

**STANDARD 5**  
**FOODBORNE ILLNESS AND FOOD DEFENSE**  
**PREPAREDNESS AND RESPONSE**

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## **STANDARD 5**

### **FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE**

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury and outbreaks.

#### **Requirement Summary**

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

#### **Description of Requirement**

##### **1. Investigative Procedures**

- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury\*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
- b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury\* or contamination of food.
- c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
- d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury\* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
- e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
- f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.
- g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury\*, or outbreak investigations.

- h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.
- i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

## **2. Reporting Procedures**

- a. Possible contributing factors to the food-related illness, food-related injury\* or intentional food contamination are identified in each on-site investigation report.
- b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks\* with CDC.

## **3. Laboratory Support Documentation**

- a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
- b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

## **4. Trace-back Procedures**

- a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

## **5. Recalls**

- a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.
- b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

- c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

## 6. Media Management

- a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

## 7. Data Review and Analysis

- a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury\* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury\*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.
- b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
  - 1) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* in a single establishment;
  - 2) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Disease Outbreaks\* in the same establishment type;
  - 3) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* implicating the same food;
  - 4) Foodborne Disease outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* associated with similar food preparation processes;
  - 5) Number of confirmed foodborne disease outbreaks\*;
  - 6) Number of foodborne disease outbreaks\* and suspect foodborne disease outbreaks\*;
  - 7) Contributing factors most often identified;
  - 8) Number of complaints involving real and alleged threats of intentional food contamination; and
  - 9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.
- c. In the event that there have been no food-related illness or food-related injury\* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak\* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak\* investigations occur.

**Note:** *Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more*

*comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: <http://www.cdc.gov/nceh/ehs/nears/index.htm> )*

### **Outcome**

A food regulatory program has a systematic approach for the detection, investigation, response, documentation and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

### **Documentation**

The quality records required to meet this standard include:

1. Logs or databases of alleged food-related illness and food-related injury\* complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food-related illness, food-related injury\*, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual review and analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

*[\*Note: See the Standards Definitions for the meaning of these defined terms.]*