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Food Safety and Inspection Service

Small Plant News



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Food Safety Assessments: Lessons Learned From Experiences in the Field

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The goal of USDA's Food Safety and Inspection Service (FSIS) is to ensure that food produced in the U.S. is safe, wholesome, and unadulterated. Food Safety Assessments (FSAs) are one tool used to achieve that goal. FSAs play a key role in helping protect public health and ensure that food is produced in a safe and sanitary environment.

FSIS Directive 5100.1, titled "Enforcement, Investigations, and Analysis Officer (EIAO) Food Safety Assessment Methodology," provides instructions to FSIS EIAOs on how to perform FSAs.

In 2009, FSIS began performing routine FSAs at an average frequency of one every 4 years. This timetable complements the "for cause" FSAs that FSIS also conducts. "For cause" FSAs are scheduled as described in FSIS Directive 5100.4. These reasons for a "for cause" FSA include your plant being implicated in a recall, your products being associated with a foodborne

illness outbreak, failed microbiological sampling sets, increased issuances of noncompliance records of public health concern, and other reasons. These criteria are further described in detail in FSIS' Public Health Decision Criteria Report, available on the FSIS Web site at www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990-c697f34a797f/2010_Public_Health_Decision_Criteria_Report.pdf?MOD=AJPERES.

Whether FSAs are routine or for cause, being notified that your plant is scheduled for an FSA can be overwhelming. However, you can use this assessment as an opportunity to learn about how to improve your food safety system. EIAOs who conduct FSAs are provided with the most current policy to assess regulatory compliance, and they'll share detailed information and findings with you as the FSA progresses. The FSA represents the comprehensive

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assessment of your plant's food safety system, and these assessments play a key role in helping protect public health.

In addition to ensuring that meat and poultry products are safe, wholesome, and unadulterated, the data from the FSAs are used for other purposes. These include reviewing the data for trends to aid in policy effectiveness, gauging risk assessment, using the data to assist in updating compliance guidelines for industry, and determining FSIS training needs.

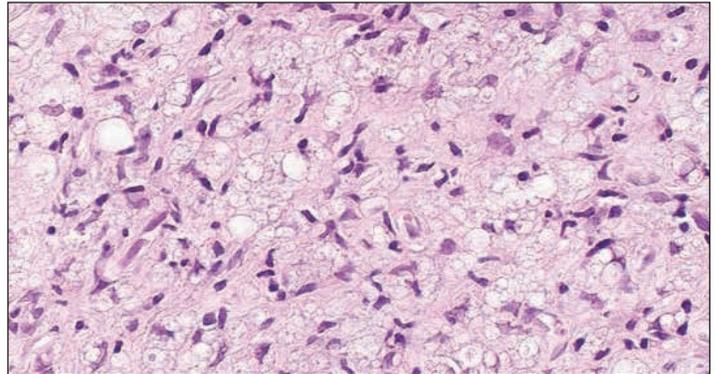
By summarizing the findings from FSAs, FSIS can provide your plant with information so that you can focus your attention on areas where further improvements in your food safety systems may be needed. A review of FSAs over 4 years in the Northeastern United States found several establishments deficient in sanitation and in the design and recordkeeping components of their Hazard Analysis and Critical Control Point (HACCP) programs in accordance with Title 9 of the Code of Federal Regulations (9 CFR). These common findings included the following:

The establishment did not include all steps of the process in the hazard analysis and/or flow diagram as required by 9 CFR 417.2(a)(1) and 417.2(a)(2), respectively.

- » Plants with inadequate or incomplete hazard analyses commonly have insanitary conditions. Plants that do not address all hazards are more likely than those who do to create products that are injurious to health. It is important to have a flow chart to depict the steps of the process. Hazards and control measures should be indicated and clearly visible.

The establishment did not consider hazards as reasonably likely to occur in the production process as required by 9 CFR 417.2(a)(1).

- » Some examples include not identifying hazards such as *Escherichia coli* O157:H7 in ground beef or *Listeria monocytogenes* in post-lethality exposed, ready-to-eat meats. Ingredients added after lethality treatment, such as spices, are another commonly overlooked hazard.



The establishment did not perform monitoring at frequencies specified in the HACCP plan in accordance with 9 CFR 417.5(a)(3).

- » For example, some plants fail to monitor the critical control points (CCPs) at a frequency stated in their HACCP plan. By failing to monitor the CCPs at the specified frequency, the plant could miss processing deviations that might occur, leading to underprocessing, temperature abuse, contamination, or other food safety issues in the product.

The establishment failed to maintain supporting documentation for decisions made in the hazard analysis as per 9 CFR 417.5(a)(1).

- » This includes supporting documentation to demonstrate that prerequisite programs (for example, a receiving program or a *Listeria* monitoring program) are being executed as intended and are effective in controlling or preventing the identified hazards.
- » The lack of supporting documentation (for example, letters of guarantee or certificates of analysis) as prescribed by written programs, may include a failure to have purchase specifications or standard operating procedures that show each lot as being safe, unadulterated, or not injurious to health.

The establishment failed to maintain documentation supporting the monitoring and verification procedures and frequencies within

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the HACCP plan as per 9 CFR 417.5(a)(2).

- » This includes supporting the procedures and frequencies for CCP monitoring, thermometer calibration, records review, and direct observation of monitoring.

The establishment maintained inadequate Letters of Guarantee that did not support the decisions made in the hazard analysis in accordance with 9 CFR 417.5(a)(1).

- » The letters did not contain specific and necessary information to support the safety and wholesomeness of meat and poultry ingredients, non-meat ingredients, and packaging materials. Further, Letters of Guarantee cannot be the sole support for why *Escherichia coli* O157:H7 and the non-O157 Shiga toxin-producing *Escherichia coli* (STEC) are not hazards likely to occur in the raw, non-intact beef processes.

The establishments did not document corrective actions sufficiently as required by 9 CFR 417.3.

- » If a deviation occurs from a critical limit, plants are required to take corrective actions to bring the process under control. These corrective actions must include measures to prevent recurrence of the deviations. In some cases, the corrective actions written by the plants did not provide sufficient explanation to demonstrate how future deviations would be prevented.

The establishment failed to conduct the annual reassessment of the HACCP plan, which is required by 9 CFR 417.4(a)(3).

The establishment was not documenting “results” for Direct Observation or Records Review verification activities as required in 9 CFR 417.5(a)(3).

The establishment failed to maintain sanitary operations and failed to maintain equipment and utensils in a sanitary manner in accordance with the sanitation regulations contained throughout 9 CFR, Part 416, including the design and execution of the Sanitation Standard Operating Procedures (SSOP).

- » 9 CFR 416.2(b) ensures that facilities and equipment are sanitary and in good repair so that cross-contamination is minimized.
- » 9 CFR 416.13 covers monitoring and may be defined as a planned sequence of observations or measurements to assess whether sanitary conditions are being maintained. Accurate records must be kept to document monitoring



activities. Timely and accurate monitoring is essential to food safety management in that it facilitates tracking of processes to prevent direct contamination or adulteration of product.

By reviewing the examples provided above and by addressing deficiencies in your food safety programs, you can help ensure that you meet basic regulatory requirements. In addition, by reviewing your programs to ensure that possible weaknesses are addressed, you can produce safe products and protect the health of your customers.

Remember, when designing your food safety programs, “do what you say, and say what you do.” If you have any questions regarding FSAs, contact the USDA FSIS Small Plant Help Desk by telephone at 1-877-374-7435 or through electronic mail at infosource@fsis.usda.gov.

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Commonly Asked Questions & Answers

Q *Do Enforcement Investigation and Analysis Officers (EIAO) write Noncompliance Records (NRs), or do they instruct inspection program personnel to write them?*

A It is not the role of an EIAO to issue an NR or to instruct inspection program personnel to issue an NR. However, EIAOs can recommend that inspection program personnel write an NR to document regulatory noncompliance observed during a Food Safety Assessment.

Q *What can I do if I do not agree with the documentation on the Noncompliance Record (NR)?*

A You have the right to appeal all or part of the NR. The appeal should be addressed through the FSIS chain of command. 9 CFR 306.5 and 9 CFR 381.35 state that the establishment shall appeal to the immediate supervisor of the person who made the decision. The chain of command can be found in the *Compliance Guideline for Small and Very Small Plants Appealing Inspection Decisions*.

Q *If “retraining employees” is the proposed preventive measure for meeting the corrective action requirement, is an establishment required to document the specific retraining event when it occurs?*

A If the establishment’s preventive measure is that the employee “will be retrained,” documentation that retraining occurred is required to demonstrate that the training was performed to meet the requirement of 9 CFR 416.15(b) and 9 CFR 416.16(a).

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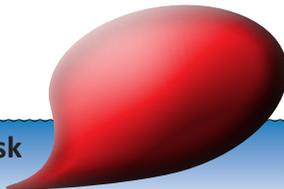
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The screenshot shows the homepage of the Small Plant News website. At the top, there are social media icons for Facebook, Twitter, YouTube, and LinkedIn. Below the title "Small Plant News", a paragraph explains that the newsletter and guidebooks are written for small and very small federal- and state-inspected establishment owners and operators who produce meat, poultry and egg products. It offers help in plain language, translating FSIS rules and regulations into daily operational practices. There is a link to "To Contact the Editors". Below this is a red envelope icon with the text "Receive Email Notification When New Issues of Small Plant News or New Guidebooks Are Published". The main content area is titled "SMALL PLANT NEWS GUIDEBOOK SERIES" and lists several resources: "How to Develop a Meat and Poultry Product Recall Plan (May 2013; PDF Only) | Korean PDF", "PowerPoint Presentation: Developing a Recall Plan: Guidelines for Meeting 9 CFR 5418 | PDF (Apr 30, 2013)", "Introduction to the Microbiology of Food Processing (Jul 2012; PDF Only; 2.36mb)", and "Help for Dealing With Plant Emergencies (Jun 2011; PDF Only; 1.45mb) | Korean PDF (1.8mb) | En Español PDF (2.00mb)". Below this is a section titled "NEWSLETTERS" with the text "Choose PDF for the 4-page, full-color newsletter. A plain text version is also provided."

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