

# OUTBREAK INVESTIGATION PREPARATION – RECOMMENDATIONS FOR FOOD ESTABLISHMENTS

**I**n the interest of public health, food safety should be a Food Establishment owner/operator/manager's top priority. It is also good business! By understanding and implementing recommended safe food handling practices on a day-to-day basis, Food Establishment owner/operator/managers can not only reduce opportunities for contamination, survival and or growth of foodborne pathogens and prevent illness, they can strengthen their ability to respond effectively should foodborne illness or an outbreak occur.

The U.S. Food and Drug Administration (FDA) has published a model Food Code approximately every two years from 1993 through 2001; and since that time, a revised version every 4 years. This model represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The Food Code is available for adoption by government agencies as the legal basis for their food inspection program and assists regulatory jurisdictions in initiating and maintaining effective programs for prevention of foodborne illness. While the recommendations in these Industry Guidelines is based, in part, on Food Code recommendations, specifically those found in Chapter 2 and its annex on Public

Health Reasons, it is important for users to understand that:

- Local and/or State regulatory and/or public health requirements may vary;
- Government agencies leading a foodborne outbreak investigation may differ from the agency engaged on a daily basis, and;
- Depending on specific outbreak events, these Industry recommendations may be modified by the government agency leading the outbreak investigation.

Here are suggested steps to prepare for a possible outbreak investigation:

A. Have a list of key contact names and phone numbers (including after-hours numbers) available for reference. Consider listing information for:

- Regulatory/Health Authority Office
- Specific Regulatory/Health Inspector(s)
- Food Establishment Owner
- Food Establishment Operator/Manager(s)
- Corporate Office (if applicable)
- Quality Assurance/QA Hotline (if applicable)
- All Employees
- Distributors and Suppliers, including those used only occasionally
- Attorney or Legal Representative

B. Get to know the Regulatory/Health Authority inspector and build a good working relationship ahead of time. Trying to do so during a crisis is difficult.

C. Identify the media spokesperson for the Food Establishment before any emergencies occur. Consult with the Regulatory/Health Authority, Public Relations representative and/or Legal Counsel before releasing any media statements regarding the outbreak.

D. Remember, no one knows the operation better than the owner/operator/manager. Cooperate with Regulatory/Health Authorities and be willing to offer information to them about the operations, food safety systems/tools, etc. that might help them to identify the possible source of illness.

E. Be prepared to provide contact information for customers, especially for large group reservations, special events, or orders catered outside the facility. Loyalty cards may be a source of contact information; however, ensure compliance with local privacy laws and company policy.

F. If Confidential or Proprietary information is requested, be sure to tell this to the Regulatory/Health Authority and notify the Food Establishment's legal counsel.

G. The Regulatory/Health Authority is prevented by law from giving out the names of ill customers and other identifying information. The Regulatory/Health Authority will clarify what information they can release specific to an ill employee or customer. They may be able to provide information on numbers of people reporting illness and other information that does not identify individuals.

H. The Food Establishment owner/operator/manager must share all needed records, such as purchasing invoices, work schedules, etc. Certain records, such as customer credit card receipts, may or may not be able to be provided based on various local/state laws or privacy policies of credit card companies. Check with the corporate office/owner/management person to coordinate the data transfer while ensuring privacy laws or policies are followed.

I. The Food Establishment owner/operator/manager must retain records/record-keeping including:

- Records of employee work schedules;
- Employee work duties;
- Purchase invoices for all foods received;

- Records of all foods picked up locally by the Food Establishment (purchased at wholesale food establishments, grocery stores and produce markets, etc., if applicable).

Should illness occur, it is in a Food Establishment owner/operator/manager’s best interest to work with the Regulatory/Health Authority

to determine what happened and what actions may be needed to prevent future illness. The owner/operator/manager should fully cooperate with the Regulatory/Health Authority, obtain all information needed for the investigation, and respond quickly. Failure to do so may result in additional illnesses, as well as a loss of reputation impacting sales, future business and growth.

## HOW TO KNOW IF YOU HAVE A POSSIBLE OUTBREAK

- Have customers complained of any illness from consuming the food from your Food Establishment? (To record multiple illnesses, refer to Appendix TOOL 1 - ILLNESS COMPLAINT TRACKING LOG FORM. To record specific information on individuals, refer to Appendix TOOL 2 – CUSTOMER FOODBORNE ILLNESS COMPLAINT FORM.)
- Were multiple illnesses reported to the Food Establishment by the Regulatory/Health Authority?
- Has the Food Establishment owner/operator/manager (or the Food Establishment’s corporate office) been notified of illness in its employees or customers that may be part of a larger outbreak associated with a food product or ingredient?

**NOTE:** If an outbreak is suspected, share any information collected from customers with the Regulatory/Health Authority. If there are no additional illness reports, consult the Regulatory/Health Authority before continuing with any further steps in these guidelines.

## MENU / FOOD SERVED

The Regulatory/Health Authority may need to gather more information on specific foods eaten by customers to potentially identify common foods or ingredients that might be associated with the suspected illnesses. Be prepared to supply it, if asked:

- A copy of the menu or food served for the time period requested and meals/foods identified.
- Information about garnishes, sauces, side dishes and variations on basic menu items.
- A recipe or list of ingredients for each menu item in question —(Refer to Appendix TOOLS 3A and 3B – MENU INGREDIENT LISTING FORM AND EXAMPLE MENU INGREDIENT LISTING FORM.)
- If possible, determine the total number of meals and transactions (dine-in, delivery, or carry-out) served or sold during the time period in question and provide this to the Regulatory/Health Authority.

## LARGE ORDERS, SPECIAL EVENT ORDERS, CATERING OR DELIVERY

If the Food Establishment participates in catering, large group reservations/special event orders, or delivery, be prepared to provide any available contact information and meals served.

### EMPLOYEE COMMUNICATIONS

If there is a suspected outbreak involving the Food Establishment, it is important to communicate early and regularly with employees to inform them of the situation, control rumors and clarify expectations.

At a minimum, it is suggested the following might be shared with employees:

A. General information about the outbreak including the organism or chemical causing illness, if known.

B. Preventive measures employees can take to protect themselves or others from becoming ill. Be specific to the illness in question, if known.

C. The expectation that all employees provide all relevant information requested by the Regulatory/Health Authority, including their health status.

D. Specific guidance on responding to questions by the public and/or the media, e.g. all question should be directed to management or a designated media spokesperson.

E. Possible collection of clinical specimens, e.g. stool or blood if requested by the Regulatory/Health Authority.

F. The expectation of the employee to have a positive interaction with the Regulatory/Health Authority when they visit the Food Establishment.

G. Potential for recommended treatment of the employee by the Regulatory/Health Authority if exposed to certain diseases or chemicals.

H. A review of the Food Establishment's sick leave policy. It is suggested that employees who become ill with certain symptoms must notify the Person-in-Charge and leave work immediately. (Refer to Appendix TOOL 4 – EMPLOYEE COMMUNICATIONS MEETING)

## EMPLOYEE WORK HISTORY

Since outbreaks sometimes involve employees who may have infected others, were victims of the outbreak, or whose actions may have led to the outbreak, the Regulatory/Health Authority may ask for information regarding their duties, illness history, and work schedules. Be prepared to provide this information to the Regulatory/Health Authority if asked.

Employee schedules, duties, and work habits may assist the Regulatory/Health Authority in determining whether the Food Establishment is connected to the illnesses and, if so, what the causative factor(s) may be and what control measures are necessary.

Provide a list of current and former employees (within the time period in question) with contact information. (Refer to Appendix TOOL 5 – EMPLOYEE LIST FORM.) The list should include:

- A. Ex-employees who worked at the restaurant/Food Establishment.
- B. Employees transferred in or out of the Food Establishment (identify Food Establishment transfer locations, dates, and tasks performed).

## EMPLOYEE ASSESSMENTS

The FDA Food Code recommends that the Food Establishment's owner/operator/manager require employees to report certain information regarding their health or activities as they may relate to diseases that can be transmitted through food. Information provided by employees should include symptoms such as vomiting, diarrhea, jaundice, etc.; date when symptoms started; any diagnosis from a health care provider of illness that could be food-related; such as norovirus, hepatitis A, *Shigella spp.*, etc. If this information is collected by industry on a routine basis for the purposes of excluding and restricting employees from work, this would provide the owner/operator a good model of employee health management practices that will help ensure better response during a foodborne outbreak event.

During a suspected or confirmed foodborne illness outbreak, it is important to communicate with employees to assess their health, provide information to help in protecting them from illness, and to assist the Regulatory/Health Authority with their investigation. The Regulatory/Health Authority will usually ask to conduct employee interviews outside the presence of a Food Establishment owner/operator/manager. The Food Establishment owner/operator/manager or corporate representative may also wish to conduct individual assessments with all employees after the Regulatory/Health Authority conducts their own, as these can provide valuable information on the following:

- Recent or current employee illness(es) or exposures that could trigger employee testing, restriction of work duties and/or exclusion from work.
- Potential exposure to communicable illness(es) that could require medical follow-up; e.g., healthcare visits, vaccination, etc. (Refer to Appendix TOOL 6 – EMPLOYEE HEALTH ASSESSMENT FORM.)

These recommendations are intended for day-to-day operation and management of a Food Establishment. While this can be used as general guidance in a foodborne outbreak event, consultation with the Regulatory/Health Authority to get outbreak-specific employee health guidance is recommended.

If employees are ill, the Food Establishment owner/operator/manager may need to restrict their activities or exclude them from working. If the Food Establishment does not already have a policy in place, consult with the Regulatory/Health Authority for information on worker restrictions or exclusions.

- To assist in decision making when other guidance is not available on what actions to be taken if employees are/were ill, and return-to-work guidance, refer to Appendix TOOL 7A – EMPLOYEE ILLNESS DECISION GUIDE. This tool is based on the 2009 Food Code recommendations, and may differ from local/state regulations in the area where the Food Establishment is located.
- If a Food Establishment owner/operator/manager has knowledge of the guidance or regulations for worker exclusion/restriction in their jurisdiction, they may

wish to create a quick policy reference for themselves. (Refer to Appendix TOOL 7B - EXAMPLE OF EMPLOYEE ILLNESS DECISION QUICK GUIDE FOR PERSON-IN-CHARGE, for Establishments not serving highly susceptible populations, for a sample.) Keep in mind that this is an example only, and does not replace what may be required by local or state law in your area.

- Provide the Regulatory/Health Authority a list of all employees and specify which employees have indicated they have reported being ill. (SEE TOOL 5.)
- Provide the Regulatory/Health Authority a copy of the employee health policies.
- Also useful before, during, or after an investigation are the following \*FDA posters:

TOOL 7c  
*My Story Could Change Your Life*

TOOL 7d  
*Do I Feel Well Today?*

TOOL 7e  
*I Should Have Stayed Home*

TOOL 7f  
*Would You Want These People in Your Kitchen?*

TOOL 7g  
*Don't Let What Happened to Me Happen to You*

\*NOTE: These and more posters may be found at [www.fda.gov/foodemployeetraining](http://www.fda.gov/foodemployeetraining)

## CONSUMER AND EMPLOYEE PRIVACY

It is important to protect the privacy and health information of both employees and consumers; recognize that Regulatory/Health Authorities are typically bound by privacy laws to do this. Consult with the Regulatory/Health Authority and the Food Establish-

ment’s legal counsel regarding local, state and/or federal laws regarding employee and consumer privacy and the protections required in safeguarding individual health information.

## EMPLOYEE SPECIMEN TESTING

Along with interviews, clinical specimens as indicated by the Regulatory/Health Authority may be required from the employee by the Regulatory/Health Authority for testing to assess employee health and provide the Regulatory/Health Authority and/or the Food Establishment owner/operator/manager with valuable information regarding the investigation. Employee test results may do the following:

- Provide information to help determine if the employee may be associated with the outbreak;
- Determine whether employee restrictions or exclusions should be put in place;

- Determine whether medical follow-up and/or treatment may be necessary;
- Provide information to the investigation;
- Assist with control measures.

Be ready to provide assistance to the Regulatory/Health Authority if they determine that employees should undergo a health evaluation and/or laboratory testing. If suspect employee testing is necessary, as directed by the Regulatory/Health Authority, and the testing services are provided by a non-government medical facility through the Food Establishment, Industry must ensure local/federal privacy laws and any internal Risk Management policies are followed.

## EMPLOYEE HEPATITIS A VACCINATION (WHERE APPLICABLE)

In some outbreak situations, it might be necessary as directed by the Regulatory/Health Authority for employees to be vaccinated. If employees do not consent to vaccination and/or other treatment (immune globulin-IgG), the Regulatory/Health Authority or Food

Establishment owner/operator/manager may restrict or exclude the employee from work. (For more information, refer to the Regulatory/Health Authority and TOOLS 7A and 7B.)

## PRODUCT SAMPLES

The Regulatory/Health Authority may sample foods from the Food Establishment or its supply chain and perform laboratory analysis in an attempt to find the source of the illness. The source of illness could be a food that was contaminated prior to its arrival at the Food Establishment or contaminated onsite by a sick employee; mishandled; cross contaminated from raw food or equipment; or contaminated by the consumer or other food handler/preparer. It is important to rapidly determine the source of the problem and initiate control measures at all appropriate levels including the Food Establishment, Distributor, Supplier, etc.

- Immediately consult the Regulatory/Health Authority prior to sampling, using, moving or discarding any food that may have been served during the time period of interest for the outbreak. Any food that is implicated in an outbreak should be held under control until the Regulatory/Health Authority determines if they will need to collect samples for laboratory analysis.
- Industry may voluntarily choose to sample products and have laboratory tests performed, but should consult with the Regulatory/Health Authority before collecting and submitting any samples to find out if the Regulatory/Health Authority plans to do so. This is to ensure adequate product is available for Regulatory/Health testing (“split samples”) and to protect against accidental contamination of product.
- Before collecting its own samples, Industry should ensure that their laboratory is accredited for food testing and collaborate with the Regulatory/Health Authority to identify key products of interest for sampling, what laboratory tests should be done, and to ensure sample integrity is maintained and accidental contamination does not occur during sampling. All sample results should be shared with the Regulatory/Health Authority. (Refer to Appendix TOOL 8 – PRODUCT SAMPLING PROCEDURE.)
- Consult with food testing professionals, legal advisors, and/or the accredited laboratory before having the samples tested to make sure that correct tests are done on the key products of interest.
- Unopened packages of food from the same lot suspected of causing illness may be the most reliable laboratory sample. Be sure to secure unopened packages and store appropriately until release by the Regulatory/Health Authority.
- If independent sampling is done, it is important for the Food Establishment owner/operator/manager or their representative to collect the samples appropriately and maintain the Chain of Custody of the samples. (Refer to Appendix TOOL 9 SAMPLE CHAIN OF CUSTODY FORM.)
- The Regulatory/Health Authority’s test results will typically be considered “official” and used to determine further public health and/or regulatory actions.



## DISTRIBUTOR AND/OR SUPPLIER INFORMATION

The Regulatory/Health Authority may need to determine if food received by the Food Establishment is the source of the illness. The Food Establishment owner/operator/manager needs to provide detailed information about what products were received from each Distributor or Supplier that delivered to the Food Establishment in the time period in question. This includes lot numbers or other identifying information on the suspected foods and when those lot numbers were actually used by the Food Establishment and consumed by the public.

It is also important that the Food Establishment owner/operator/manager identify any unusual occurrences that required them to use a different Supplier or product during the time period in question.

- Identify Distributors and/or Suppliers of suspected products and provide invoices to the Regulatory/Health Authority.
- Identify code # or lot # of suspected/implicated product – (Refer to Appendix TOOL 10 - DISTRIBUTOR AND SUPPLIER INFORMATION FORM.)