the Sanitary Food Transportation Act provisions:
 - Applies to shippers, receivers, loaders and carriers.
 - Prevent food from becoming unsafe during transportation, including
 - adequate temperature control
 - Preventing cross contamination from raw foods or foods containing allergens
 - Excluded are food facilities that are regulated exclusively, throughout the entire facility, by the USDA.
 - DJEs, therefore, are not excluded from FSMA requirements
 - A USDA establishment could be the shipper, loader and carrier
 - Existing USDA regulations address:
 - shipping hazards such as temperature abuse (9 CFR 417.2(a))
 - sanitation of the means of conveyance (9 CFR 325, 9 CFR 381.190, 9 CFR 416)
- USDA and FDA will collaborate to ensure proactive strategies are implemented, including FSMA, which promote safe food handling practices and protect the public health

Food Safety and Inspection Service: Questions??

