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Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation

January 2011

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Public Health Agency of Canada
Canadian Food Inspection Agency

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INTRODUCTION

A foodborne illness outbreak investigation is complex and multidisciplinary, involving the collection of data from laboratory, food safety and epidemiological investigations by different government Departments. Each investigation is unique, non-linear and dynamic. As each responsible organization gathers more data and more detailed information, the situation is updated, thus providing strength to the weight of evidence for risk mitigation action.

Food recalls issued by regulatory authorities, are one of the risk management tools in response to food product contamination with foodborne pathogens and/or resulting human illness. The scientific evidence needed to proceed with an action to implement control measures as quickly as possible and prevent further illnesses is usually based on a combination of laboratory, food safety and epidemiological evidence. As part of the lessons-learned exercise resulting from the Canadian deli-meat listeriosis outbreak, which occurred in the summer of 2008, a team was assembled to examine and determine recommendations for what type of evidence is necessary and/or sufficient to take action. This document was developed in response to recommendation 29 of the "*Report of the Independent Investigator into the 2008 Listeriosis Outbreak*" which states; *"Health Canada, the Canadian Food Inspection Agency and the Public Health Agency of Canada should review, update and publish the criteria for proceeding with a food recall to ensure that the weight of evidence takes into account epidemiological information, including suspected illnesses and deaths, geographic distribution, and food sample test results whether packages are opened or unopened."*

In the *Foodborne Illness Outbreak Response Protocol* (FIORP), a foodborne illness outbreak is defined as: "*an incident in which two or more persons, from different households and therefore not linked, experience similar illness after a common source of exposure. An outbreak is often identified through laboratory surveillance or other surveillance mechanism demonstrating an increase in illness that is unusual in terms of time and/or place. An outbreak is confirmed through laboratory, food safety and/or epidemiological evidence.*"

The following is a general guidance document primarily for federal level decision-makers during foodborne outbreak investigations. The document describes factors to consider and provides guidance on how much weight to assign when assessing evidence obtained from the microbiological, epidemiological and food safety investigations. While it is not possible to account for all potential scenarios that may present during an outbreak investigation, the document outlines generally the type and weight of evidence sufficient to take action, thus providing a framework to facilitate timely and appropriate actions. Although intended primarily for a federal audience, decision-makers at all levels of government would consider similar criteria and weighting. However, the point at which different levels of government take action may differ based on differing legislative powers and other factors specific to the jurisdiction involved.

INTERPRETING DECISION DIAGRAMS

Figure 1 is a simplified decision-diagram showing how information obtained from three areas/streams of investigation feeds into the total weight of evidence accumulated, which is then used to perform a Health Risk Assessment (HRA) which could lead to potential recall action. The triggers for an outbreak investigation are cases of illness, following which an investigation is launched*. Each box within the decision-diagram represents a task for which information should be gathered during an outbreak investigation. Many of the boxes have a corresponding section within the document which outlines the required information needed to complete the task, as well as to assign 'strength' to the evidence gathered, e.g., weak or strong. The interpretation of the proper amount of evidence weight needed to proceed with action will vary with each outbreak investigation, and would likely be based on the experience of the investigator(s), as well as distinct factors in each situation. The individual boxes also contain the name of the agency responsible for determining the weight of evidence in the given situation, e.g., Public Health Agency of Canada (PHAC), is responsible for determining the weight of evidence in an epidemiological analysis. The arrows originating from the boxes indicate whether enough information was gathered to complete the task (yes/no). This should facilitate a more timely decision-making process. When the evidence in a given box is very strong (as determined by the responsible agency), the "strong evidence" arrow should be followed. At times, when yes/no/strong evidence cannot be applied to an action, black arrows should be followed which provide direct linkage between tasks.

Depending on the outcome of the information gathering, different sections of the decision diagram can be consulted. In some situations, certain evidence may be so strong that it may override other pieces of evidence and lead to faster decision-making action. The interpretation of 'strength' is left up to the collective decision-making of well-seasoned evaluators/investigators, usually by the Outbreak Investigation Coordinating Committee. The total weight of evidence during a foodborne illness outbreak is assessed by Health Canada through a Health Risk Assessment, which then may assign a health risk to a food(s). Appropriate risk management actions are then taken. It is important to note that each outbreak situation is unique and the diagram provided should not introduce delays in moving to "action, when necessary", but should be used to facilitate a timely decision-making process.

A simplified schematic of this process is shown below:

FIGURE 1: Simplified decision-diagram of the steps leading to the total weight of evidence that is considered during a foodborne illness outbreak investigation.

* Figure 2 is a more complex and realistic decision-diagram

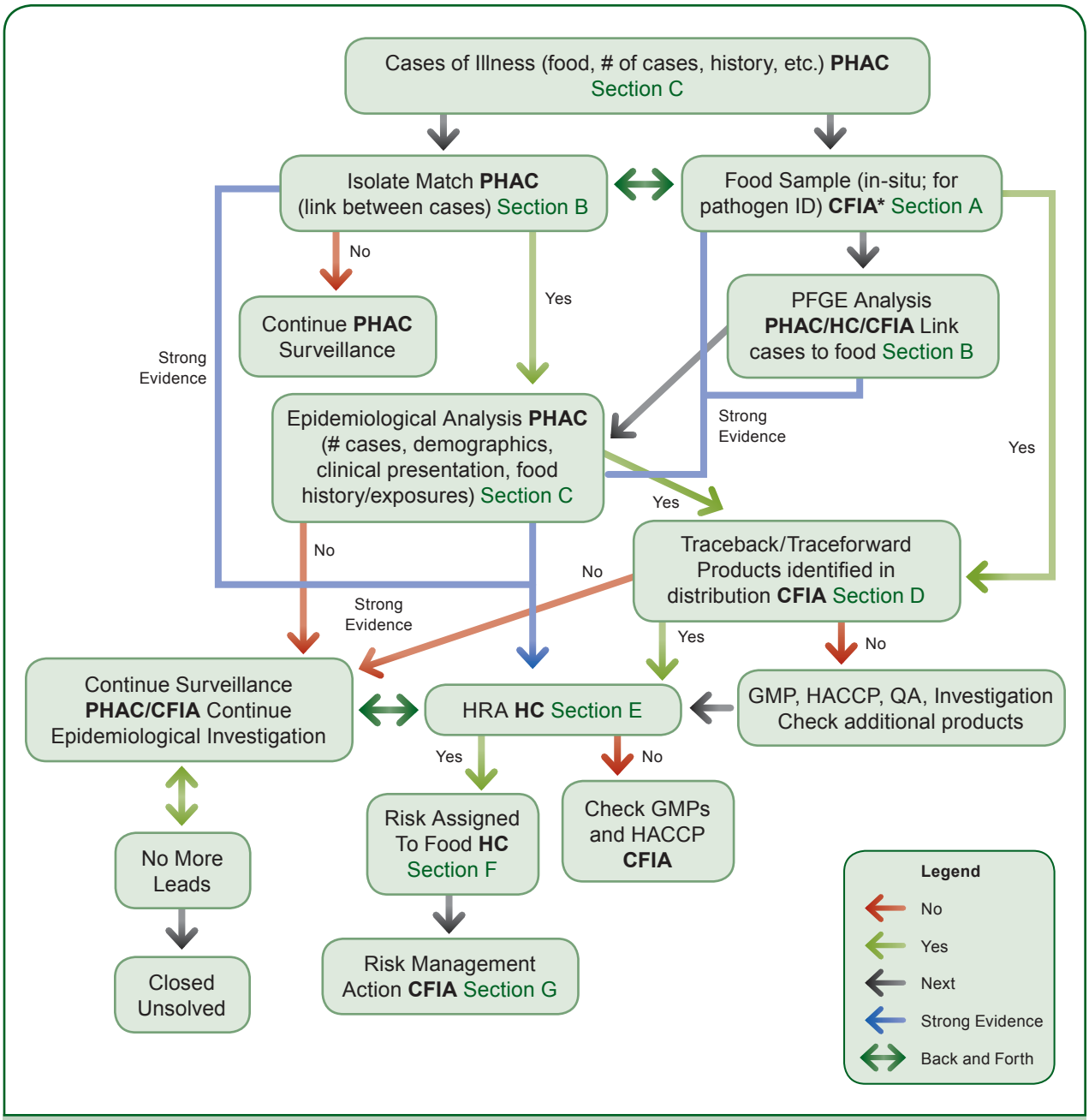

FIGURE 2: Decision-diagram for weight of evidence to be considered for action in an outbreak investigation.

* Public Health Inspectors may also be involved in sample collection. An epidemiological investigation (section C) itself, may provide strong evidence for possible risk management action(s).

INTACT AND NON-INTACT SAMPLE INFORMATION

When a foodborne illness is suspected, an investigation may be undertaken by various levels of government (municipal, provincial, federal) in order to link the illness to a food source. During the investigation, samples are collected from foods which may have been eaten by the ill individual(s). During this sample collection, various factors are investigated such as; place of collection, name of food manufacturer, lot/UPC numbers, ingredients, hygienic conditions of the sample/storage and the laboratory which will be investigating the case. Often an intact package of the sample is unavailable for testing and the investigator must collect samples from opened packages. In that case, it is especially important to demonstrate that the presence of a pathogen in such a sample occurred due to contamination in the home (resulting in an isolated incident of foodborne illness) or whether contamination occurred prior to handling by the consumer (resulting in a potential recall of affected product). Therefore, aseptic techniques (such as “coring”) should be used at all times during sample collection to prevent any cross-contamination. Sample submission forms are included as reference material in the Appendix. These forms indicate what type of food information is often collected when sampling food samples which may be linked to human illness. The forms are not meant to replace any forms currently in use by government agencies, but rather are only included as guidance when sample information is collected.

ISOLATE MATCH

Once food samples consumed by the ill persons are collected by the investigators, the samples are tested for the presence of foodborne pathogens. If pathogens are identified in the food sample, they are compared to the pathogens which have been previously isolated from the affected persons. During an outbreak investigation, it is important to demonstrate that the isolate causing human illness is indistinguishable from the isolate from an implicated food. These detailed comparisons between isolates are often performed through molecular-typing techniques, of which pulsed-field-gel-electrophoresis (PFGE) is most commonly used as the gold standard method of isolate comparison. The following Table details the strength of the microbiological/molecular typing evidence for a number of different criteria.

Strength of Microbiological Evidence: Determining the Relevance of Food and Clinical Isolates that Match by Pulsed-Field Gel Electrophoresis (PFGE)*

Criteria	Nature of Evidence	Weight
A. Does the organism show suitable diversity by PFGE?	Based on historical data, the organism shows suitable diversity by PFGE; historic sporadic cases show diverse PFGE patterns.	Strong
	Little or no historical data exists for this organism.	
	Based on historical data, the organism shows little diversity by PFGE; a large proportion of sporadic cases have indistinguishable or highly similar PFGE patterns.	Weak
B. Are clinical and food isolate PFGE patterns indistinguishable by 2 enzymes? *Interpretation of evidence is inter-connected with criterion A.*	Clinical and food isolates are indistinguishable by two enzymes.	Strong
	Clinical and food isolates have indistinguishable 1st enzyme and distinguishable 2nd enzyme patterns; minor differences are in the lower molecular weight region.	
	Clinical and food isolates have distinguishable 1st and 2nd enzyme PFGE patterns, minor differences are in the lower molecular weight region.	
	Clinical and food isolates do not match (e.g. by multiple bands, particularly in the higher molecular weight region).	Weak
C. What is the historic frequency of the PFGE pattern combination?	The PFGE pattern, or pattern combination, is new.	Strong
	Based on historic pattern frequency, the PFGE pattern is not common.	
	Based on historic pattern frequency, the PFGE pattern is common.	Weak
D. Are other subtyping results available; are they consistent with PFGE?	Additional subtyping data are available and are in agreement with PFGE. (e.g., phagetype, antimicrobial resistance profile, toxin types, MLVA, MLST, Serology, etc).	Strong
	Additional subtyping data are not available.	
	Additional subtyping data are available and are not in agreement with PFGE.	Weak

* PFGE is the gold standard subtyping method for *E. coli* O157:H7, *Listeria monocytogenes, Salmonella,* and *Shigella.* In some situations, other subtyping methods may be used as the primary method of differentiation instead of PFGE (e.g., for very rare serotypes of *Salmonella,* serotype may be sufficient). Similar criteria apply for interpretation: diversity of the organism by that method, historic frequency of the subtype, agreement with other subtyping results and epidemiological data.

SUMMARY OF EPIDEMIOLOGICAL EVIDENCE

The following "Weight of Epidemiological Evidence in a Foodborne Illness Outbreak Investigation" Table is based loosely on Hill's criteria for causality, which provides a useful framework for assessing the weight of epidemiological evidence (Hill AB. Proceedings of the Royal Society of Medicine. 1965;58:295-300). Different types of epidemiological evidence obtained during foodborne outbreak investigations are categorized within seven of the most relevant of Hill's nine criteria. The weight of the evidence within each category is ranked from strong to weak. The various "Nature of Evidence" noted in the Table are independent of each other, as most things happen at the same time; new information is continuously received and the epidemiological evidence updated. The overall weight of the epidemiological evidence is a composite of the weights within each category.

In addition to the epidemiological evidence itself, the overall risk must also take into account the context of the outbreak (i.e., severity of illness, escalation or decline in case count) and the likelihood that the appropriate action will prevent further illnesses. The following Table in section C provides guidance for assessing the weight of the epidemiological evidence without further consideration to the broader issues that would influence the risk assessment and risk management decisions.

The Table applies generally to foodborne illness outbreaks due to any pathogen including *Listeria monocytogenes,* as per recommendation 29 of the "Report of the Independent Investigator into the 2008 Listeriosis Outbreak". When assessing the epidemiologic evidence, consideration should be given to the specific characteristics of the causative organism (e.g., incubation period, infectious dose, ability to survive in different environments, modes of transmission, etc.), which will influence the interpretation of the epidemiologic data observed.

The gold standard epidemiologic evidence would be a well designed analytical study (e.g., case-control or cohort study) demonstrating a strong and statistically significant association between a single, specific food product or brand of the food product and the foodborne illness, and the majority of cases reporting consumption of this food product within the exposure period. However, there are other situations in which the weight of the evidence would be considered sufficiently strong to warrant regulatory action based on the epidemiological evidence alone (e.g., majority of a substantial number of cases identified within a tight time frame, a very specific and typically rarely consumed food product within the exposure period).

Steps in an outbreak investigation: The following points outline the steps in an outbreak investigation and were adapted from Dr. M.B. Gregg, Field Epidemiology, 2002. Although the steps are arranged in a logical order, they are not followed in a strictly linear fashion, e.g., control measures are implemented throughout the investigation as new information becomes available, and the diagnosis may also be refined as new laboratory information becomes available:

- Determine if an outbreak exists
- Confirm the diagnosis
- Assemble team
- Define case(s), initiate case finding
- Implement immediate control measures (if possible)
- Describe data in terms of person, place, time
- Determine who is at risk
- Generate hypotheses regarding the source of the outbreak
- Conduct analytical studies to test hypotheses (e.g., case control/cohort study)
- Define objectives for further research (if applicable)

- Write report and recommendations
- Debrief team
- Develop long-term prevention and control measures

Throughout the investigation, direct and supportive epidemiologic information and data are gathered. As part of the epidemiological assessment, the Public Health Agency of Canada in collaboration with jurisdictions reporting cases would analyse the following case information:

Case demographics

- Case definition – define who is part of the outbreak
- Number of cases
- Age and sex distributions
- Geographic distribution by Provinces/Territories (P/T), regional/district/local health authority
- Time distribution – epidemic curve based on onset date, exposure curve for restaurant-associated outbreaks
- Occupation – to determine possible exposure venues
- Residence – community versus health care facility
- General health prior to onset of illness (Are they immunocompromised, etc?)

Clinical presentation

- Major symptoms
- Date(s) of symptom onset
- Severity of illness
- Hospitalization
- Outcome (recovery, death, sequelae)

Exposure/Food History

- Food, water, animal, travel, other exposure histories for hypothesis generating
- Travel dates and destinations
- Restaurant/food service establishment names, locations and meal dates
- Name and location of stores where food is typically purchased
- Specific type, brand names, product codes and expiry dates of foods consumed
- Similar exposure information from a group of controls for comparison with the cases (i.e., case-control study)
- In event-associated outbreaks (e.g., conference, banquet), similar exposure information for non-cases who attended for comparison with cases (i.e., cohort study)

WEIGHT OF EPIDEMIOLOGICAL EVIDENCE IN A FOODBORNE ILLNESS OUTBREAK INVESTIGATION

Criteria	Nature of Evidence	Weight
Plausibility Is it plausible that a given food item is the vehicle of infection? *(Usually assessed in the early stages of the outbreak investigation to develop hypotheses.)*	The specific food item has been implicated in previous outbreaks of the same foodborne illness.	Strong
	The pathogen has not been identified in a wide variety of food types but has been previously identified in the suspect food type.	
	The pathogen is commonly identified in the food product's geographic area of origin and is rarely identified in the geographic area where cases reside.	
	The pathogen has been previously identified in a variety of different food types including the suspect food type.	
	The pathogen has not previously been identified in the specific food type. The food type has not been implicated in previous outbreaks of the same foodborne illness. However, the food type can support survival of the pathogen.	
	The pathogen has not previously been identified in the specific food type. The food type has not been implicated in previous outbreaks and the food type does not support survival of the pathogen.	
	No information available regarding previous outbreaks of this pathogen or the isolation or survival of the pathogen in the food type.	Weak
Consistency Is a given food item consistently reported across different populations? *(Based on descriptive and analytical epidemiology. Strength of the evidence increases with the number of case clusters and cases on which data are based. Analytical epidemiological evidence would be given more weight than descriptive evidence.)*	A majority of otherwise unrelated cases from two or more different case clusters excluding household clusters (e.g., events, restaurants) reported consuming a specific food item within their exposure period.	Strong
	A majority of otherwise unrelated cases reported consuming a specific food item within their exposure period and the proportion exposed is significantly higher than expected based on food consumption data (e.g., FoodNet or C-EnterNet surveys) for a similar season and demographic. The more varied the population of cases, the stronger the evidence (e.g., cases from multiple provinces/territories).	
	Several cases from two or more different case clusters excluding household clusters (e.g., events, restaurants) reported consuming a specific food item within their exposure period.	
	Several cases from a small cluster (e.g., small private gathering, household) reported consuming the food item within their exposure period.	
	If cases with unique or restricted diet report consuming the same food item as other cases within their exposure period, this adds strength to the above evidence.	Weak
Consistency Is the temporal and/or spatial clustering of cases consistent with the availability/distribution of a particular food product? *(Based on descriptive epidemiology. Strength of the evidence increases with the number of cases on which data are based.)*	There is tight temporal and geographic clustering of cases that correlates well with the availability or distribution of a particular lot, brand or otherwise specific food item (e.g., ready-to-eat Greek pasta salad with short shelf life).	Strong
	There is a geographic or temporal correlation between cases and distribution of food product but not both. Cases have been identified where or when the specific product was distributed and no cases have been reported despite enhanced passive surveillance where or when the product was not distributed. The temporal correlation may be absent due to a long product shelf life or ongoing contamination. The geographic correlation may be absent due to wide geographic distribution or the pattern of product contamination.	
	No temporal or spatial relationship between cases and the food product has been demonstrated.	Weak

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Specificity Does the information provided indicate a single specific food product as the vehicle of infection?	A majority of cases are able to provide the lot code or brand name of a food product and report consuming the same lot code or brand.	Strong
	The food item consistently reported by cases is very specific (e.g., ready-to-eat Greek pasta salad versus chicken), food item purchased from specialty store, consumed at same restaurant.	
	The population affected is specific to the target population of the food product (e.g., formula consumed by infants, tofu consumed by vegetarians).	
	A majority of otherwise unrelated cases reported consuming a food item of interest at higher than expected frequency while all other plausible food vehicles were reported at expected frequencies.	
	Multiple brands or locations of purchase are reported by cases.	
	Cases are not able to recall brand names or specific locations of purchase and the food item is commonly consumed (e.g., chicken).	Weak
Strength of the association How strong is the statistical association between a given food item and the foodborne illness?	A well designed analytic study (e.g., case-control or cohort) demonstrates a strong, statistically significant association between consumption of a single food product and the foodborne illness after controlling for potential confounders.	Strong
	A well designed analytic study (e.g., case-control or cohort) demonstrates a weak but statistically significant association between consumption of a single commonly consumed food product (e.g., chicken, eggs) and the foodborne illness after controlling for potential confounders.	
	A well designed, analytic study demonstrates a strong but not statistically significant association between consumption of a single food product and the foodborne illness.	
	An analytic study demonstrates a strong, statistically significant association between consumption of a single food product and the foodborne illness but there are some limitations to the design of the study (e.g., potential bias in control selection).	
	A well designed analytic study demonstrates statistically significant associations between more than one food item and the foodborne illness.	
	The analytic study is not well designed or does not identify a statistically significant association between any particular food items and the foodborne illness.	Weak
Temporal Do cases report eating food within the accepted exposure period?	The majority of cases report consuming the suspect food item within their incubation period and the food item is not a commonly consumed food (e.g., pistachios).	Strong
	The majority of cases report consuming the suspect food item within their exposure period and the food item is a commonly consumed food (e.g., eggs).	
	The cases report consuming the suspect food item but not within the accepted exposure period (e.g., food consumed slightly outside expected exposure period for salmonellosis).	Weak
Dose-Response Does the strength of the association increase with increasing consumption of the food item?	Where the frequency of consumption or quantity of a food item consumed within the exposure period is obtained, a dose-response analysis may be conducted. If the strength of a statistical association between a food item and the foodborne illness increases with increasing consumption of the food item, this will add additional strength to the evidence. This may be particularly useful when the causative pathogen has a relatively large infectious dose and when the food is a commonly consumed food item. However, this type of analysis is often impractical due to sample size and the precision of information provided in food histories.	Strong if shown

Are PFGE results consistent with epidemiological evidence?	PFGE results are consistent with epidemiological evidence.	Strong
	PFGE results and epidemiological evidence do not agree.	Weak
Consideration of Alternate Explanations To what extent have other plausible hypotheses been ruled out? Dependent on thorough investigation of cases.	No other food item reported with greater than expected frequency based on analytic study assessing multiple plausible hypotheses identified during hypothesis-generation.	Strong
	Extensive list of foods ruled out by detailed interview of several cases in the hypothesis-generating process.	
	Limited information available regarding other exposures/foods consumed by cases.	Weak

TRACEBACK AND TRACEFORWARD

Once a food has been linked to cases of illness, in order to help inform a risk management decision, the investigator attempts to determine where the food originated from (traceback) and/or determine other places to where the food was distributed (traceforward). Traceback and traceforward can be initiated at various places, from the consumer's fridge, from the point of purchase, the distributor, the manufacturer, processor or importer and/or down to the farm level. The following situations can be used as a guide in obtaining the weight of evidence needed in order to issue a recall and/or other risk management action(s), to ensure all contaminated product is identified and the source of contamination is found.

Traceback begins with a food history. Suspect foods are identified and traceback is conducted based on distribution documents to identify company (companies) responsible for growing, packing, importing or manufacturing the suspect product. If product cannot be traced due to lack of supporting documentation, general product identification may be performed and associated with a common product name, location(s) and time of sale, that can be used for taking the appropriate product action.

Traceforward begins from any identified points of distribution. At each distribution point additional customers, products and sizes may be identified. The process of traceforward continues until all customers have been contacted and affected products identified. If, for example, ham is implicated at the manufacturing or processor level, a traceforward examines where the ham was distributed, e.g., to a sandwich manufacturer, pizza parlour, etc.

Consumer Traceback/Point of Consumption Traceback and Traceforward: Answers the question: Can the product found in a consumer's home/catering establishment be traced back to the manufacturer either directly or via the distributor?

Criteria	Nature of Evidence	Weight
Does the product identity allow direct tracing to the manufacturer?	Complete original package-allows direct tracing to manufacturer or importer	Strong
	Incomplete package with some markings (name, UPC or code, etc.) and manufacturer is known	
	Incomplete package with some markings (name, UPC or code, etc.) and manufacturer is unknown but distributor is known	
	Original package not available, verbal description provided-requires distribution traceback	
	For HRI (Hotel, Restaurant, Institution) consumption the name of the serving (i.e. menu item) for tracing in distribution may be required	
	No information available	Weak

Point of Purchase Traceback/Traceforward: Determines whether the product can be traced back from its point of purchase (e.g., grocery store) to the manufacturer either directly or via the distributor.

Criteria	Nature of Evidence	Weight
Can the point of purchase be identified? *Leads to distribution traceback*	Information on the package leads to point of purchase	Strong
	Store receipts indicate point of purchase	
	Credit card receipts indicate point of purchase	
	Membership/loyalty cards indicate point of purchase	
	Verbal description implicates a point of purchase	Weak

Distribution Traceback/Traceforward: Determines whether the information obtained at the distributor level may lead to the manufacturer and/or may indicate the point of purchase, if unknown.

Criteria	Nature of Evidence	Weight
Can the product identity lead to manufacturer?	Complete original package-allows direct tracing to manufacturer or importer	Strong
	Incomplete package with some markings (name, UPC or invoices, etc.) allows tracing to the manufacturer	
	Incomplete package with some markings (name, UPC or code, etc.) and manufacturer is unknown, but distributor is known	
	Original package not available; verbal description provided-requires distribution traceback	
	Further suppliers can be identified therefore investigator should attempt search in next distribution location	
	No information	Weak

Distribution Channel Traceback/Traceforward: Particularly useful when going down the distribution chain in an attempt to identify the product manufacturer.

Criteria	Nature of Evidence	Weight
Distribution Channel	Information on the package leads to manufacturer or importer	Strong
	Receipts/Invoices/Point of Sale/Loyalty card leads to manufacturer or importer	
	Receiving and shipping logs lead to manufacturer or importer	
	Verbal description leading to manufacturer or importer	Weak

Manufacturer Traceback/Traceforward: Once the manufacturer has been identified, it allows for the traceback of information to the wholesaler and then to the farm level.

Criteria	Nature of Evidence	Weight
Can the product be traced back to the wholesaler?	Package contains UPC code and wholesaler information	Strong
	Manufacturer logs indicate wholesaler information	
	Crate number of the product allows traceback to wholesaler	
	Verbal description of wholesale product	Weak

HEALTH RISK ASSESSMENT (HRA)

Health Risk Assessments (or situation-specific HRAs) for microbiological hazards are requested by CFIA technical assessors and/or by provinces and territories and performed by Health Canada. For issues involving microbiological hazards, a HRA is requested when a food safety standard, guideline and/or policy pertaining to a specific situation has not been established by Health Canada. When food safety standards/ guidelines policies are established, a HRA is conducted by the CFIA assessor. There are situations when an Advisory Opinion and not an HRA is required, e.g., in the disposition of products that are not in distribution and remain under the CFIA control. For issues considered High Visibility, which include foodborne disease outbreak situations, HC is always contacted and a HRA is requested. The HRA includes the following:

Background

A summary of the background information on the problem and reason for the HRA request.

Hazard Identification

Hazard Identification is sometimes described as a brainstorming session designed to develop a list of potential hazards for consideration during the hazard evaluation stage.

Hazard Evaluation

Hazard Evaluation is the process used to determine which potential hazards, identified in Hazard Identification, present a significant health risk to consumers. This evaluation should be based on information obtained from literature search, processing conditions, packaging conditions, past HRAs, etc.

Exposure Assessment

Exposure Assessment involves an estimation of the likelihood of occurrence and potential concentration of the pathogen/toxin in the food at the time of consumption. This assessment includes dose-response assessment, likelihood of occurrence, etc.

Dose-Response Assessment

The probability of infection/intoxication from exposure to a particular concentration of the organism or toxin. What is the minimum dose of microorganism ingested which will result in illness?

Hazard Exposure Characterization

This parameter is used to determine the size of the Canadian population at risk. The population at risk is considered to be the number of people who may consume a food which has the potential to be contaminated and the risk of secondary transmission.

Hazard Characterization

This step provides a qualitative or quantitative description of the severity and duration of adverse effects that may result from ingestion of a microorganism or its toxin in the food. The severity of the hazard provides a guideline (low, medium, high) or quantitative ranking of the severity of the hazard based on characterization.

Risk Characterization (Estimation)

The likelihood of occurrence of the hazard due to consumption of the product.

Health Canada has standard operating procedures (SOPs) with specific timelines to provide the HRAs. The HRA (pg. 16) template shows the information that is included in the HRA.

HEALTH RISK ASSESSMENT SITUATION SUMMARY

The following are examples of specific information which is gathered by a scientific evaluator at Health Canada while conducting a risk assessment. At times, some information may be unavailable, and it will be up to the scientific evaluation team at Health Canada to make the best decision based on the information that is available at the time of the risk assessment.

1. Common Name
2. Brand Name
3. Container size
4. UPC
5. Lot Code
6. Best before Date
7. Domestic/Imported
8. Manufacturer Name
9. Manufacturer Address
10. Importer Name
11. Importer Address
12. Country of Origin
13. Manufacture Date
14. Import Date
15. Quantity imported
16. Quantity distributed
17. How/When problem discovered
18. Epidemiological evidence provided
19. Consumer exposure
20. Originator
21. Health Risk

INFORMATION NEEDED BY HEALTH CANADA FOR THE HEALTH RISK ASSESSMENT

Issue Description and Situation Summary What prompted request?	
Area of Concern	
Date of Request/Requestor name	
Hazard Identification (microbial, chemical, allergens, etc.) • Can the product support growth (pH, temperature, a_w)? • Can more than 1 microbial pathogen contaminate the product? Which is more/most likely, etc.? • How did the contamination occur?	
Hazard Characterization • Describe the severity and duration of the adverse effects that may result from exposure to the hazard.	
Exposure Assessment • Dose-response and/or the likelihood of occurrence of the hazard in the product and hazard exposure characterization. • Can any inhibition/inactivation technologies be used to control the pathogen (e.g., heat, high pressure pasteurization, sodium diacetate)? • Are these methods effective? • Qualitative and/or quantitative evaluation of the likely intake of biological or physical agent via food.	
Risk Characterization • What is the risk of eating this food/product (see health risk categories)?	
Other Relevant Information • e.g., Best-before-date information can be relevant in terms of action taken. • Epidemiological Information. • Traceforward / Traceback Information. • Microbiological Information. • Front of package labelling to consumers on safe preparation practices.	

HEALTH RISK DEFINITIONS

The level of Health Risk is determined by taking into account the Hazard Identification, the Exposure Assessment and the Hazard Characterization.

Health Risk 1 (HR 1)

The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

Health Risk 2 (HR 2)

The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences, or that the probability of serious adverse consequences is considered remote.

Health Risk Category 3 (HR 3)

This represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence. The situation identified may be an indication of a breakdown in Good Manufacturing Practices (e.g., sanitation, quality issues, etc.); in Good Agricultural Practices (e.g., pesticide residue in food above the established maximum residue limit-MRL); in Good Practices in Veterinary Medicine (e.g., animal drug residue in food above the MRL) or some other relevant factor (e.g., food containing non-permitted nutrients or food, additives above the permitted levels, nutrients that do not meet label claim, health-related labelling infractions, etc.).

POTENTIAL RISK MANAGEMENT ACTIONS AFTER A HEALTH RISK ASSESSMENT

When the level of risk associated with the product in question is determined following a Health Risk Assessment, there are a number of risk management actions which can be undertaken. The type of action taken will depend on a wide variety of factors, including the level of the Health Risk.

Product Action:

1. Recall based on Health Risk 1, Health Risk 2 or Health Risk Category 3
2. Precautionary recall following a precautionary risk assessment
3. No recall, but continue investigation if no Health Risk assigned

Continue Investigation:

1. Traceback and traceforward
2. Further sampling and testing – intact or additional non-intact products
3. Good Manufacturing Practices (GMPs)/Hazard Analysis Critical Control Points (HACCP) evaluations
4. Issue and monitor corrective action reports

Other Potential Risk Management Activities:

1. Enhanced consumer education, i.e., fact sheets
2. Review and enhance industry procedures and requirements
3. Updating of policies and/or development of new policies, standards or guidelines

Risk Communication:

"Guidelines for Communicating with the Public and Those at Greater Risk" of the "Canada Foodborne Illness Outbreak the Response Protocol to Guide a Multi-Juristictional Response" is consulted and followed as appropriate. Additional information is available in the "Protocol for Joint CFIA/PHAC/HC Food Safety Issues Communications".

Responsibilities:

CFIA is responsible for making decisions with regards to issuing public warnings and advisories for food recalls.

Advisories can also be issued by the PHAC or other government (provincial) relevant to an outbreak, when no food is identified.

SCENARIO EXAMPLES

Case Descriptions:

These case studies are **MEANT FOR GUIDANCE ONLY.** Each case/outbreak is unique and the scenarios below *should **NOT** be used directly for action/enforcement.* The scenarios may relate to one point in time during a particular event and as events un-fold and more information is gathered, scenarios and actions may change. These scenarios can be used to better understand the decision-diagram (Figure 2). Although some potential risk management actions after a health risk assessment are outlined in the given outbreak scenario, they are not the only action(s) that can/should be taken. There are many actions that can be suitable in a given situation. The first two scenarios are examples of actual Canadian outbreaks and show a more detailed view of the investigation which occurred prior to action.

Long example 1

A province reports 20 confirmed cases of *Salmonella* Mbdanka. Seventeen of 20 confirmed cases have reported consuming or purchasing Company X head cheese. *Salmonella* itself has not been identified in the head cheese. No deviations were noted on the raw ingredient receiving records. All of the environmental swabs taken by the manufacturer were reported as testing negative for *Salmonella spp.* The plant's GMP program was reviewed by CFIA inspection staff and reported as satisfactory. It was also reported that the plant has controls in place at the crossover points between the raw and RTE sides of the facility. There are currently no results for any product testing associated with this situation. PHAC also provides the following situation assessment: 'i) Given that 17 of 20 cases report consumption of the suspect head cheese, ii) the head cheese is not commonly consumed by the general public iii) the food while purchased in different locations can be traced to a single producer, and iv) that no other common food source has been identified, PHAC considers the epidemiological evidence to be strong and supports the province's conclusions that these cases are likely associated with the suspect head cheese'; therefore the manufacturer recalled the product.

Long example 2

Three-hundred people attend a catered event in a province. Of these, 220 report being ill with symptoms consistent with *Cyclospora* infection. There were 60 laboratory-confirmed cases. Epidemiological analysis of data collected from attendees found one particular food dish to be significantly associated with risk for illness. All individuals who became ill reported eating the pesto appetizer provided by the catering company. The pesto was made on-site and it was not a commercially available product. On two separate occasions, other individuals became ill with symptoms consistent with *Cyclospora* infection after eating leftovers of this particular appetizer. Throughout the investigation, several food specimens and food ingredients were sent for testing, but the actual ingredient which contained *Cyclospora* could not be ascertained. All laboratory test results came back either negative or indeterminate for *Cyclospora.* A provincial advisory was issued.

1. Cases of illness:	Many
Number of Foods Analyzed:	2; both from same nursing home
Intact or Non-Intact Food Sample:	Both Non-Intact
Epi Evidence:	None or weak
Food/Clinical Isolate PFGE match:	No
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	No*; continue investigation; tracing sampling

* Refers to possible actions during the outbreak scenario, please refer to section G.

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2. Cases of illness:	Many
Number of Foods Analyzed:	5; all from same nursing home
Intact or Non-Intact Food Sample:	All Non-Intact, but 3/5 are different foods, same company
Epi Evidence:	None or weak
Food/Clinical Isolate PFGE match:	Yes
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	No*; product action, continue investigation
3. Cases of illness:	Many
Number of Foods Analyzed:	1
Intact or Non-Intact Food Sample:	Non-Intact
Epi Evidence:	None or weak
Food/Clinical Isolate PFGE match:	No
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	No*; but continue epi investigation
4. Cases of illness:	Many
Number of Foods Analyzed:	1
Intact or Non-Intact Food Sample:	Non-Intact
Epi Evidence:	Strong
Food/Clinical Isolate PFGE match:	Yes
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	Yes*; continue investigation; look for intact samples
5. Cases of illness:	2 or many
Number of Foods Analyzed:	1, 2, or several
Intact or Non-Intact Food Sample:	**Intact**
Epi Evidence:	None or weak
Food/Clinical Isolate PFGE match:	Yes
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	Yes*; recall product, continue investigation; use traceforward to identify additional products
6. Cases of illness:	2 or many
Number of Foods Analyzed:	1, 2, or several
Intact or Non-Intact Food Sample:	**Intact**
Epi Evidence:	None or weak
Food/Clinical Isolate PFGE match:	No
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	Yes*; recall product, continue investigation; use traceforward to identify additional products
7. Cases of illness:	2 or many
Number of Foods Analyzed:	1, 2, or several
Intact or Non-Intact Food Sample:	**Intact**
Epi Evidence:	Strong
Food/Clinical Isolate PFGE match:	No
Risk Assessment – possible? (Y/N)	Yes
Possible Action:	Yes*; recall product, continue investigation; use traceforward to identify additional products

DOCUMENT DEFINITIONS

Action: Any risk management response carried out by a government organization.

Advisory: Is a news release that is not related to a specific food recall or firm, but advises that a food may pose a risk to human health.

Aseptic Technique: Is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination and cross-contamination by pathogens.

Correction: Taking appropriate measures/action on the product to bring it into compliance without physical removal to some other location.

Corrective Action Request (CAR): Issued to an operator by CFIA inspectors whenever a verification task is assigned an unacceptable level of compliance. The CAR identifies the non-compliance and requires the operator to implement corrective measures by: (a) providing an acceptable action plan by a specified date; (b) effectively implementing the corrective and preventative measures as described in the action plan by a specified date.

Dose-Response Assessment: The probability of infection/intoxication from exposure to a particular concentration of the organism or toxin. What is the minimum dose required which will result in illness?

Evidence: That which demonstrates or shows an association between events. Evidence of an association between a consumed food and human illness may be epidemiological and/or based on the results of food safety investigations or laboratory analysis.

Epidemiological Investigation: Investigation to determine the existence of an outbreak, to characterize it as to time, space and personal characteristics, to develop and test a hypothesis explaining the specific exposure that caused disease.

Epidemiological Evidence: Data demonstrating an association between a food and human illness which may be descriptive (i.e., data describing an increase in cases in a population, place or timeframe with exposure to a plausible vehicle of infection) or analytical in nature (i.e., epidemiological study involving a comparison group demonstrating a statistically-significant association between illness and food).

Exposure Period: The time period during which infection likely occurred. A range calculated by subtracting the maximum and the minimum incubation period from the date of symptom onset.

Exposure Assessment: Exposure assessment involves an estimation of the likelihood of occurrence and potential concentration of the pathogen/toxin in the food at the time of consumption.

Foodborne Illness Investigation: An investigation of a possible association between human illnesses and a food product that includes epidemiologic, laboratory and environmental assessments.

Foodborne Illness Outbreak: An outbreak of human illness (involving two or more persons from different households) with confirming evidence (either epidemiological or laboratory) indicating a food was the common source of exposure to the contaminant causing illness.

Food Safety Investigation: Inspection and related activities undertaken by regulatory officials to verify whether or not a food hazard which could cause human illness exists, and to determine the nature and extent of the problem.

Good Manufacturing Practice (GMP): Control and management of manufacturing and quality control testing of foods.

Hazard Analysis Critical Control Point (HACCP): A food safety management system consisting of the following seven principles:

1) Assess the hazards and risks associated with growing, harvesting, raw materials, ingredients processing, manufacturing, distribution, marketing, preparation and consumption of the food in question
2) Determine the CCP(s) required to control the identified hazards
3) Establish the critical limits that must be met at each identified CCP
4) Establish procedures to monitor the CCP
5) Establish corrective actions to be taken when there is a deviation identified by monitoring a given CCP
6) Establish procedures for verification that the HACCP system is working correctly
7) Establish effective record-keeping systems that document the HACCP plan

Health Risk Assessment: Is a process which integrates a hazard identification, hazard characterization and exposure assessment determination to obtain a unique risk estimate.

Health Risk 1: Represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

Health Risk 2: The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences, or that the probability of serious adverse consequences is considered remote.

Health Risk Category 3. This represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence. The situation identified may be an indication of a breakdown in Good Manufacturing Practices (e.g., sanitation, quality issues, etc.); in Good Agricultural Practices (e.g., pesticide residue in food above the established maximum residue limit-MRL); in Good Practices in Veterinary Medicine (e.g., animal drug residue in food above the MRL) or some other relevant factor (e.g., food containing non-permitted nutrients or food, additives above the permitted levels, nutrients that do not meet label claim, health-related labelling infractions, etc.).

High Visibility: Any situation that might have, for example, political, public health, serious economic or legal implications should be considered a high visibility issue. There may be occasions when routine situations, for one reason or another, escalate and reach the status of high visibility.

Intact Sample: Food product remains protected from the external environment and therefore is protected from environmental microbial and/or other external contamination (contaminants).

Laboratory Evidence: Evidence shown by the isolation/identification of the same microorganism, toxin or contaminant from cases of human illness and the suspect food.

Non-Intact: Food sample that was taken from an unpackaged lot a previously opened or a torn package or from a package that due to design (air holes, etc.) could allow pathogens or other contaminants that may exist on the exterior to contaminate the food product.

Outbreak: An incident in which two or more persons, from different households and therefore not linked, experience similar illness after a common source of exposure.

Pulsed-Field Gel Electrophoresis: A sub-typing gel electrophoresis technique used to separate very large (megabase) DNA fragments of bacteria.

Public Warning: News release that pertains to a specific food recall. A public warning is issued for those recalls requiring the recall of a product to the consumer level.

Recall: Denotes the process of removing the affected product and encompasses all tiers of the affected product distribution system. A voluntary recall is a recall that is initiated and carried out by the recalling firm without a Ministerial Order.

Recall Classification: Means the numerical designation, i.e., Class I, Class II or Class III assigned by the office of food safety and recall (OFSR), CFIA to a particular product recall to indicate the relative degree of health risk presented by the product being recalled:

> **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death
>
> **Class II** is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote
>
> **Class III** is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequence

Risk Characterization (Estimation): The likelihood of occurrence of the hazard due to consumption of the product.

Suspect Product: The product which triggered the food safety investigation or the product which through further food safety investigation has been determined to be the most likely cause of the issue.

Traceback Investigation: A method used by investigators to determine and document with a high degree of confidence, the distribution and the origin of a particular food that has been contaminated or associated with foodborne illness.

Traceforward Investigation: A method used by the inspectors to determine and document with a high degree of confidence the distribution and the final destination of a particular food that has been contaminated or associated with foodborne illness.

APPENDIX – SAMPLE SUBMISSION FORMS

Foodborne Outbreak Investigation
Food Sample Information Required

1. General Information

Name of Inspector: _____

Department (affiliation): _____

Address: _____

E-mail address: _____

Phone Number: _____

Fax Number: _____

Date and time of collection: _____

Place of collection:

- ☐ Household
- ☐ Food establishment
- ☐ Restaurant
- ☐ Cafeteria
- ☐ Hospital
- ☐ Day care/preschool
- ☐ Long-term care facility
- ☐ Old age facility
- ☐ Conferences/meetings halls
- ☐ Other, please specify: _____

Name of facility where the sample was collected: _____

Facility address: _____

Facility contact: _____

Reason for sampling: e.g., food implicated in the outbreak of salmonellosis at the long-term care facility.

_____

Laboratory address: _____

Photograph sample (cover photo of packaging materials, seals and markings)

Members of family who ate each sampled food

_____

Comments: _____

Signature and Date: _____

2. Food Information

Name of food submitted	Main Ingredient(s)	Food/Ingredient submitted	Comments
		☐ leftover ☐ non-intact ☐ intact	
		☐ non-intact ☐ intact	
		☐ leftover ☐ intact	
		☐ leftover ☐ intact	
		☐ non-intact ☐ intact	
		☐ leftover ☐ non-intact	

Signature and Date: _____

3. Food/Ingredient Submitted Information Required

1. Common Name: _____

Is the food: ☐ Ready-to-Eat ☐ Raw ☐ Cooked at Home

Brand: _____

Lot No.: _____

UPC: _____

Best Before or Expiry Date: _____

Package type: e.g., vacuum sealed in plastic, metal can or deli-counter _____

Package size: e.g., 350 g ☐ Non-intact package ☐ Intact package

Purchased at: _____

Date of purchase: _____

Is the food (meal) submitted obtained from the same lot as the food that was consumed?

☐ Yes ☐ No ☐ Not sure, e.g., it is the same product but a different lot

Please ensure that a picture of product labelling is obtained, if possible

Photo obtained and provided: ☐ Yes ☐ No

Receipt Available _____

2. Common Name: e.g., lettuce _____

Brand: N/A

Lot No.: N/A

UPC: N/A

Best Before or Expiry Date: _____

Package type: e.g., "bunch" or loose head of lettuce, or cut lettuce in plastic container

_____

Package size: _____

Purchased at: _____

Date: _____

Was the same lot/ package that was used for the food (meal) consumed?

☐ Yes

☐ No – Explain, e.g., it is the same product, but a different lot. _____

Comments: _____

Receipt Available: _____

Signature and Date: _____

4. Handling and Preparation of Submitted Food (Meal)

Food/Meal: e.g., sandwich or BBQ chicken _____

Prepared by: _____

Place: _____

Date: _____

Time: _____

Heated: ☐ No ☐ Yes Temperature: _____°C If so for how long? _____

If not served immediately:

How long was it kept warm? _____ At what temperature? _____ For how long? _____

How long was it kept at room temperature? _____ For how long? _____

Was it refrigerated? _____ At which temperature? _____

Was it frozen? _____

Comments: _____

Signature and Date: _____

5. Hygienic Conditions

Conditions in the refrigerator:

Cleanliness: ☐ Very good ☐ Satisfactory ☐ Unsatisfactory

Temperature: _____°C

Overloading ☐ No Air circulation ☐ Proper

☐ Yes Air circulation ☐ Poor

General cleanliness in the food establishment:

Potential for contaminated equipment ☐ High ☐ Medium ☐ Low

General cleanliness of food contact surfaces ☐ High ☐ Medium ☐ Low

Potential for contaminated working surface ☐ High ☐ Medium ☐ Low

Improper storage and/or holding temperature and source (walk-in cooler, temperature, etc.)

Storage temperature: _____°C

Holding temperature: _____°C

Temperature abuse:

☐ Undercooking

☐ Holding

☐ Storage

Food Worker (hygiene, illness, etc.): _____

Comments: _____

Storage Conditions and Location: _____

Signature and Date: _____