
FSIS DIRECTIVE

5500.3

7/19/2006

INCIDENT INVESTIGATION TEAM REVIEWS

I. PURPOSE

This directive defines Incident Investigation Teams (IITs), explains when and how the teams are formed, and provides the protocols that the teams will use to conduct reviews. Specialized methodologies that the IITs can use as guidance for sampling procedures will be developed and will be available on the Food Safety and Inspection Service (FSIS) web site at http://www.fsis.usda.gov/regulations/Emergency_Management_Policies/. As these specialized methodologies are developed, FSIS will issue a notice announcing their availability. This directive was formerly 6500.2 and is being renumbered to be included in the correct numbering series.

II. CANCELLATION

FSIS Directive 6500.2, dated 8/10/05

III. [RESERVED]

IV. REFERENCES

9 CFR Parts 416, 417, and 500
FSIS Directives 5500.2 and 10,010.1 Rev. 1

V. BACKGROUND

The FSIS Emergency Management Committee (EMC) is a standing committee that may be activated at anytime to address and manage the Agency's response to a non-routine incident involving the adulteration of FSIS –regulated product or to manage a significant event or potential public health issue that requires coordination and sharing of resources among program areas. From time-to-time, the EMC may need to form an IIT to investigate and provide information regarding an emergency incident.

VI. IITs

A. Team Reviews

The Emergency Management Committee will determine the need for IIT reviews and based on the nature of the incident, establish the lead program area. IIT reviews typically will be in response to:

1. An illness or outbreak in which a meat, poultry, or egg product produced by the establishment has been implicated;
2. Significant or repetitive contamination or adulteration incidents; or
3. Repetitive microbiological sampling failures as a result of either the Agency or establishment testing (e.g., *Escherichia coli* O157:H7, *Listeria monocytogenes*, or *Salmonella*).

B. Team Members

The EMC, with concurrence from the Assistant Administrators (AA) will designate team members.

IITs will typically include persons that:

1. can conduct investigations that involve ensuring evidence chain-of-custody, analysis of records, conduction of interviews, collecting and preparing samples for laboratory analysis, and maintaining contact and coordinating activities with the Office of Inspector General (OIG) and other regulatory or law enforcement agencies;
2. can review microbial testing results to assess (a) probable causes of food safety failures and (b) where it would be most useful to take samples;
3. can analyze scientific data and make technical judgments concerning the design and execution of the establishment's food safety systems and the factors that may be causing them to fail;
4. can examine epidemiological evidence (particularly in cases where a foodborne illness has occurred or has the potential to occur);
5. are familiar with the meat, poultry, and egg product regulations and FSIS inspection-related directives and notices; and
6. are familiar with in-distribution channels and appropriate related authorities.

NOTE: If other Federal or State agencies participate in reviews (e.g., when a foodborne illness has occurred), FSIS officials will take the lead. Other officials will be expected to operate under and adhere to FSIS statutory and regulatory requirements.

If the situation involves deliberate contamination of product, OIG or another law enforcement agency may take the lead.

C. Team Leader (TL)

The EMC designated lead program area will identify the TL who will be responsible for managing the team, facilitating the communication among team members, assigning team member responsibilities, and communicating with the District Office (DO) and the EMC concerning the progress of the review. The TL will conduct an entrance and exit conference with the establishment and is the contact person for the establishment should the establishment have any questions or concerns. The TL is also responsible for ensuring the completeness of the report and determining when the team's work is completed. In cases of deliberate product contamination, the TL is responsible for coordinating investigative activities with OIG and any other regulatory or law enforcement agencies that are involved.

D. Establishment Notification

The DO will notify the establishment that an IIT will be conducting a review and specify which records and documents should be made available to the IIT when it arrives at the establishment.

NOTE: If, while conducting the review, the establishment does not provide requested records or documents, FSIS may obtain an administrative subpoena in accordance with Agency's statutory authorities to compel production of the requested information. The TL should work with the OPEER, CID team member or contact the OPEER Regional Manager to obtain the subpoena. OIG or another law enforcement agency may restrict or limit establishment notification when deliberate product contamination is involved.

E. Team Review

1. First meeting – The IIT meets or teleconferences offsite before arriving at the establishment to discuss the incident and how to conduct the review. The TL will determine the responsibilities of each team member at this meeting.

2. Entrance Conference – Upon arriving at the establishment, the IIT participates in a meeting with establishment officials (e.g., plant manager, quality assurance manager, HACCP coordinator). The TL explains the purpose of the visit and requests further information or documentation, if needed.

3. Conducting the Review – How the IIT conducts the review is dependent upon the incident that prompted the investigation. The specialized methodologies for specific reviews will be available on the FSIS web page.

4. Exit Conference – After concluding its review, the IIT meets with establishment officials to discuss the findings of the review. The IIT gives the

establishment officials a complete oral review of its findings. The TL will document the exit conference proceedings and include them in the report.

5. Report of Findings – The IIT writes a report that documents all relevant findings of the review and that summarizes discussions with the establishment at the entrance and exit conferences. The report is to include any conclusions the IIT has reached and the IIT's recommendations. The TL will forward the report to the AA of the lead program area and the EMC.

NOTE: The team review process may be modified in cases where deliberate contamination is alleged.

Based on the findings and recommendations of the report, the EMC will determine whether any enforcement action is needed. The report is not to be released to the establishment until the EMC or OIG, in the case of deliberate contamination, has made this determination. OPEER or OIG may also use the report to support enforcement action or other legal sanction (e.g., withdrawal of inspection service, criminal or civil sanctions).

NOTE: Disbanding the team is at the discretion of the TL, with the concurrence of the EMC, and usually occurs after the exit conference has been conducted and the report has been written.



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