

## APPENDIX A

# FDA's Recommended National Retail Food Regulatory Program Standards

STANDARD NO. 5

## FOODBORNE ILLNESS INVESTIGATION & RESPONSE

This standard applies to the investigation and subsequent review of alleged foodborne illness incidents and outbreaks.

### Requirement Summary

The program has an established system to collect and investigate complaints of food-related illness and injury; and investigate foodborne disease outbreaks.

### Description of Requirement

The retail food program and the appropriate epidemiological investigation program or other department or agencies have an established operating procedure or, if appropriate a Memorandum of Understanding (MOU) for conducting investigations of foodborne illness. The operating procedure or the MOU clearly identifies the roles, duties and responsibilities of each party.

Food program management, alone or in cooperation with another department or agency, maintains a log or database of all complaints alleging food-related illness or injury. Follow up on complaints that involve alleged illness or injuries are conducted by the regulatory agency within 24 hours of receiving the complaint. At the conclusion of the complaint investigation, the findings are recorded in the log or database, and the investigation reports are filed in or linked to the establishment record for retrieval purposes. The final report of the investigation is shared with the state epidemiologist and Centers for Disease Control and Prevention.

During illness or injury investigations, procedures used and information collected are similar to those found in the *International Association for Food Protection Procedures to Investigate A Foodborne Illness, Fifth Edition* and include the possible contributing factors to the illness or injury.

The laboratory support for illness or injury investigations, follow-up sampling and surveillance activities related to foodborne illness investigation is identified and described in writing by the food program and, if appropriate, MOU's between the food program and a laboratory are developed. Laboratory support includes in-house capability or access to external sources. Laboratory support includes the ability to conduct environmental sample

analysis, food sample analysis and clinical sample analysis. The types of pathogens, chemical agents, or other food adulterants that can be identified by the laboratory are also described. Program management has an established procedure to address the trace-back of food implicated in an illness or outbreak. These procedures include provisions for the coordinated involvement of the appropriate agencies as well as the identification of an appropriate coordinator to guide the investigation efforts of all the agencies involved. A final report is shared with the agencies involved, including CDC.

Recall of a product is initiated based on conclusions of the illness or injury investigation. Recall procedures equivalent to *21 CFR, Part 7*, are utilized when the jurisdiction has the responsibility to request or monitor a recall. Written procedures are established for conducting effectiveness checks of actions by firms when requested by cooperating agencies. Procedures are established that define criteria for when information is provided to the public regarding a FBI outbreak. The media person for the agency is identified.

An annual review of the data in the log or data base and the illness or injury investigations is conducted to identify the trends and possible contributing factors that are most likely to cause illness or injury. The review focuses on, but is not limited to:

1. Multiple complaints on the same establishment;
2. Multiple complaints on the same establishment type;
3. Multiple complaints implicating the same food;
4. Multiple complaints associated with similar food preparation processes;
5. Number of laboratory-confirmed, food-related outbreaks;
6. Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks;
7. Contributing factors most often identified.

### **Outcome**

A food regulatory program has a systematic approach for the investigation, documentation and analysis of alleged food-related illness and injury.

### **Documentation**

The quality records required to meet this standard include:

1. That the log or database of alleged food-related illness or injury complaints is maintained and findings recorded.
2. The illness, injury, outbreak investigation procedures and the data collection instrument utilized.
3. Investigation reports of alleged foodborne illness. Reports are retrievable by implicated establishment name.
4. A written description of laboratory support available or the MOU that outlines laboratory support and includes the types of samples that can be analyzed and the analysis that can be conducted.
5. The procedure addressing the trace-back of food products implicated in an illness or outbreak.

6. *21 CFR, Part 7*, or a document comparing the food program's recall procedures to the recall procedures outlined in *21 CFR, Part 7*. Procedures for monitoring or conducting effectiveness checks of a firm's actions when requested by cooperating agencies.
7. The annual report of the review of the log or database and the report of the review of illness or injury investigations.
8. Procedure and contact person for release of public information.