CHAPTER VII: CONDUCTING AN ENVIRONMENTAL INVESTIGATION

IMPORTANT RESOURCES

Food Protection Program **617-983-6712**	For policy and technical assistance with the environmental investigation such as conducting a HACCP risk assessment, initiating enforcement actions and collecting food samples. On-site investigation assistance is often available for larger outbreaks.
Epidemiology Program **617-983-6800**	For technical assistance with the epidemiologic investigation such as obtaining medical histories, coordinating stool specimen submissions and developing questionnaires. On-site investigation assistance is often available for larger outbreaks.
State Public Health Laboratory **617-983-6616**	For technical assistance with the collection protocol for food and enteric specimens.

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The local board of health (LBOH) is the public health agency responsible for conducting an environmental investigation in response to a suspect foodborne illness complaint. The objective of the environmental investigation is to identify the reason for, or source of, contamination and to initiate corrective actions to eliminate contaminated foods or poor food handling practices which may result in contaminated foods. Further illnesses may be avoided if potentially contaminated foods are promptly identified and removed from sale or service to the public and poor food-handling practices are corrected. Other reasons for initiating an environmental investigation include government responsibility, consumer expectation and vindication of innocent establishments. Investigative findings are important information. They, as well as regular inspection reports, are public records and may be subpoenaed for legal proceedings.

A. Being Prepared for an Environmental Investigation

1. Knowledge:

Food inspectors who respond to foodborne illness complaints should be well educated in food microbiology, etiology of foodborne disease, high-risk factors in foodborne illness outbreaks, the application of HACCP principles, food preparation review and food establishment investigation procedures, regulatory provisions and enforcement procedures outlined in *105 CMR 590.000,* in order to do a thorough investigation. Courses through the MDPH, the Massachusetts Environmental Health Association, the Massachusetts Health Officers' Association and the Federal Food & Drug Administration's (FDA) ORAU at www.fda.gov should have been completed to be prepared for this level of investigation.

2. Communication:

Good communication skills are also required to conduct a thorough investigation. When identifying yourself to the Person-in-Charge (PIC), explain the purpose of the foodborne illness investigation and be prepared for a variety of reactions. Food establishment operators are often tense, nervous, defensive, and sometimes, in complete denial at the prospect of being responsible for a customer's illness. Stay calm, respectful and professional. Encourage cooperation by explaining that it is the LBOH's responsibility, as well as the food establishment, to ensure that practices and procedures are adequate to prevent foodborne diseases. In some cases, this environmental investigation may help prove that the establishment is not involved, or is not responsible, for the outbreak. If necessary, and only as a last resort, remind the PIC that failure to cooperate in the investigation may result in the suspension or revocation of the food permit. In any situation, maintain an unbiased attitude and assure the PIC that other plausible causes will be addressed.

The designated LBOH spokesperson responsible for talking to the media and affected groups in high-profile investigations, such as larger outbreaks, should also be knowledgeable in risk management issues and have a medical or public health background.

3. Equipment and Forms:

Review Attachment 7-1: Inspection Equipment Checklist and Attachment 7-2: Food Inspection Report Form, found at the back of this chapter, to make sure that you have the required equipment and forms to conduct the investigation.

The primary objective of the environmental investigation is to determine what specific factors may have contributed to the illness or outbreak and, if discovered, assure that they are corrected. Unlike routine inspections, a quality environmental investigation of a foodborne disease outbreak may take **several hours** because it involves the evaluation of all suspected processes. It should start with a review of the previous routine inspection reports of the implicated food establishment.

A complete 72-hour food history should have been completed as part of the initial complaint intake, so that a reasonable list of possible suspect foods is in-hand when the environmental investigation begins.

B. Sample Collection; Food and Enteric

To avoid important evidence from being inadvertently discarded during your investigation, always identify and collect leftovers of the suspect food(s) immediately. The samples ultimately may not be tested for a variety of reasons, but in some circumstances having the samples could prove invaluable. Food collection should be completed prior to initiating the HACCP risk assessment of the suspect food.

As with food samples, stool specimens must be collected as soon as possible in order to confirm a clinical diagnosis. If, in discussions with the PIC, it is determined that there have been sick food employees, the food inspector must be prepared to handle that issue as well. If possible, and staffing permits, the Public Health Nurse may be called to assist with the issue of sick food employees. Bring an adequate supply of enteric kits and instructions for collection. Determine who is responsible for distributing enteric stool kits to food employees. Determine who is responsible for instructing food employees on how stool specimens should be collected, as well as educating the food service staff on the reason sampling is necessary. See Chapter IX for instructions on collecting, packaging, completing lab submission forms and transporting samples to the State Public Health Laboratory. See Chapter VIII for additional information on sick food employees.

C. Background Information for the HACCP Risk Assessment

1. What is HACCP?

HACCP is a science-based method of evaluating food handling procedures to identify or prevent hazards which contribute to foodborne disease. A HACCP-based investigation focuses on the suspect food or meal implicated, rather than on a cursory inspection of the physical and sanitary facilities of the food establishment. The production of the implicated food item(s) is evaluated for hazards which can contribute to the occurrence of foodborne disease. This is done at each step of handling from receipt to sale or service to the consumer.

The ideal steps in conducting a HACCP risk assessment of the implicated food include actual observation of the suspect food being prepared, taking temperatures and identifying potentially faulty food handling practices. Since this may not be feasible if the food establishment is not producing the implicated food at the time of the investigation, it will be necessary to interview the PIC of food production on how the food was handled from receipt to sale or service. General food handling practices should be evaluated by observing food workers and by measuring temperatures of various Time/Temperature Control for Safety (TCS) foods (formerly potentially hazardous foods).

2. Applied Food Microbiology

An understanding of how pathogens (disease-causing microorganisms) can contaminate food, survive and/or multiply, and in some instances, produce toxins, is essential to evaluate risk. Pathogens may be present in raw foods as well as in infected food employees. Pathogens in food, present either naturally or by contamination, can survive if the food requires no further cooking, or is undercooked. It is important to note that while bacteria may survive and multiply in TCS foods, viruses and parasites may survive but cannot multiply without a living host. Pathogens in infected food employees may be shed in feces, infected lesions and respiratory secretions and thus can be transmitted to food. See Chapter II for a more extensive discussion of disease characterization and pathogenesis.

TCS foods are those high-risk foods in which bacteria can survive, multiply and with certain bacteria, produce toxin. Foods with a pH of 4.6 or above and a water activity of 0.85 a_w or greater are regarded as TCS foods. TCS foods are also defined as any food or ingredient, natural or synthetic, in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms or the slower growth of *Clostridium botulinum*. Attachment 7-3, the effects of pH, and Attachment 7-4, the effects of water activity ($a_{w)}$ are provided at the end of this chapter. TCS foods include an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation.

The optimum growth temperature range for the majority of pathogens is between 60 and 120 degrees F. Some pathogens such as *Listeria* and *Yersinia* grow best under refrigeration temperature ranges. Under optimum growth temperatures, bacteria, in their vegetative state, can double in number every 15 to 20 minutes. At temperatures below freezing, foodborne pathogens may survive but cannot grow. Most pathogens are destroyed at temperatures above 135 degrees F.

While TCS foods may provide the optimum environment for the growth of pathogens, other non-TCS foods may be the causal factor in a foodborne illness outbreak by simply acting as the food vehicle in which bacteria, parasites or viruses can survive until ingested. Some foods, such as cut tomatoes and cut leafy greens, have been added to the TCS food list over the years due to them being implicated as the source of a large number of foodborne illness outbreaks. It is important, however, to remember that non-TCS foods can also be the source of foodborne illness, such as, but not limited to, jalapeno peppers, black pepper and peanut butter, that were found to be implicated as the source of past multi-state foodborne illness outbreaks.

Many pathogens which are naturally found in soil-grown vegetables, grains and spices have a dormant spore state which can be heat shocked into a vegetative state after cooking. With the exception of infant botulism, bacterial spores do not cause foodborne disease. However, if a pathogen's spore, such as *Bacillus cereus* in rice, is heat shocked into its vegetative state after cooking, the *Bacillus cereus* bacteria can then multiply rapidly if left at optimum growth temperatures of 60 to 120 degrees F.

3. High-Risk Factors in Food Preparation

Significant factors in foodborne illness outbreaks have been documented in several foodborne disease investigation surveillance studies. They can be divided into three hazard categories: contamination, survival, and growth.

Contamination:
- infected person
- contaminated ingredients
- hand contact/implicated food
- unclean equipment
- toxic container
- cross-contamination
- added poisonous chemicals
- unapproved source
- natural toxicant
- consumption of raw or lightly cooked food of animal origin

Survival:
- inadequate cooking
- inadequate reheating

Growth:
- inadequate refrigeration
- preparation several hours before serving
- inadequate hot-holding
- improper cooling
- anaerobic packaging

D. Application of HACCP Principles in a Foodborne Illness Investigation

A *HACCP Risk Assessment Form* (Attachments 7-5, 7-6, and 7-7, a blank and completed form with instructions is at the back of the chapter) can be used to facilitate risk assessment of the suspect food and, if used, must be attached to the inspection report. The form is structured to assist with identifying the procedures used in the establishment in preparing the suspect food, as well as to identify corrective actions initiated as a result of the investigation.

A HACCP risk assessment must be conducted for each suspect food item prepared. If baked chicken and gravy is the suspect food, the preparation of each must be evaluated separately. In outbreaks, when multiple foods have been identified, a *HACCP Risk Assessment Form* can be used to evaluate procedures for a particular category of food such as soups, salads, or sandwiches.

(Please see also Attachment 7-8, Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors and Attachment 7-9, The Process Approach, both from the 2013 Federal Food Code Annexes.)

Figure 7-1. Steps in a HACCP Risk Assessment

1. Identify ingredients, weight/volume, and steps involved in the preparation of suspect food(s).
2. Identify food handling procedures at each step in the preparation of suspect food(s).
3. Based on observation or interview, identify potential hazards and critical control points (CCP).
4. Identify violations and initiate corrective actions.
5. Verify corrective actions undertaken by the food establishment.

STEP 1: Identify ingredients, weight/volume, and steps involved in the preparation of suspect food(s).

a. Ingredients in the suspect food: Obtain recipes and list all ingredients for each suspect food item. Ingredients must be from an approved source, especially high-risk ingredients such as raw shellfish or canned low-acid foods. It is usually not necessary to obtain exact measurements of each ingredient unless there is a question on the pH of the food. Note new changes in recipes or ingredient substitutions. **Note that recipes are proprietary information and must be treated with strict confidentiality.**

b. The suspect food is contaminated at the source (farm/ocean) or at the manufacturing level: Contaminated produce, eggs, seafood and commercially-processed foods have been implicated in many foodborne illness outbreaks. When such products, contaminated at the source, are implicated, it is crucial to obtain as much information as possible from the food establishment or consumer to identify the exact source and/or manufacturer/distributor. Product lot numbers, expiration dates and sales records are necessary when conducting a traceback to identify an implicated source. When investigating such products, be sure to obtain the following product information. See Attachment 7-10: Traceback Methodology for additional information on tracebacks.

Figure 7-2: Manufactured Product Identification

- Brand Name
- Product Name
- Code/Lot Number
- Expiration/Sell by/Use by Date
- Size/Weight
- Package Type
- Date of Purchase
- Manufacturer's Name and Address
- Distributor's Name and Address
- Retail Food Establishment Where Purchased

Shellfish identification tags should always be obtained for clams, oysters, quahogs and other molluscan shellfish associated with a foodborne illness.

c. Volume of the suspect food prepared by the food establishment: List the weight/volume of the suspect food prepared. Large volumes may indicate problems with cooling or food handling procedures, especially if the food was prepared a day or more before service. If the volume was greater than what is normally prepared, different procedures may have been used.

d. Suspect food preparation schedule: Dates and the length of time are important information needed to determine potential time/temperature abuse. It is important to document date and time prepared, when applicable, to determine if there was ample time for temperature abuse which may have resulted in the growth of pathogens or the production of toxin.

e. Identify steps in preparing the suspect food: Each step in the preparation of a food item is regarded as a "**control point**." List each step or control point on the *HACCP Risk Assessment Form*. Listing the steps as a flow chart permits the visualization of each preparation step.

STEP 2: Identify food handling procedures at each step in the preparation of suspect food(s):

a. Clearly document how the food was handled at each step: The method used to identify food handling procedures at each step is to observe the actual process. Since this may not be feasible in some situations, it is essential to interview the PIC of food production and then walk through the preparation steps in the kitchen afterwards. Identify how suspect foods were thawed, cooked, cooled, reheated, served and transported. Identify how food employees determined final cooking temperatures. Indicate what equipment was used in the preparation of the suspect food. Specify if food workers use disposable gloves or utensils to handle cooked and ready-to-eat foods. Indicate handwashing practices observed.

b. Clearly document who prepared the food: It is recommended that the initials of the employee responsible for handling food be documented. An infected food employee with poor hygiene may be the source of contamination. The initials of the actual worker, and not just his/her position are very helpful when comparing the positive or symptomatic food employees to their job functions, to determine if there is a relationship. Inquire if the food employee has been recently ill. Ask if the worker is a new employee, or new to the particular operation, because a new or different food employee unaware of the proper procedure may have been responsible for preparing the suspect food. Review the food establishment's sick or infected food employee policies.

c. Focus on the significant factors in foodborne illness outbreaks: When conducting a HACCP Risk Assessment, focus on poor food handling practices which can contribute to foodborne disease. Definitions for each significant factor are listed in Step 3 below, in addition to questions that may need to be addressed during your assessment.

STEP 3: Based on observation or interview, identify potential hazards and critical control points (CCP):

A **critical control point (CCP)** is a preparation step in which a hazard, if present, can result in a foodborne disease. For example, any step in the production of a ready-to-eat food such as tuna salad, where contamination is likely to occur, may be considered a CCP since pathogens introduced during storage or preparation may survive until ingested. Thus, each step where contamination occurs in a ready-to-eat food is "critical." However, if a food employee handles raw chicken with bare hands, this step would not be critical, since the chicken would be cooked in the next step, destroying all pathogens introduced into the food. In this example, cooking would be a CCP because adequate cooking is necessary to destroy all pathogens naturally present or introduced during preparation. Failure to cook the chicken properly would allow the survival of pathogens, which could result in a foodborne illness.

The level of risk for a suspect food depends on the probability of occurrence of a hazard or the sequential occurrences of several hazards identified in the preparation procedure. The three main microbiological hazards, as previously mentioned in this chapter are Contamination (C), Survival (S) and Growth/Toxin Production (G/T).

A. Contamination: Determine if there are risks at each step in the food preparation for microbial contamination (C) from either the food employee, food, or improperly cleaned and sanitized equipment/utensils. Food could be raw animal foods already contaminated, or foods which were contaminated at the point of harvesting, and intended to be consumed raw such as lettuce, raspberries and unpasteurized apple cider.

Epidemiological data indicates that microbiological hazards pose the highest risks to the greatest number of persons. Physical and chemical hazards usually affect individuals rather than groups. Microbiological contamination such as bacteria, viruses and parasites are present in infected food employees and raw foods of animal origin. Indirect or cross-contamination from raw foods of animal origin to ready-to-eat foods, that will receive no further heating, can also result in microbiological contamination.

Contributing Factors Associated with Contamination:

1. **Contaminated Ingredients:** The suspect food or a component of the food contained the pathogenic agent when it arrived at the point of preparation.
    - Determine if the suspect food harbors contaminants normally found in soil fertilizers or raw animal foods (e.g., raw meat, poultry, seafood, root vegetables, etc.).
    - Check to determine if the water/ice supply was possibly contaminated.
    - Check to determine if back-flow prevention devices were present on plumbing cross-connections.
    - Check to determine if the suspect food was from an approved source.
    - Check to determine if the source may have contributed to the suspect food's contamination (e.g. shellfish from a contaminated growing bed).

2. **Unapproved Source:** The suspect food was obtained from a source that does not comply with appropriate regulatory standards (e.g., shellfish harvested from closed growing beds).
    - Determine if all foods, including water and ice, were obtained from an approved source.
    - Check identification tags on shellfish and if they are retained for 90 days.

3. **Infected Person:** A food employee involved in the preparation of the suspect food was infected or was suspected of being infected at the time the food was prepared. This individual was identified as the probable source of the agent in the outbreak.
    - Identify the persons responsible for preparing the suspect foods.
    - Determine if any of the food employees were ill before, or during, the time that the suspect food was being prepared.
    - Check if any of the food employees were observed with infected cuts or wounds on their fingers or hands.

4. **Consumption of Raw or Lightly Cooked Food of Animal Origin:** The suspect food was eaten raw or after a heat treatment that would not have reduced the level of agent contamination to below an infectious dose.
    - Determine if the suspect food of animal origin was served raw or undercooked.
    - If required by law, check if consumer advisories were properly posted.

5. **Cross-Contamination:** The pathogen was transferred to the suspect food during preparation by contact with contaminated worker hands, equipment, utensils, drippage, or spillage. If worker hands were the mode of contamination, the worker was not necessarily infected with or a carrier of the organism.
    - Determine if raw foods were stored separately from cooked and ready-to-eat foods.
    - Check if food employees were properly washing their hands and using a physical safety barrier such as disposable gloves, deli papers and utensils in-between handling raw, and cooked, or ready-to-eat foods.
    - Check equipment, utensils and food contact surfaces for proper cleaning and sanitizing between uses.

6. **Unclean Equipment:** the suspect food was prepared with, or stored in, equipment that was contaminated with the agent.
    - Check if the equipment and utensils used to prepare the suspect food were properly cleaned and sanitized in accordance with 105 CMR 590.000.

7. **Hand Contact with Implicated Food:** A food employee who was identified as the source of the agent prepared the suspect food with his/her bare hands.
    - Check if infected workers used their bare hands to handle or to prepare cooked and ready-to-eat foods.
    - Determine if food workers are trained to use physical safety barriers such as disposable gloves, deli papers and utensils in-between handling raw, and cooked, or ready-to-eat foods.

8. **Added Poisonous Chemicals:** The chemical agent was deliberately or inadvertently added to the suspect food. In former cases, this addition typically occurred at the time of preparation or packaging of the suspect food.
    - Determine if any toxic substances were improperly stored or used around the suspect food.
    - Check if there were any recent situations involving a disgruntled employee possibly seeking revenge.
    - Investigate whether any toxic substance in the immediate vicinity of the suspect food may have been mislabeled.

9. **Natural Toxicant:** A chemical agent of biologic origin that occurs naturally in the suspect food or bioaccumulates in the suspect food, prior to, or soon after, harvest.
    - Investigate whether a suspect food is known to harbor natural toxicants, such as histamine in scombroid fish, aflatoxins in grain, toxins in poisonous mushrooms, and dinoflagellate toxins in shellfish.

10. **Toxic Container:** A chemical agent originated in the material from which the food container was made. The agent migrated from the container into the suspect food.
    - Determine if the suspect food was in direct contact with lead, copper, aluminum, tin, cadmium or other heavy metals.
    - Is the suspect food acidic (pH < 7)? The more acidic the product, the greater potential for the metals to leach into foods. Check to see that food is stored in the proper containers.

B. Survival: Determine if pathogens survived (S) the cooking process. The survival of pathogens is determined by the "thermalization" or cooking procedure used. Pathogens are easily destroyed by adequate cooking or reheating. The consumption of undercooked or raw foods of animal origin is a significant factor in foodborne disease outbreaks. Complete cooking times and temperatures can be found in 105 CMR 590.000, Chapter 3-4 Destruction of Organisms of Public Health Concern, Section 3-401 Cooking.

Figure 7-3:

Chart 4-A

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Raw Eggs prepared for immediate service **Commercially Raised Game Animals and Exotic Species of Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Raw Eggs not prepared for immediate service **Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats** **Mechanically Tenderized Meats**	70°C (158°F) **68°C (155°F)** 66°C (150°F) 63°C (145°F)	< 1 second **15 seconds** 1 minute 3 minutes
Poultry **Baluts** **Stuffed Fish; Stuffed Meat;** **Stuffed Pasta;** **Stuffed Poultry; Stuffed Ratites** **Stuffing Containing Fish, Meat, Poultry, or Ratites** **Wild Game Animals**	**74°C (165°F)**	**15 seconds**
Food Cooked in A Microwave Oven	**74°C (165°F)**	**and hold for 2 minutes after removing from microwave oven**

SOURCE: 2013 Federal Food Code, Annex 7, page 746.

Contributing Factors Associated with Survival:

1. **Inadequate Cooking:** The suspect food was not heated to a temperature and for a time adequate to destroy the agent or to reduce the level of contamination to below an infectious dose.
    - Determine whether the raw animal origin foods were cooked to proper time/temperatures in accordance with 105 CMR 590.000.
    - Check if the establishment has the required food thermometers and whether they are being used to test final cooking temperatures.
    - Determine if cooking temperature logs are being used and maintained, if required.

2. **Inadequate Reheating:** The suspect food, which had been previously cooked and cooled, was not heated to a temperature sufficient to destroy the agent or to reduce the level of contamination to below an infectious dose.
    - Determine how the suspect food was reheated.
    - Determine if the suspect food was properly reheated in accordance with 105 CMR 590.000.
    - Determine if a thermometer was used to test the final reheat temperature of the suspect food.

Figure 7-4:

Chart 4-B

Summary Chart for Minimum Food Temperatures and Holding Times Required by Chapter 3 for Reheating Foods for Hot Holding

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) and (D) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) and (D) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after reheating	2 hours
¶ 3-403.11(C) and (D) Food that is taken from a commercially processed, hermetically sealed container or intact package	57°C (135°F)	No time specified	2 hours
Roasts: Option A ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Not applicable
Roasts: Option B ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	74°C (165°F)	15 seconds	2 hours

SOURCE: 2013 Federal Food Code, Annex 7, page 747.

C. Growth/Toxin Production: Determine if the pathogens had ample time to grow (G) and/or produce toxin (T). The growth of pathogens and the production of toxins can occur in TCS foods which achieve temperatures between 41 degrees and 135 degrees F for several hours. Time/temperature abuse can result from inadequate cooking procedures, holding at room temperature and inadequate hot and cold holding units. While reheating contaminated food may destroy pathogens, it may not deactivate heat-stable toxins produced by pathogens such as *Staphylococcus aureus*. It is recommended that TCS foods be cooled from 135 degrees F to 70 degrees F within two hours and from 135 degrees F to 41 degrees F or less within a total of 6 hours.

Contributing Factors Associated with Growth and Production of Toxins:

1. **Improper Cooling:** The suspect food was cooled from a cooking or ambient air temperature to a refrigeration temperature by a means that allowed the growth of a pathogen to an infectious dose or the production of toxin.
    - Determine if implicated TCS foods were cooled to 41 degrees F within 6 hours by pre-chilling ingredients, using shallow containers, ice baths or reducing the size of the product.

2. **Inadequate Refrigeration:** The suspect food was not held at a temperature of 41 degrees F or less either due to improperly functioning refrigeration equipment or because it was being held outside of refrigeration. The period of time held at an improper temperature was sufficient to permit the growth of a pathogen to an infectious dose or the production of toxin.
    - Determine if there was an adequate number of refrigeration units to maintain the suspect TCS food at or below 41 degrees F.
    - Determine if refrigeration units were properly operating at or below 41 degrees F.

3. **Inadequate Hot Holding:** The suspect TCS food was not held at, or above, 135 degrees F due to improperly functioning hot holding equipment, or was not being held in hot holding equipment. The period of time the food was held was sufficient to permit the multiplication and growth of the pathogen to an infectious dose.
    - Determine if the suspect food was left out for storage or display at ambient air temperature.
    - Determine how long the suspect TCS food was below 135 degrees F.
    - Determine if temperatures of suspect foods in hot holding units were at, or above, 135 degrees F.
    - Determine if the food employees have and use thermometers to measure temperatures of the suspect TCS food in hot holding units.
    - If required, check temperature logs for hot holding units.

4. **Preparation Several Hours Before Service:** The suspect food was prepared long before service, and this practice permitted a time/temperature abuse of the food.
    - Determine the length of time between preparation and service of the suspect food.
    - Determine how long the suspect food was stored between preparation and service.

5. **Anaerobic Packaging:** The suspect food was stored in a container that provided an anaerobic environment, which permitted the multiplication and growth of the agent.
    - Check to determine whether the suspect food was stored in an anaerobic package or container (e.g., vacuum packaging, container filled to capacity and tightly covered, hermetically sealed containers, and garlic in oil products).
    - If the suspect food was in a vacuum package or container, investigate at what temperature it was stored.
    - Determine if the suspect food was prepared in a cook-chill or sous-vide operation.

- If the suspect food was in a vacuum package or container, review the label storage instructions, and make sure the food establishment was in compliance with label instructions.

Step 4: Identify violations and initiate corrective actions

Documenting **violations** is a critical step in the investigation, especially if further enforcement action is necessary. Violations may be referenced on the *HACCP Risk Assessment Form* in the "Item No." column and then attach the form to the food establishment inspection report form. If a *HACCP Risk Assessment Form* is not completed at the time of the investigation, the violations must be documented on the narrative section of the inspection report form. Failure to properly document violations may result in the LBOH being legally challenged for its actions.

You must also document **corrective actions**. Indicate immediate corrective or enforcement actions taken, as well as how and when existing violations will be corrected, particularly for critical control points. If violations involving critical control points are detected, a **re-inspection** should be conducted within 24 to 48 hours to verify correction. In the column "Verified" on the *HACCP Risk Assessment Form* indicate the date and the inspector verifying correction. Corrective actions may include:

- **Modifying faulty food handling practices:** Initiating corrective actions is the most critical aspect of the environmental investigation, if unsafe food handling practices are discovered. Ensuring that faulty food handling practices which can result in foodborne disease are corrected is one of the primary objectives of the investigation. **Emphasize critical control points correction.** Discuss with the PIC monitoring procedures that can be implemented by the food establishment to ensure that steps designated as "critical" are properly carried out by food employees. Correction plans can include recommendations to improve food safety. For example, the use of raw eggs in a Caesar salad dressing may not be a violation of the regulations. However, recommending that the establishment use a pasteurized product is reasonable since the use of a pasteurized product can reduce the risk of disease transmission.

- **Education:** Efforts to educate the owner/PIC on the risks posed by identified poor food handling practices should be made by the food inspector. In some situations, it may be necessary for the owner to hire a consultant to assist in making changes or training staff. The designated PIC will be required to participate in a food safety management program, if not already certified.

- **Removal of contaminated food from sale or distribution:** If it is determined that food prepared on the premises is possibly contaminated and may cause a foodborne illness, the LBOH may initiate a voluntary disposal of the food or an embargo in accordance with 105 CMR 590.012. Such action should be taken only with clear evidence of contamination or time/temperature abuse. See Chapter IX: Working with the State Public Health Laboratory for information on taking food samples.

  Most of the focus should be placed on foods that will not receive further cooking or reheating, since it is these foods in which bacteria and toxins, if present, may survive until ingested. However, some food poisonings, such as scombroid poisoning can occur even after food is cooked. Remember that corrective actions may not always require disposal.

- **Restriction of infected food workers:** If a sick food employee is noted at any time during the environmental investigation, work with the PIC to take steps to restrict the food employee from working with food in accordance with 105 CMR 590.000. See Chapter VIII for complete coverage of sick food employees and recommendations for particular things to note during the inspection if hepatitis A is involved. Attachment 7-16 is a model Food Employee Reporting Agreement that can be used by food service establishments to assist with obtaining compliance with illness reporting requirements.

- **Emergency closure or suspension of operations:** In certain situations, it may be necessary to close an establishment or suspend a particular operation if imminent health hazards exist that cannot be corrected immediately. Failure to immediately correct violations that may result in a foodborne disease, usually associated with critical control points, should invoke an emergency closure or suspension of operation(s).

  For example, if it is discovered that a mechanical salad bar refrigeration unit is not maintaining TCS temperatures at or below 41 degrees F, and there is no ice source, the salad bar operation should be closed until the unit is repaired. Another example that may warrant an emergency closure is in an outbreak situation when it is determined that the majority of the food employees must be restricted from working with food, and there are no replacement workers. A food establishment may desire to voluntarily close to avoid negative publicity. Remember, closures and suspensions are a serious matter to all involved and should be well planned before being implemented.

  If a closure or suspension is initiated, the permit holder and the PIC must be notified of the order in writing. The order is effective upon posting on the premises. Afterwards, the LBOH must hold a hearing within three business days after receipt of a written request for a hearing. Whether or not a hearing is requested, the LBOH may end the suspension at any time if the reasons for the suspension no longer exist.

Figure 7-5. An Emergency Closure Order Must State the Following:

1. The LBOH has determined that an imminent health hazard exists which requires immediate suspension of operations or closure;
2. The violations leading to that determination; and
3. A hearing will be held, upon written request by the permit holder filed within ten days of receipt of the notice of suspension or closure.

Refer to 590.014 of the MA Food Code for complete information involving the closure of an establishment.

STEP 5: Verify corrective actions have been undertaken by the establishment

All corrective actions must be verified by the LBOH to ensure that steps to reduce or eliminate the hazards have actually occurred. Failure to correct critical violations or to comply with other necessary measures (e.g., food employee specimen submission or work restrictions) should result in the LBOH taking further enforcement actions such as suspension or emergency closure. Verification may be completed during the investigation by actually observing the corrective actions or by re-inspection.

A HACCP risk assessment may require more than one contact with the permit holder or PIC during site visits or telephone calls in order to obtain all the information necessary to assess the procedures. Elements in the investigation may change and can require shifts of focus in suspect procedures. Try to stay open-minded and patient. When investigating suspect food items, which may have been contaminated prior to being received at the retail food establishment, it is important to obtain as much product information as possible to identify the exact source, and remove contaminated products from distribution.

Conducting a HACCP risk assessment of the implicated food is necessary in order to effectively identify potential hazards or points of contamination and time/temperature abuse. A report that reflects a HACCP-based investigation provides specific information to the reviewer (permit holder, PIC, complainant, LBOH, MDPH Working Group on Foodborne Illness Control, lawyers, etc.) on how the food was handled by the establishment.

Findings may demonstrate how a food establishment is employing safe food handling procedures in preparing the suspect food. Findings may also reveal critical control points in the preparation of the suspect food that were not being safely performed or monitored. In this case, a HACCP risk assessment will clearly identify faulty food handling practices as well as the recommendations to initiate corrective actions. Poor food handling practices can be replaced with safe practices and procedures, thereby averting future occurrences of foodborne disease.

E. National Environmental Assessment Reporting System (NEARS)

In spring 2017, a letter was sent to LBOHs by the Food Protection Program (FPP) requesting voluntary involvement in the CDC's NEARS program which is a nationwide surveillance system designed to capture environmental assessment data from foodborne illness outbreak investigations. Participating in NEARS can greatly assist Massachusetts and other states to prevent foodborne illness outbreaks. The NEARS data can be used to

- Identify environmental causes of outbreaks.
- Take follow-up action to reduce or prevent future foodborne illness outbreaks.
- Evaluate food safety programs and make improvements based on established guidelines.
- Develop or modify program policies or regulations.
- Focus limited program resources on actions with the highest impact.

The CDC and national food safety partners recommend that all food safety programs use NEARS to improve food safety nationally. Environmental assessment data provided by LBOHs is critical to prevent and reduce future outbreaks. The CDC and its national food safety partners will use NEARS to analyze standardized data to understand how and why outbreaks occur, and share findings or recommend actions to better respond to outbreaks and prevent future ones.

Regulatory agencies, such as the FDA, can use information from NEARS to develop intervention strategies and to recommend regulations, such as updates to the Food Code. Food safety programs use this information during outbreak investigations, and on a daily basis, for issuing permits and inspecting restaurants and other facilities.

The LBOH role in NEARS will be to complete the *NEARS Establishment Observations Checklist* (Attachment 7-12), in addition to other paperwork described in this chapter, but ONLY IN THE EVENT OF AN OUTBREAK. The Food Protection Program will provide technical assistance to complete this form. Additional information about the NEARS program can be found at https://www.cdc.gov/nceh/ehs/nears/

References:

"MA Food Code," Regulation 105 CMR 590.000: Minimum Sanitation Standards for Food Service Establishments, Article X: https://www.mass.gov/files/documents/2018/10/09/105cmr590.pdf

The 2013 FDA Food Code and 2015 Supplement to the 2013 Code are available on FDA's website at: https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm

CIFOR (Council to Improve Foodborne Outbreak Response): Guidelines for Foodborne Disease Outbreak Response - 2nd Edition and Industry Guidelines, plus other resources at http://cifor.us/

https://www.foodshield.org/ Many videos available, particularly FDA videos on actual cases of foodborne illness designed for food service establishments; also, MA-RRT (Rapid Response Team): "Conducting Environmental Assessments."

FDA document for regulators of retail and food service establishments entitled, "Managing Food Safety: A Regulators' Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems." Available at https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM078159.pdf

Attachments:

Attachment 7-1: Equipment List
Attachment 7-2: Food Inspection Report Form
Attachment 7-3: Effects of pH
Attachment 7-4: Effects of Water Activity
Attachment 7-5: Blank HACCP Risk Assessment Form
Attachment 7-6: Instructions for Completing the HACCP Risk Assessment Form
Attachment 7-7: Completed HACCP risk Assessment Form
Attachment 7-8: Management of Food Safety Practices
Attachment 7-9: The Process Approach
Attachment 7-10: Traceback Methodology
Attachment 7-11: Food Employee Reporting Agreement
Attachment 7-12: NEARS Establishment Observations Checklist

Attachment 7-1: Inspection Equipment Checklist

FIELD EQUIPMENT
Picture I.D.
Inspector Business Cards
Temp Measuring Device (TMD, i.e. Thermocouple, Food Stem Thermometer)
Infra-Red Thermometer (optional)
Alcohol Swabs
160º F Temp. Sensitive Tapes
Sanitizer Test Kits (chlorine, iodine, quaternary ammonia)
pH test papers
Flashlight/Batteries
Clipboard
Black Light/Battery/Bulb (optional)
Educational Materials (optional)
Camera (optional)
RECOMMENDED CLOTHING
Lab Coat
Hair/Beard Restraint
Rubber-Soled Nonslip Footwear
DOCUMENTS
Regulations
Inspection Forms
HAVE ACCESS TO
Sterile Bags & Vials
Cooler & Ice Packs

Attachment 7-2: Food Inspection Report

For copy of most recent version of inspection report, go to: https://www.mass.gov/lists/retail-food

Food Establishment Inspection Report – City/Town of ____________

Establishment:	Date:	Page 1 of ___
Address:	Time in:	Time out:
Telephone: Permit No.:	Number of Violated Provisions Related to Foodborne Illness Risk Factors and Interventions (Items 1 through 29):	
Owner:		
Person-in-charge:	Number of Repeat Violations Related to Foodborne Illness Risk Factors and Interventions (Items 1 through 29):	
Inspector:		

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

IN = in compliance **OUT**= out of compliance **N/O** = not observed **N/A** = not applicable **COS** = corrected on-site during inspection **R** = repeat violation

	Compliance Status	IN	OUT	N/A	N/O	COS	R
	Supervision						
1	Person-in-charge present, demonstrates knowledge, and performs duties						
2	Certified Food Protection Manager						
	Employee Health						
3	Management, food employee and conditional employee; knowledge, responsibilities and reporting						
4	Proper use of restriction and exclusion						
5	Procedures for responding to vomiting and diarrheal events						
	Good Hygienic Practices						
6	Proper eating, tasting, drinking, or tobacco use						
7	No discharge from eyes, nose, and mouth						
	Preventing Contamination by Hands						
8	Hands clean & properly washed						
9	No bare hand contact with ready-to-eat food						
10	Adequate handwashing sinks properly supplied and accessible						
	Approved Source						
11	Food obtained from approved source						
12	Food received at proper temperature						
13	Food received in good condition, safe, & unadulterated						
14	Required records available: shellstock tags, parasite destruction						

	Compliance Status	IN	OUT	N/A	N/O	COS	R
	Protection from Contamination						
15	Food separated and protected						
16	Food-contact surfaces: cleaned & sanitized						
17	Proper disposition of returned, previously served, reconditioned & unsafe food						
	Time/Temperature Control for Safety						
18	Proper cooking time & temperatures						
19	Proper reheating procedures for hot holding						
20	Proper cooling time and temperature						
21	Proper hot holding temperature						
22	Proper cold holding temperature						
23	Proper date marking and disposition						
24	Time as a Public Health Control						
	Consumer Advisory						
25	Consumer advisory provided for raw / undercooked food						
	Highly Susceptible Populations						
26	Pasteurized foods used; prohibited foods not offered						
	Food/Color Additives and Toxic Substances						
27	Food additives: approved & properly used						
28	Toxic substances properly identified, stored & used						
	Conformance with Approved Procedures						
29	Compliance with variance / specialized process / HACCP Plan						

Official Order for Correction: Based on an inspection today, the items marked "OUT" indicated violations of 105 CMR 590.000 and applicable sections of the 2013 FDA Food Code. This report, when signed below by a Board of Health member or its agent constitutes an order of the Board of Health. Failure to correct violations cited in this report may result in suspension or revocation of the food establishment permit and cessation of food establishment operations. If you are subject to a notice of suspension, revocation, or non-renewal pursuant to 105 CMR 590.000 you may request a hearing before the board of health in accordance with 105 CMR 590.015(B).

Date of Reinspection: **Discussion with Person-in-Charge:**

Signature of Person-in-Charge:	**Date:**
Signature of Inspector:	**Date:**

MDPH model form – 10/5/18 version

Food Establishment Inspection Report – City/Town of ____________

Establishment:	Date:	Page 2 of ___

GOOD RETAIL PRACTICES AND MASSACHUSETTS-ONLY SECTIONS

IN = in compliance **OUT**= out of compliance **N/O** = not observed **N/A** = not applicable **COS** = corrected on-site during inspection **R** = repeat violation

	Compliance Status	IN	OUT	N/A	N/O	COS	R
	Safe Food and Water						
30	Pasteurized eggs used where required						
31	Water & ice from approved source						
32	Variance obtained for specialized processing methods						
	Food Temperature Control						
33	Proper cooling methods used; adequate equipment for temperature control						
34	Plant food properly cooked for hot holding						
35	Approved thawing methods used						
36	Thermometers provided & accurate						
	Food Identification						
37	Food properly labeled; original container						
	Prevention of Food Contamination						
38	Insects, rodents, & animals not present						
39	Contamination prevented during food preparation, storage and display						
40	Personal cleanliness						
41	Wiping cloths: properly used & stored						
42	Washing fruits & vegetables						
	Proper Use of Utensils						
43	In-use utensils properly stored						
44	Utensils, equipment & linens: properly stored, dried, & handled						
45	Single-use / single-service articles: properly stored & used						
46	Gloves used properly						
	Utensils, Equipment and Vending						
47	Food & non-food contact surfaces cleanable, properly designed, constructed & used						

	Compliance Status	IN	OUT	N/A	N/O	COS	R
48	Warewashing facilities: installed, maintained, & used; test strips						
49	Non-food contact surfaces clean						
	Physical Facilities						
50	Hot & cold water available; adequate pressure						
51	Plumbing installed; proper backflow devices						
52	Sewage & waste water properly disposed						
53	Toilet features: properly constructed, supplied, & cleaned						
54	Garbage & refuse properly disposed; facilities maintained						
55	Physical facilities installed, maintained, & clean						
56	Adequate ventilation & lighting; designated areas used						
	Additional Requirements listed in 105 CMR 590.011						
M1	Anti-choking procedures in food service establishment						
M2	Food allergy awareness						
	Review of Retail Operations listed in 105 CMR 590.010						
M3	Caterer						
M4	Mobile Food Operation						
M5	Temporary Food Establishment						
M6	Public Market; Farmers Market						
M7	Residential Kitchen; Bed-and-Breakfast Operation						
M8	Residential Kitchen: Cottage Food Operation						
M9	School Kitchen; USDA Nutrition Program						
M10	Leased Commercial Kitchen						
M11	Innovative Operation						
	Local Requirements						
L1	Local law or regulation						
L2	Other						

Type of Operation(s):	Type of Inspection:	Other Information:
☐ Food Service Establishment	☐ Routine	
☐ Retail Food Store	☐ Re-inspection	
☐ Residential Cottage Foods	☐ Pre-operational	
☐ Residential; Bed & Breakfast	☐ Illness investigation	
☐ Mobile/Pushcart	☐ General complaint	
☐ Temporary Food Estab.	☐ HACCP	
☐ Other ________	☐ Other ________	

Signature of Person-in-Charge:	**Date:**
Signature of Inspector:	**Date:**

MDPH model form – 10/5/18 version

Food Establishment Inspection Report – City/Town of ____________

Establishment:	Date:	Page ___ of ___

Temperature Observations

Item / Location	Temp (°F)	Item / Location	Temp (°F)	Item / Location	Temp (°F)

Observations and/or Corrective Actions

Violations cited in this report must be corrected within the time frames stated below or in Section 8-405.11 of the Food Code

Item Number	Section of Code	Description of Violation	Date to Correct By

Signature of Person-in-Charge:	**Date:**
Signature of Inspector:	**Date:**

MDPH model form – 10/5/18 version

pH: (hydrogen ion concentration, relative acidity or alkalinity). The pH range of a microorganism is defined by a minimum value (at the acidic end of the scale) and a maximum value (at the basic end of the scale). There is a pH optimum for each microorganism at which growth is maximal. Moving away from the pH optimum in either direction slows microbial growth.

A range of pH values is presented here, as the pH of foods, even those of similar types, varies considerably. Shifts in pH of a food with time may reflect microbial activity, and foods that are poorly buffered (i.e., do not resist changes in pH), such as vegetables, may shift pH values considerably. For meats, the pH of muscle from a rested animal may differ from that of a fatigued animal.

A food may start with a pH that precludes bacterial growth, but as a result of the metabolism of other microbes (yeasts or molds), pH shifts may occur and permit bacterial growth.

pH Values of Various Foods

BAKERY PRODUCTS	pH
Bread	5.3 - 5.8
Éclairs	4.4 - 4.5
Napoleons	4.4 - 4.5
Biscuits	7.1 - 7.3
Crackers	7.0 - 8.5
Cakes, Angel food	5.2 - 5.6
Cakes, Chocolate	7.2 - 7.6
Cakes, Devil's food	7.5 - 8.0
Cakes, Pound	6.6 - 7.1
Cakes, Sponge	7.3 - 7.6
Cakes, White layer	7.1 - 7.4
Cakes, Yellow layer	6.7 - 7.1
Flour	6.0 - 6.3
BERRIES	**pH**
Blackberries	3.2 - 4.5
Blueberries	3.7
Blueberries, Frozen	3.1 - 3.35
Cherries	3.2 - 4.1
Cranberries, Sauce	2.4
Cranberries, Juice	2.3 - 2.5
Currants (red)	2.9
Gooseberries	2.8 - 3.1
Grapes	3.4 - 4.5
Raspberries	3.2 - 3.7
Strawberries	3.0 - 3.5
Strawberries, Frozen	2.3 - 3.0
DAIRY PRODUCTS/ EGGS	**pH**
Butter	6.1 - 6.4
Buttermilk	4.5
Milk	6.3 - 8.5
Acidophilus	4.0
Cream	6.5
Cheese, Camembert	7.4
Cheese, Cheddar	5.9
Cheese, Cottage	5.0
Cheese, Cream cheese	4.88
Cheese, Edam	5.4
Cheese, Roquefort	5.5 - 5.9
Cheese, Swiss Gruyere	5.1 - 6.6
Eggs, White	7.0 - 9.0
Eggs, Yolk	6.4
Egg solids, whites	6.5 - 7.5
Eggs, Whole	7.1 - 7.9
Eggs, Frozen	8.5 - 9.5
FISH	**pH**
Fish (most fresh)	6.6 - 6.8
Clams	6.5
Crabs	7.0
Oysters	4.8 - 6.3
Tuna fish	5.2 - 6.1
Shrimp	6.8 - 7.0
Salmon	6.1 - 6.3
Whitefish	5.5
Freshwater (most)	6.9 - 7.3
Sturgeon	5.5 - 6.0
Herring	6.1 - 6.4
Fruits	**pH**
Apples, Delicious	3.9
Apples, Golden Delicious	3.6
Apples, Jonathan	3.33
Apple, McIntosh	3.34
Apple, Winesap	3.47
Apple, Juice	3.4 - 4.0

Apple, Sauce	3.3 - 3.6
Apricots	3.3 – 4.0
Apricots, Dried	3.6 - 4.0
Apricots, Canned	3.74
Bananas	4.5 - 5.2
Cantaloupe	6.17-7.13
Dates	6.3 - 6.6
Figs	4.6
Grapefruit	3.0 - 3.3
Grapefruit, Canned	3.1 - 3.3
Grapefruit, Juice	3.0
Lemons	2.2 - 2.4
Lemons, Canned juice	2.3
Limes	1.8 - 2.0
Mangos	3.9 - 4.6
Melons, Casaba	5.5 - 6.0
Melons, Honeydew	6.3 - 6.7
Melons, Persian	6.0 - 6.3
Nectarines	3.9
Oranges	3.1 - 4.1
Oranges, Juice	3.6 - 4.3
Oranges, Marmalade	3.0
Papaya	5.2 - 5.7
Peaches	3.4 - 3.6
Peaches, In jars	4.2
Peaches, In cans	4.9
Persimmons	5.4 - 5.8
Pineapple	3.3 - 5.2
Pineapple, Canned	3.5
Pineapple, Juice	3.5
Plums	2.8 - 4.6
Pomegranates	3.0
Prunes	3.1 - 5.4
Prunes, Juice	3.7
Quince (stewed)	3.1 - 3.3
Tangerines	4.0
Watermelon	5.2 - 5.8
Meat, Poultry	**pH**
Beef, Ground	5.1 – 6.2
Beef, Ripened	5.8
Beef, Unripened	7.0
Beef, Canned	6.6
Beef, Tongue	5.9
Ham	5.9 - 6.1
Lamb	5.4 - 6.7
Pork	5.3 - 6.9
Veal	6.0
Chicken	6.5 – 6.7
Turkey (roasted)	5.7 – 6.8
VEGETABLES	**pH**
Artichokes	5.6
Artichokes, Canned	5.7 – 6.0
Asparagus	4.0 – 6.0
Asparagus, Canned	5.2 - 5.3

Asparagus, Buds	6.7
Asparagus, Stalks	6.1
Beans	5.7 - 6.2
Beans, String	4.6
Beans, Lima	6.5
Beans, Kidney	5.4 – 6.0
Beets	4.9 - 5.6
Beets, Canned	4.9
Brussel sprouts	6.0 - 6.3
Cabbage	5.2 - 6.0
Cabbage, Green	5.4 - 6.9
Cabbage, White	6.2
Cabbage, Red	5.4 - 6.0
Cabbage, Savoy	6.3
Carrots	4.9 - 5.2
Carrots, Canned	5.18-5.22
Carrots, Juice	6.4
Cauliflower	5.6
Celery	5.7 - 6.0
Chives	5.2 - 6.1
Corn	6.0 - 7.5
Corn, Canned	6.0
Corn, Sweet	7.3
Cucumbers	5.1 - 5.7
Dill pickles	3.2 - 3.5
Eggplant	4.5 - 5.3
Hominy (cooked)	6.0
Horseradish	5.35
Kale (cooked)	6.4 - 6.8
Kohlrabi (cooked)	5.7 - 5.8
Leeks	5.5 - 6.0
Lettuce	5.8 - 6.0
Lentils (cooked)	6.3 - 6.8
Mushrooms (cooked)	6.2
Okra (cooked)	5.5 - 6.4
Olives, Green	3.6 - 3.8
Olives, Ripe	6.0 - 6.5
Onions, Red	5.3 - 5.8
Onions, White	5.4 - 5.8
Onions, Yellow	5.4 - 5.6
Parsley	5.7 - 6.0
Parsnip	5.3
Peas	5.8 - 7.0
Peas, Frozen	6.4 - 6.7
Peas, Canned	5.7 - 6.0
Peas, Dried	6.5 - 6.8
Pepper	5.15
Pimiento	4.6 - 4.9
Potatoes	6.1
Potatoes, Tubers	5.7
Potatoes, Sweet	5.3 - 5.6
Pumpkin	4.8 - 5.2
Radishes, Red	5.8 - 6.5
Radishes, White	5.5 - 5.7

Rhubarb	3.1 - 3.4
Rhubarb, Canned	3.4
Rice, Brown (cooked)	6.2 - 6.7
Rice, White (cooked)	6.0 - 6.7
Rice, Wild (cooked)	6.0 - 6.4
Sauerkraut	3.4 - 3.6
Sorrel	3.7
Spinach	5.5 - 6.8
Spinach, Cooked	6.6 - 7.2
Spinach, Frozen	6.3 - 6.5
Squash, Yellow (cooked)	5.8 - 6.0
Squash, White (cooked)	5.5 - 5.7
Squash, Hubbard (cooked)	6.0 - 6.2
Tomatoes (whole)	4.2 - 4.9
Tomato, Paste	3.5 - 4.7
Tomatoes, Canned	3.5 - 4.7
Tomato, Juice	4.1 - 4.2
Turnips	5.2 - 5.5
Zucchini (cooked)	5.8 - 6.1
MISCELLANEOUS	**pH**
Caviar (domestic)	5.4
Cider	2.9 - 3.3
Cocoa	6.3
Corn syrup	5.0
Corn starch	4.0 - 7.0
Ginger ale	2.0 - 4.0
Honey	3.9
Jams/Jellies	3.1 - 3.5
Mayonnaise	4.2 - 4.5
Molasses	5.0 - 5.5
Raisins	3.8 - 4.0
Sugar	5.0 - 6.0
Vinegar	2.0 - 3.4
Yeast	3.0 - 3.5

SOURCE: Food and Drug Administration. Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins. Second Edition, Appendix 3.

Explain What Water Activity is and how it Relates to Bacterial Growth. Differentiate between the major types of foodborne diseases - infection, intoxication, and toxin-mediated infection.

Water in food that is not bound to food molecules can support the growth of bacteria, yeast, and mold. The term water activity (a_w) refers to this unbound water.

The water activity of a food is not the same thing as its moisture content. Although moist foods are likely to have greater water activity than are dry foods, this is not always so. In fact, a variety of foods may have exactly the same moisture content and yet have quite different water activities.

The water activity (a_w) of a food is the ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding air media, and the vapor pressure of distilled water under identical conditions. A water activity of 0.80 means the vapor pressure is 80 percent of that of pure water. The water activity increases with temperature. The moisture condition of a product can be measured as the equilibrium relative humidity (ERH) expressed in percentage or as the water activity expressed as a decimal.

Most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point that will inhibit the growth of microorganisms.

Water activity values of selected foods

Food	Water activity
Fresh meat and fish	.99
Liverwurst	.96
Cheese spread	.95
Bread	.95
Red bean paste	.93
Caviar	.92
Aged cheddar	.85
Fudge sauce	.83
Salami	.82
Soy sauce	.8
Jams and jellies	.8
Peanut butter	.7
Dried fruit	.6
Cookies	.3
Instant coffee	.2

Predicting Food Spoilage

Water activity (a_w) has its most useful application in predicting the growth of bacteria, yeast, and mold. For a food to have a useful shelf-life without relying on refrigerated storage, it is necessary to control either its acidity level (pH) or the level of water activity (a_w) or a suitable combination of the two. This can effectively increase the product's stability and make it possible to predict its shelf life under known ambient storage conditions.

Food can be made safe to store by lowering the water activity to a point that will not allow pathogens such as *Clostridium botulinum* and *Staphylococcus aureus* to grow in it. The table below illustrates the water activity (a_w) levels that can support the growth of particular groups of bacteria, yeast, and mold.

Effect of a_w on Spoilage of Foods

a_w	Spoilage microorganism	Food
0.90-1.00	Bacteria	Cottage cheese, meat
0.85 - 9.0	Bacteria, molds, yeasts	Margarine, condensed milk, whipped butter
0.80 - 0.85	Yeasts	Fruit syrups
0.75 - 0.80	Xerophilic molds, molds and yeasts	Dried figs, jams
0.70 - 0.75	Yeasts	Confections
0.65 - 0.70	Osmophilic yeasts	Molasses
0.60 - 0.65	Xerophilic molds, osmophilic yeasts	Dried fruit

Semi-moist foods

For foods with a high water activity correct proper refrigeration is always necessary. These include most fresh foods and many processed foods, such as soft cheeses and cured meats. However, many foods can be successfully stored at room temperature by proper control of their water activity (a_w). These foods can be described as semi-moist and include fruitcakes, puddings, and chocolate and caramel sauce.

When these foods spoil, it is usually the result of surface mold growth. Most types of mold do not grow at a water activity level below 0.8. Some will grow slowly at this a_w, so it is usually recommended that products of this type not have a water activity greater than 0.75. While this will not completely prevent microbial spoilage, those few yeast and molds that do grow at lower water activities need only to be considered when special shelf life conditions must be met.

Article Sources:

http://extension.psu.edu/food-safety/food-preservation/issues/water-activity-of-foods/water-activity-of-foodstable

http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm

If you have questions, contact Dr. Angela Fraser, Associate Professor/Food Safety Education Specialist, Clemson University, Clemson SC.

FBI MANUAL SOURCE: http://www.foodsafetysite.com/educators/competencies/general/bacteria/bac5.html

HACCP RISK ASSESSMENT

City/Town of:_____

Product/ Process:		**ESTABLISHMENT NAME**
INGREDIENTS	**Source**	**ADDRESS**
		PERSON IN CHARGE
		INFORMATION FOR THIS RISK ASSESSMENT WAS OBTAINED BY: ☐ **Observation Of Suspect Food/Process** ☐ **Observation Of General Food Handling and Sanitation Practices** ☐ **Interview With Food Employee Responsible For Preparing Implicated Food.** ☐ **Interview With Person-In-Charge Or Other Employee**
Weight/Volume of Suspect Food Prepared or Served:		**Dates of Investigation:**

PLEASE PRINT CLEARLY

	Describe Product Flow **(Preparation Steps)** Who, What, Where, When	**Describe Environmental Data Collected to Verify Control or Lack of Control of Hazards.**	**HAZARDS** -Contamination -Survival -Proliferation	**Describe Corrective and Preventive Measures Initiated** (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	**Date Verified**
☐CCP					
☐CCP					
☐CCP					
☐CCP					

Page No.___ Of ____

	Describe Product Flow **(Preparation Steps)** Who, What, Where, When	**Describe Environmental Data Collected to Verify Control or Lack of Control of Hazards.**	**HAZARDS** -Contamination -Survival -Proliferation	**Describe Corrective and Preventive Measures Initiated** (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	**Date Verified**
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Comments:

How to Conduct a HACCP Risk Assessment for an Implicated Food or Food Process.

1. Identify List Of **Ingredients/ Food Source/ Weight/Volume of** Food Prepared
2. Confirm general steps used in preparing suspect food. (Use **flow diagrams** to direct investigation)
3. Describe **Preparation Steps** in greater detail. Use flow diagrams or table to highlight each step. (Explain how food was handled and hazards were controlled at each step from receiving to service or sale) Include:
    a. *WHO (Identify name of food employee handling suspect food at each step. Include any significant finding relative to health and hygiene).*
    b. *WHAT (Identify what is being done with the food at each step including the type of equipment being used)*
    c. *WHEN (Identify date and time at each step)*
    d. *WHERE (Identify location where food is being handled)*
4. Identify most likely **Critical Control Points** (steps in the procedure where food operator must ensure that critical limits are being met to eliminate or significantly reduce the risk of potential hazards.)
5. Verify **Monitoring Procedures** used to control hazards (*Identify HOW potential hazards are or are not being reduced or eliminated at each step, especially at critical control points.)* Use observations and interviews. Obtain recipes, formulations, operation procedures and monitoring records, if possible.
6. Identify **Significant Hazards,** which may have occurred at each step.

    Include:

    a. *Contamination from raw ingredients, food employee/customer, unclean equipment/utensils, environment.*
    b. *Survival of pathogens in foods that are ready-to-eat or are offered raw or partially cooked.*
    c. *Proliferation (growth) of pathogens and production of toxins in PHFs.*
7. Identify and Verify **Corrective Actions and Preventive Measures** taken as a result of the investigation to ensure that hazards resulting from unsafe food and/or inadequate food handling practices have been eliminated or significantly reduced.

    Include:

    a. *Orders for Correction (risk factors and major interventions)*
    b. *Changes in Food Handling Policies and Procedures at each step*
    c. *Embargos/Voluntary Disposals*
    d. *Emergency Suspension or Closure*
    e. *Employee Testing /Restriction/Exclusion*
    f. *Food Employee/PIC Training*
    g. *Orders for Correction (good retail practices)*
    h. *Recalls/Press Releases and News Alerts*
    i. *Equipment/Physical Facility Modifications*

8. **Summarize Contributing Factors** identified for the food or process.

HACCP RISK ASSESSMENT

City/Town of: London, MA

Product/ Process: Stuffed Manicotti		**ESTABLISHMENT NAME** Tony's Catering
INGREDIENTS	**Source**	**ADDRESS** 85 Merry St. London, MA
Ricotta cheese (5 lbs)	Mozzarella House, Everett	**PERSON IN CHARGE** Tony and Tina Smithers
Gr.A Jumbo Brown Eggs (5) Brand: Healthy Ray Fresh Eggs	Buckeye Egg Farm, L.P. Croton, OH	
Spices	Hallsmith Sysco	**INFORMATION FOR THIS RISK ASSESSMENT WAS OBTAINED BY:**
Manicotti Pasta Shells	Spaghetti Maker Brands, New York	☐ Observation Of Suspect Food/Process
Tomato Sauce	Hallsmith Sysco	☒ Observation Of General Food Handling and Sanitation Practices
		☒ Interview With Food Employee Responsible For Preparing Implicated Food.
Weight/Volume of Suspect Food Prepared or Served: 4 aluminum pans		☐ Interview With Person-In-Charge Or Other Employee

PLEASE PRINT CLEARLY

DATE/TIME (When)	**DESCRIBE EACH STEP and HOW HAZARDS ARE CONTROLLED.** (Who, What, Where and How)	**HAZARDS** -Contamination -Survival -Growth/Toxin	**CORRECTIVE AND ENFORCEMENT ACTIONS** (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	**DATE VERIFIED**
5/11 ☐CCP	1. Fresh frozen manicotti shells placed in refrigerator to thaw in original container. JL	C		
5/12 9:00AM ☐CCP	2. Ricotta cheese received in ½ gallon containers. TS	C		
9:30 AM 10 min ☐CCP	3. Ricotta cheese, eggs and spices manually mixed together in bowl with wire wisk (eggs stored in refrigerator at 38-40°F)by JL.	C		
10 min ☐CCP	4. Manicotti shells stuffed with cheese by JL using a pastry bag. Pastry bags are washed but not sanitized.	C	Pastry bags are now being sanitized. Sanitizing solutions are being tested daily to ensure adequate sanitization.	5/17
10 min ☐CCP	5. Manicotti placed on layer of tomato sauce on sheet pan. Layer of tomato sauce is spread over the crepes.	C		

CCP Critical Control Point

DATE/TIME	DESCRIBE EACH STEP and HOW HAZARDS ARE CONTROLLED.	HAZARDS -Contamination -Survival -Growth/Toxin	CORRECTIVE AND ENFORCEMENT ACTIONS (Include changes in food handling procedures, orders for correction, embargoes/disposals, food employee restrictions, food safety training, emergency suspensions and closures, etc.)	DATE VERIFIED
10- 11:00AM ☒CCP	6. Manicotti baked at 350 °F. for one hour. Temperature not routinely tested after cooking by JL.	S	Temperature of each batch is now being tested to ensure 165 F final cooking temperature.	5/17
11- 11:30AM ☐CCP	7. Covered with aluminum foil and placed in a Cambro for hot holding until 11:30 AM. Pick-up.		Cambro units will be cleaned and manually sanitized at the end of each day.	5/17
11:30AM ☐CCP	8. Picked up.			
12:00PM ☐CCP	9. Served			
☐CCP				

Completed By: George Lovely

Date: 6/1/99

3. THE HACCP PRINCIPLES

(A) Principle #1: Conduct a Hazard Analysis

(1) What is a food safety hazard?

A hazard is a biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(2) What are biological hazards?

Biological hazards include bacterial, viral, and parasitic microorganisms. See Table 1 in this Annex for a listing of selected biological hazards. Bacterial pathogens comprise the majority of confirmed foodborne disease outbreaks and cases. Although cooking destroys the vegetative cells of foodborne bacteria to acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may germinate and grow if food is not properly cooled or held after cooking. The toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by reheating. Post-cook recontamination with vegetative cells of bacteria such as *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of retail and food service establishments.

Viruses such as norovirus, hepatitis A, and rotavirus are directly related to contamination from human feces. Recent outbreaks have also shown that these viruses may be transmitted via droplets in the air. In limited cases, foodborne viruses may occur in raw commodities contaminated by human feces (e.g., shellfish harvested from unapproved, polluted waters). In most cases, however, contamination of food by viruses is the result of cross-contamination by ill food employees or unclean equipment and utensils. Unlike bacteria, a virus cannot multiply outside of a living cell. Cooking as a control for viruses may be ineffective because many foodborne viruses seem to exhibit heat resistance exceeding cooking temperature requirements, under laboratory conditions. Obtaining food from approved sources, practicing no bare hand contact with ready-to-eat food as well as proper handwashing, and implementing an employee health policy to restrict or exclude ill employees are important control measures for viruses.

Parasites are most often animal host-specific, but can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross-contamination of ready-to-eat food with raw animal foods, untreated water, or contaminated equipment or utensils. Like viruses, parasites do not grow in food, so control is focused on destroying the parasites and/or preventing their introduction. Adequate cooking destroys parasites. In addition, parasites in fish to be consumed raw or undercooked can also be destroyed by effective freezing techniques. Parasitic contamination by ill employees can be prevented by proper handwashing, no bare hand contact with ready-to-eat food, and implementation of an employee health policy to restrict or exclude ill employees.

Annex 4, Table 1a – 1c. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

Annex 4, Table 1a. Selected Bacterial Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Bacillus cereus (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination
Clostridium botulinum	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
Clostridium perfringens	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
E. coli O157:H7 (other shiga toxin-producing *E. coli*)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing, prevention of cross-contamination, pasteurization or treatment of juice
Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross-contamination
Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, pasteurization or treatment of juice
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
Staphylococcus aureus (preformed heat stable toxin)	RTE TCS foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
Vibrio spp.	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination, cold holding

RTE = ready-to-eat TCS = time/temperature control for safety food

Annex 4, Table 1b. Selected Parasitic Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Anisakis simplex	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
Taenia spp.	Beef and pork	Cooking
Trichinella spiralis	Pork, bear, and seal meat	Cooking

RTE = ready-to-eat TCS = time/temperature control for safety food

Annex 4, Table 1c. Selected Viral Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing
Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

RTE = ready-to-eat TCS = time/temperature control for safety food

(3) What are Chemical Hazards?

Chemical hazards may be naturally occurring or may be added during the processing of food. High levels of toxic chemicals may cause acute cases of foodborne illness, while chronic illness may result from low levels.

The Code of Federal Regulations (http://www.access.gpo.gov/nara/cfr/cfr-table-search.html), Title 21 Food and Drugs, provides guidance on naturally occurring poisonous or deleterious substances, e.g., 21 CFR Parts 109 Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, and 184 Direct Food Substances Affirmed as Generally Recognized as Safe. The CFR also provide allowable limits for many of the chemicals added during processing, e.g., 21 CFR Part 172 Food Additives Permitted for Direct Addition to Food For Human Consumption.

FDA's Compliance Policy Guidelines also provide information on naturally occurring chemicals (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm). See Chapter 5 – Foods, Colors and Cosmetics. Examples include sections:

- 540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals – Fresh, Frozen or Processed – Methyl Mercury,
- 555.400 Foods – Adulteration with Aflatoxin, and
- 570.200 Aflatoxin in Brazil Nuts, .375 Peanuts and Peanut Products, and .500 Pistachio Nuts.

Table 2 of this Annex provides additional examples of chemical hazards, both naturally occurring and added.

(4) Food Allergens As Food Safety Hazards

Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an "allergen." For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies:

- Milk
- Egg
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation.

In August 2004, the Food Allergen Labeling and Consumer Protection Act (Public Law 108-282, Title II) was enacted, which defines the term "major food allergen." The definition of "major food allergen" adopted for use in the Food Code (see paragraph 1-201.10(B)) is consistent with the definition in the new law. The following requirements are included in the new law:

- For foods labeled on or after January 1, 2006, food manufacturers must identify in plain language on the label of the food any major food allergen used as an ingredient in the food, including a coloring, flavoring, or incidental additive.
- FDA is to conduct inspections to ensure that food facilities comply with practices to reduce or eliminate cross-contact of a food with any major food allergens that are not intentional ingredients of the food.
- Within 18 months of the date of enactment of the new law (i.e., by February 2, 2006), FDA must submit a report to Congress that analyzes the results of its food inspection findings and addresses a number of specific issues related to the production, labeling, and recall of foods that contain an undeclared major food allergen.
- Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term "gluten-free" on food labeling.
- FDA is to work in cooperation with the Conference for Food Protection (CFP) to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.

Annex 4, Table 2a-b. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Annex 4, Table 2a. Naturally Occurring Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Scombrotoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP) Diarrhetic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada Molluscan shellfish from Gulf of Mexico Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	Ensure molluscan shellfish are: • from an approved source; and • properly tagged and labeled.
Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Borginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phtyohaemmagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

Annex 4, Table 2b. Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Added Chemical Hazards	Associated Foods	Control measures
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.

Added Chemical Hazards	Associated Foods	Control measures
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrates.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

(5) What are Physical Hazards?

Illness and injury can result from foreign objects in food. These physical hazards can result from contamination or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their food safety management systems, Annex 4, Table 3 can be used to aid in the identification of sources of potential physical hazards to the food being prepared, served, or sold. Annex 4, Table 3 provides some examples of common physical hazards.

Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources[a, b]

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

[a] Adapted from Corlett (1991).

[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

SOURCE: 2013 Federal Food Code, Annex 4, pages 553-563.

Attachment 7-9

4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL

(A) Why Focus on HACCP Principles at Retail and Food Service?

FDA recognizes that there are important differences between using HACCP principles in a food safety management system developed for food manufacturing plants and applying these same principles in food safety management system developed for use in retail and food service establishments.

Since the 1980's, operators and regulators have been exploring the use of the HACCP principles in restaurants, grocery stores, institutional care facilities, and other retail food establishments. During this time, much has been learned about how these principles can be used in these varied operations, collectively referred to as retail food establishments. Most of this exploration has centered around the focal question of how to stay true to the NACMCF definitions of HACCP and still make the principles useful to an industry that encompasses the broadest range of conditions.

Unlike industries such as canning, other food processing, and dairy plants, the retail industry is not easily defined by specific commodities or conditions. Consider the following characteristics that retail food establishments share that set them apart from most food processors:

1. Employee and management turnover is exceptionally high in food establishments, especially for entry level positions. This means the many employees or managers have little experience and food safety training must be continuously provided.
2. Many establishments are start-up businesses operating without benefit of a large corporate support structure and having a relatively low profit margin and perhaps less capital to work with than other segments of the food industry.
3. There is an almost endless number of production techniques, products, menu items, and ingredients used which are not easily adapted to a simple, standardized approach. Changes occur frequently and little preparation time is available.

FDA fully recognizes the diversity of retail and food service establishments and their varying in-house resources to implement HACCP. That recognition is combined with an understanding that the success of such implementation is dependent upon establishing realistic and useful food safety strategies that are customized to the operation.

(B) What is the Process Approach?

When conducting the hazard analysis, food manufacturers usually use food commodities as an organizational tool and follow the flow of each product. This is a very useful approach for producers or processors since they are usually handling one product at a time. By contrast, in retail and food service operations, foods of all types are worked together to produce the final product. This makes a different approach to the hazard analysis necessary. Conducting the hazard analysis by using the food preparation processes common to a specific operation is often more efficient and useful for retail and food service operators. This is called the "process approach" to HACCP.

The process approach can best be described as dividing the many food flows in an establishment into broad categories based on activities or stages in the preparation of the food, then analyzing the hazards, and placing managerial controls on each grouping.

(C) What are the three food preparation processes most often used in retail and food service establishments and how are they determined?

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps.
Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. The terminology used for operational steps may differ between food service and retail food store operations.

Most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41°F and 135°F:

- **Process 1: Food Preparation with No Cook Step**

Example flow: Receive – Store – Prepare – Hold – Serve
(other food flows are included in this process, but there is no cook step to destroy pathogens)

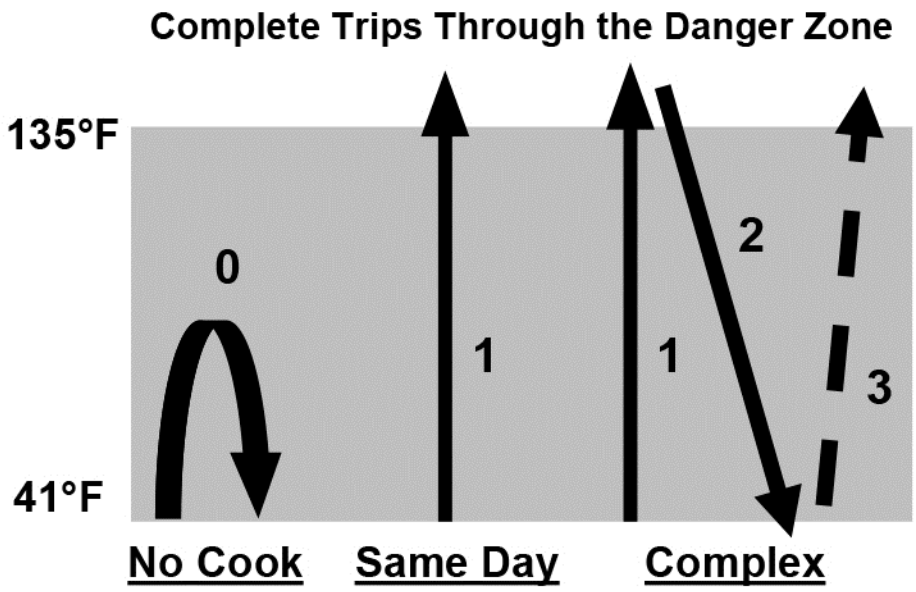
- **Process 2: Preparation for Same Day Service**

Example flow: Receive – Store – Prepare – Cook – Hold – Serve
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve
(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Although foods produced using process 1 may *enter* the danger zone, they do not pass all the way through it. Foods that go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are classified as Complex food preparation.



The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have "cook and serve" processes specific to their operation. These processes are likely to be different from the "Same Day Service" preparation processes in full service restaurants since many of their foods are generally cooked and hot held before service. In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes before the product is sold to the consumer. It is also very common for a retail or food service operator to use multiple food preparation processes to create a single menu item.

(D) How is a hazard analysis conducted in process HACCP?

In the process approach to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process achieves the same control of risk factors as preparing a HACCP plan for each individual product.

Example: An establishment has dozens of food items (including baked chicken and baked meatloaf) in the "Preparation for Same Day Service" category. Each of the food items may have unique hazards, but regardless of the individual hazards, control via proper cooking and holding will generally ensure the safety of all of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the “Same Day Service” category (Process 2).

- *Salmonella* spp. and *Campylobacter,* as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.

- Significant biological hazards in meatloaf include *Salmonella* spp., *E. coli* O157:H7, *Bacillus cereus,* and *Clostridium perfringens.*

- Despite their different hazards, the control measure used to kill pathogens in both these products is cooking to the proper temperature.

- Additionally, if the products are held after cooking, then proper hot holding or time control is also required to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165°F for 15 seconds to control the pathogen load for *Salmonella* spp. Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155°F for 15 seconds to control the pathogen load for both *Salmonella* spp. and *E. coli* O157:H7. Some operational steps such as refrigerated storage or hot holding have critical limits that apply to all foods.

Annex 4, Table 4 further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist that are not depicted here:

Annex 4, Table 4: Examples of Hazards and Control Measures for Same Day Service Items

Baked Meatloaf (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
Salmonella spp.	Refrigeration at 41°F or below
E. coli O157:H7	Cooking at 155°F for 15 seconds
Clostridium perfringens	Hot Holding at 135°F or above OR Time Control
Bacillus cereus	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

Baked Chicken (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
Salmonella spp.	Refrigeration at 41°F or below
Campylobacter	Cooking at 165°F for 15 seconds
Clostridium perfringens	Hot Holding at 135°F or above OR Time Control
Bacillus cereus	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

(E) How is the process approach helpful to industry in determining the measures that must be implemented to actively manage the foodborne illness risk factors that result in out-of-control hazards?

Even though variations in foods and in the three food preparation process flows used to prepare them are common, the control measures will generally be the same based on the number of times the food goes through the temperature danger zone. Several of the most common control measures associated with each food preparation process are discussed in this Annex. Retail or food service establishments should use these simple control measures as the core of their food safety management systems; however, there may be other risk factors unique to an operation or process that are not listed here. Each operation should be evaluated independently.

In developing a voluntary food safety management system, active managerial control of risk factors common to each process can be achieved by implementing control measures at certain operational steps designated as critical control points (CCPs) or by implementing prerequisite programs. This is explained in more detail in the Operator's Manual discussed in Part 5 of this Annex.

(F) Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, certain control measures must be implemented in all phases of the operation. All of the following control measures should be implemented regardless of the food preparation process used:

- **No bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure)** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Proper handwashing** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Restriction or exclusion of ill employees** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Prevention of cross-contamination** of ready-to-eat food or clean and sanitized food-contact surfaces with soiled cutting boards, utensils, aprons, etc., or raw animal foods.

(G) Food Preparation Process 1 – Food Preparation with No Cook Step

Example Flow: RECEIVE → STORE → PREPARE → HOLD → SERVE

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked before consumption.

Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as yogurt). In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a cook step *while at the retail or food service facility*; thus, there are no complete trips through the danger zone. Purchase specifications can be required by the retail or food service establishment to ensure that foods are received as safe as possible. Without a kill step to destroy pathogens, preventing further contamination by ensuring that employees follow good hygienic practices is an important control measure.

Cross-contamination must be prevented by properly storing ready-to-eat food away from raw animal foods and soiled equipment and utensils. Foodborne illness may result from ready-to-eat food being held at unsafe temperatures for long periods of time due to the outgrowth of bacteria.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cold holding or using time alone** to control bacterial growth and toxin production
- **Food source** (e.g., shellfish due to concerns with viruses, natural toxins, and *Vibrio* and for certain marine finfish intended for raw consumption due to concerns with ciguatera toxin)
- **Receiving temperatures** (e.g., certain species of marine finfish due to concerns with scombrotoxin)
- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns

- **Cooling** from ambient temperature to prevent the outgrowth of spore-forming or toxin-forming bacteria.

(H) Food Preparation Process 2 – Preparation for Same Day Service

Example Flow: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

In this food preparation process, food passes through the danger zone only once in the retail or food service facility before it is served or sold to the consumer. Food is usually cooked and held hot until served, e.g., fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin.

(I) Food Preparation Process 3 – Complex Food Preparation

Example Flow: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT → HOT HOLD → SERVE

Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. Food handlers should minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria
- **Hot and cold holding or using time alone** to control bacterial growth and toxin formation

- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin.

SOURCE: 2013 Federal Food Code, Annex 4, pages 570-579

Attachment 7-10: Traceback Investigation of Food Products

A. Traceback Overview

A traceback investigation is the method used to determine and document the source(s), production location(s), and distribution chain of a food product that has been implicated in a foodborne illness outbreak or is suspected of being adulterated or misbranded. A traceback investigation includes good interviewing techniques, a complete record review, and timely reporting. Additionally, a source investigation may be conducted to determine possible routes or points of contamination and /or misbranding. This investigation includes the inspection of common distribution sites, processors, and/or growers. The Food Protection Program (FPP) is responsible for conducting and coordinating traceback investigations within Massachusetts in cooperation with local, federal and other state agencies.

B. Reasons for Conducting Tracebacks

Traceback investigations are conducted:

1) to identify the source and distribution of the implicated food in order to remove the adulterated/misbranded product from the marketplace,
2) to assist in distinguishing between two or more implicated food products/ingredients,
3) to determine potential routes and/or sources of contamination in order to prevent future illnesses.

C. Information Needed for Tracebacks

1) Before a traceback is initiated, the Working Group for Foodborne Illness Control (WGFIC), in conjunction with the local board of health (LBOH) involved in investigating a foodborne illness outbreak, should obtain or complete the Foodborne Illness Complaint Worksheet. That worksheet is used to record the epidemiologic evidence such as suspect etiologic agent, incubation period, onset date of illness, signs and symptoms, laboratory confirmation of etiologic agent, and total number ill by sex and age. See Chapter IV in the Foodborne Illness Investigation and Control Reference Manual, for a copy of the Foodborne Illness Complaint Worksheet and instructions for completing the form.

2) Hazard analysis information is necessary to determine if the suspect food product was the source of contamination and other factors did not contribute to the outbreak. A blank and completed HACCP Risk Assessment Form can be found in Chapter VII, of the Foodborne Illness Investigation and Control Reference Manual.

3) Product Information:

Brand Name	Package Type
Product Name	Date of Purchase
Code/Lot Number	Manufacturer Name and Address
Expiration/Sell by/Use by Date	Distributor Name and Address
Size/Weight	Retail Food Establishment Where Purchased

Shellfish identification tags should always be obtained for clams, oysters, quahogs and other molluscan shellfish associated with a foodborne illness. Failure by a facility to retain shellfish tags in accordance with regulations is to be cited on the inspection report, and appropriate action taken on product whose source is unknown.

D. Coordination with Other Agencies

1) For fresh fruits and vegetables, the U.S. Food and Drug Administration (FDA) is the primary federal regulatory agency and will be contacted by the FPP in conjunction with the Massachusetts Department of Agricultural Resources (DAR).

2) For fish and molluscan shellfish, the FDA is the primary federal regulatory agency and will be contacted by the FPP in conjunction with the Massachusetts Division of Marine Fisheries (DMF).

3) For meat, poultry, and eggs, The U.S. Department of Agriculture - Food Safety and Inspection Services (USDA-FSIS) is the primary federal regulatory agency responsible for the investigation of meat, poultry and egg products. FPP will contact USDA.

4) The FDA is the primary federal regulatory agency for other food commodities that are manufactured out-of-state, and will be contacted by FPP. The state agency where the suspect food commodity was manufactured may also be contacted by USDA-FSIS.

E. Resources

MA Department of Public Health, Working Group on Foodborne Illness Control, *Foodborne Illness Investigation and Control Reference Manual*. Chapter VII. October, 2018.

Council to Improve Foodborne Outbreak Response (CIFOR). *Guidelines for Foodborne Disease Outbreak Response*. 2nd edition. Atlanta: Council of State and Territorial Epidemiologists; 2014.

FDA Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations, April, 2001: https://www.fda.gov/downloads/iceci/inspections/inspectionguides/ucm109504.pdf

Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Food Employees

The purpose of this agreement is to ensure that Food Employees and Conditional Employees notify the Person in Charge when they experience any of the conditions listed so that the Person in charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

A. SYMPTOMS OF:
diarrhea, vomiting, jaundice, sore throat with fever, and lesions containing pus on the hand, wrist, or an exposed body part (such as boils and infected wounds, however small.)

B. MEDICAL DIAGNOSIS OF BEING ILL WITH:
norovirus, shiga toxin-producing *E. coli*, *S*. typhi (typhoid fever), *Shigella* spp., non-typhoidal *Salmonella*, and Hepatitis A, as well as other diseases that may be transmitted through food per 105 CMR 300.000. Contact the Food Protection Program at 617-983-6712 or The Epidemiology Program at 617-983-6800 for additional information.

C. PAST MEDICAL DIAGNOSIS OF DISEASES LISTED ABOVE:
Have you ever been diagnosed as being ill with one of the diseases listed above?_____
If you have, what was the date of the diagnosis?_____

D. HIGH-RISK CONDITIONS:

- Exposure to or suspicion of causing any confirmed outbreak of the diseases listed under Part B above.
- A household member has been diagnosed with diseases listed in Part B above.
- A household member attending or working in a setting experiencing a confirmed outbreak of one of the diseases listed in part B above.

I have read (or had explained to me) and understand the requirements concerning my responsibilities under 105 CMR 590/2013 Food Code and this agreement to comply with the reporting requirements specified above involving symptoms, diagnoses, and high-risk conditions specified. I also understand that should I experience one of the above symptoms or high-risk conditions, or should I be diagnosed with one of the above illnesses, I may be asked to change my job or to stop working altogether until such symptoms or illnesses have resolved.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Food Employee or Conditional Food Employee Name (Please Print)_____

Signature of Above-named Individual_____ **Date**_____

Signature of Permit Holder or Representative_____ **Date**_____

This is a model form created by MA Department of Public Health which is offered as a tool for industry to use to aid in compliance with 105 CMR 590.002(E) and the Federal Food Code 2-201.11. The use of this form is voluntary and is not required by state regulation. Revised: October, 2018

NEARS Establishment Observations

Date: _____ **MAVEN ID #** _____

Collector's Name: _____ **Establishment:** _____

Are hand sinks available in the employee restroom? ☐Yes ☐No

# of hand sinks in employee restroom _____ # hand sinks without warm water _____ # hand sinks without soap _____ # hand sinks without towels _____

Is a hand sink available in the work area? ☐Yes ☐No

# of hand sinks in work area _____ # hand sinks without warm water _____ # hand sinks without soap _____ # hand sinks without towels _____

Are there cold storage units? ☐Yes ☐No # of cold storage units _____ Types observed: ☐ Reach-in ☐Walk-in ☐Self-Serve/Salad Bar ☐Open Top

# of cold storage units above 41°F _____ Type above 41°F: ☐ Reach-in ☐ Walk-in ☐ Self-Serve/Salad Bar ☐ Open Top Unit

Are food workers using gloves while handling food? ☐Yes ☐No

Is there a supply of disposable gloves available? ☐Yes ☐No

Are any food workers handling ready-to-eat foods with bare hands? ☐Yes ☐No

Are there records of the recorded temperatures of incoming ingredients? ☐Yes ☐No ☐CNO*

Are there records of the recorded temperatures of foods, excluding incoming ingredients? ☐Yes ☐No ☐CNO

Is there evidence of cross contamination of raw animal products with ready-to-eat foods? ☐Yes ☐No ☐ No Raw Animal Products Used

Is there cooling of hot foods? ☐Yes ☐No

What cooling method(s) are used: _____

Were any foods observed in hot holding? ☐Yes ☐No ☐CNO

Were all the temperatures at 135°F or above? ☐Yes ☐No

Were any foods observed in cold holding? ☐Yes ☐No

Were all the temperatures at 41°F or below? ☐Yes ☐No

Were any foods observed during cooking? ☐Yes ☐No

Were the temperatures of measured foods during cooking at recommended temperatures? ☐Yes ☐No

Were any physical facilities &/or food handling practices different at the time of the exposure? ☐Yes ☐No

Did you observe signs & instructions posted? ☐Yes ☐No

Did the signs observed use pictures or symbols? ☐Yes ☐No

What languages did you observe on the signs? ☐ English ☐ Spanish ☐ French ☐ Chinese ☐ Japanese ☐No written words ☐ Other, describe: _____

Does the establishment serve raw or undercooked animal products? ☐Yes ☐No

Is a consumer advisory regarding the risk of raw products provided? ☐Yes ☐No

Where's the advisory located? ☐ Menu footnote ☐ Menu description ☐ Sign ☐ Other

Do customers have direct access to a buffet line or salad bar? ☐Yes ☐No

Establishment Type: ☐ Prep Serve ☐ Cook Serve ☐ Complex

Menu type: ☐ American ☐ Chinese ☐ Thai ☐ Japanese ☐French ☐Italian ☐Mexican ☐Other describe: _____

Are wiping cloths used? ☐Yes ☐No ☐CNO Are all wiping cloths stored in sanitizing solution between uses? ☐Yes ☐No ☐CNO

Are mechanical washing machines used? ☐Yes ☐No Does the wash cycle reach the recommended temperature? ☐Yes ☐No

Does the sanitizing cycle reach the recommended temperature for sanitation? ☐Yes ☐No ☐CNO

Is chemical sanitizing used? ☐Yes ☐No Does the chemical sanitizing cycle have the recommended levels for the machine? ☐Yes ☐No ☐CNO

Are there any hand washed equipment? ☐Yes ☐No ☐CNO Are hand washed equipment washed, rinsed, and sanitized? ☐Yes ☐No ☐CNO

Is the sanitizing method (heat or chemical) properly implemented? ☐Yes ☐No ☐CNO

*CNO= Could Not Observe