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## **Lessons Learned Report**

### **Health Canada's Response to the 2008 Listeriosis Outbreak**

Prepared by:

Health Products and Food Branch  
Health Canada

February 10, 2009

The information in this report was obtained through a review of relevant material and a series of interviews. This report does not draw exhaustive or definitive conclusions of fact on all the activities leading up to or taken by various individuals or entities during the Listeriosis outbreak. Rather, the observations set out in this report are meant to give a general overview to HC senior management of what worked well in this particular event and what needs further refinement for the Department to be better prepared for future outbreaks.

**Canada** 



## ACRONYMS

ACRONYMS	DEFINITIONS
AAFC	AGRICULTURE AND AGRI-FOOD CANADA
AC	ADVISORY COMMITTEE
ADM	ASSISTANT DEPUTY MINISTER
ADMO	ASSISTANT DEPUTY MINISTER'S OFFICE
BMH	BUREAU OF MICROBIAL HAZARDS (FD)
CDC	CENTERS FOR DISEASE CONTROL AND PREVENTION
CFIA	CANADIAN FOOD INSPECTION AGENCY
CIOSC	CANADIAN INTEGRATED OUTBREAK SURVEILLANCE CENTRE
CNPHI	CANADIAN NETWORK FOR PUBLIC HEALTH INTELLIGENCE
DG	DIRECTOR GENERAL
DGO	DIRECTOR GENERAL'S OFFICE
DM	DEPUTY MINISTER (HC)
EOC	EMERGENCY OPERATIONS CENTRE
EHO	ENVIRONMENTAL HEALTH OFFICER
FD	FOOD DIRECTORATE (HPFB)
FIORP	FOODBORNE ILLNESS OUTBREAK RESPONSE PROTOCOL TO GUIDE A MULTI-JURISDICTIONAL RESPONSE
FMRD	FOOD MICROBIOLOGY RESEARCH DIVISION (BMH)
FNIHB	FIRST NATIONS AND INUIT HEALTH BRANCH (HC)
FSD	FOOD SAFETY DIVISION (CFIA)
GOC	GOVERNMENT OF CANADA
HACCP	HAZARD ANALYSIS CRITICAL CONTROL POINT
HC	HEALTH CANADA
HPFB	HEALTH PRODUCTS AND FOOD BRANCH (HC)
HRA	HEALTH RISK ASSESSMENT
IDEP	INFECTIOUS DISEASE AND EMERGENCY PREPAREDNESS BRANCH
IT	INFORMATION TECHNOLOGY
LRS	LISTERIOSIS REFERENCE SERVICE
MOU	MEMORANDUM/MEMORANDA OF UNDERSTANDING
MRAS	MICROBIAL RISK ASSESSMENT SECTION (BHM)
NML	NATIONAL MICROBIOLOGY LABORATORY (PHAC)
NND	NATIONAL NOTIFIABLE DISEASE
OFSR	FOOD SAFETY INVESTIGATION RECALL (CFIA)
OICC	OUTBREAK INVESTIGATION COORDINATION COMMITTEE
P/T	PROVINCIAL/TERRITORIAL
PACCB	PUBLIC AFFAIRS, CONSULTATIONS AND CONSULTATIONS BRANCH <sup>111</sup> (HC)
PD	POLICY DEVELOPMENT (MPD)
PHAC	PUBLIC HEALTH AGENCY OF CANADA
POR	PUBLIC OPINION RESEARCH
PFGE	PULSED-FIELD GEL ELECTROPHORESIS



ACRONYMS	DEFINITIONS
RAO	REQUEST FOR ADVISORY OPINION
RTE	READY-TO-EAT
SOP	STANDARD OPERATING PROCEDURE
TPH	TORONTO PUBLIC HEALTH UNIT
USA	UNITED STATES OF AMERICA
VDD	VETERINARY DRUGS DIRECTORATE
VP	VICE-PRESIDENT
WHO	WORLD HEALTH ORGANIZATION

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## 1.0 Introduction

Health Canada (HC) routinely reviews its response to food-borne outbreaks and other emergencies. The purpose of the 2008 listeriosis outbreak lessons learned exercise is to identify the strengths and strategic areas for improvement with respect to HC's response to the outbreak. Specifically, the scope of this report is focussed on lessons learned surrounding HC's key activities in food safety management.

This report is intended to provide HC senior management with a summary of the existing documents and policies related to the listeriosis outbreak; the findings of HC's response to the outbreak in the context of a multijurisdictional environment; and the strengths and possible areas for improvement identified from this lessons learned exercise. Recommendations are also listed as possible actions to better prepare for future potential food-borne illness outbreaks.

### 1.1 Background

*Listeria monocytogenes* (commonly called Listeria) is a type of bacterium often found in food and elsewhere in nature. Listeria can survive and sometimes grow on foods being stored in the refrigerator. Moreover, foods contaminated with this bacteria look, smell and taste normal. Listeria can be killed by following proper cooking procedures.

Listeria is more likely to cause death among at-risk groups than other bacteria that cause food poisoning. It can cause a rare but serious disease called listeriosis, especially among pregnant women, the elderly or individuals with a weakened immune system. In serious cases, it can lead to brain infection and even death. In fact, 20% to 30% of food-borne listeriosis infections in high-risk individuals can be fatal. <sup>[2]</sup>

Although many different foods can be contaminated with *Listeria monocytogenes*, most outbreaks and sporadic cases of listeriosis are associated with Ready-to-Eat (RTE) foods. RTE foods are a diverse group of products that can be prepared and stored in different ways and under various conditions. <sup>[3]</sup>

The 2008 listeriosis outbreak was identified following three weeks of higher than expected case reports in Ontario. On August 6, 2008, the Toronto Public Health (TPH) Unit informed the Canadian Food Inspection Agency (CFIA) of two listeriosis cases at a Toronto nursing home. Following a food safety investigation led by the CFIA, the source of the Listeria was linked to Establishment 97B (Maple Leaf Foods Canada) RTE meat products. Although identified in Ontario, eventually seven provinces were implicated in the outbreak. Of the 56 confirmed cases (75% of which were in Ontario) and 2 probable cases, a total of 20 deaths have been reported linked to the listeriosis outbreak. A chronology of events can be found in **Appendix 1**.



During this outbreak, HC's Bureau of Microbial Hazards (BMH) within the Food Directorate (FD) of the Health Products and Food Branch (HPFB) collaborated with CFIA, the Public Health Agency of Canada (PHAC) and provincial regulatory authorities in the outbreak investigation.

FD's roles in the overall food safety system include:

- Developing policies, guidelines and standards;
- Conducting laboratory research and Health Risk Assessments (HRAs);
- Jointly running the Listeriosis Reference Service (LRS) with PHAC; and
- Providing science-based information to the Canadian public related to the microbiological safety of food.

## 1.2 Objectives and Scope

As the response to the listeriosis outbreak is a multijurisdictional effort, lessons learned exercises were conducted by the three main federal food safety organizations: HC, CFIA and PHAC. Each organization has prepared individual reports based on activities within their own jurisdiction, as well as common areas where inter-organizational activities occurred.

The objectives of the HC lessons learned exercise are to:

- Identify what worked well before, during and after the outbreak;
- Summarize areas for improvement, including response, preparedness and policy development; and,
- Outline findings and recommendations for possible future actions.

The scope of this report is based upon themes related to HC's key activities in food safety management, including:

- Understanding of roles and responsibilities;
- Policy and procedures;
- Laboratory activities;
- Health Risk Assessment;
- Information technology;
- Federal communications; and,
- External communications.

Although a collaborative project, the HC lessons learned exercise is intended to focus on the response of HC's HPFB, the Public Affairs, Consultation and Communications Branch (PACCB) and, where possible, the First Nations and Inuit Health Branch (FNIHB) to the 2008 listeriosis outbreak. An examination of the role of PHAC, CFIA or provincial/territorial activities during the outbreak is outside the scope of this report.

## 1.3 Governance

An Advisory Committee (AC) made up of HC senior managers was established to:



- Oversee the development and implementation of the lessons learned exercise;
- Provide guidance and advice to the team;
- Review and approve approaches, tools and draft documents of the exercise; and,
- Review and approve the final report.

## 2.0 Methodology

A project team from HC's Office of Evaluation developed and implemented a data collection plan. Data analysis and the preparation of findings and recommendations were carried out in consultation with, and through the direction of, the project AC. Information was gathered from a literature review as well as individual and focus group interviews.

### 2.1 Document Review

The central focus of this document review was to collect and analyze foodborne illness outbreak policies, documents, reports, procedures, memoranda of understanding, advisories, articles, and Websites across HC, PHAC, and CFIA. An initial environmental scan was conducted to identify internal and external documents relevant to the outbreak. The following document screening criteria was used for the identification of sources:

- Documents selected must come from reliable sources (e.g. official federal partner Websites, internal document databases, authorized personnel, etc.).
- Documents selected should be relevant to the listeriosis outbreak [e.g. policies, Standard Operating Procedures (SOPs) and Memoranda of Understanding (MoU)].

The review and summary of information was based on the areas identified in the scope of this report found in **Section 1.2**. A list of data sources reviewed is provided in **Appendix 2**.

### 2.2 Data Collection

Data collection activities took the form of individual interviews and focus groups conducted by project teams from the three federal partners, namely HC, PHAC and CFIA. The project commenced mid-September 2008 and took approximately 16 weeks to complete.

Where there were common areas of inquiry, the interviews/focus groups were done by a joint project team between HC, PHAC and CFIA to lessen the burden on key informants. Specifically, a project team from each federal partner hosted the interview or focus group with staff from their own organization, while project teams from other federal partners attended the discussion and asked questions relevant to their respective organizations.

HC's project team conducted interviews and focus groups with HC employees involved in the listeriosis outbreak response team, including HPFB's Assistant Deputy Minister (ADM) and employees from FD and PACCB.<sup>[4]</sup> Personnel from PHAC and CFIA who worked with HC during the listeriosis outbreak were also included.



HC interview questions were developed based on issues identified during a post-mortem meeting conducted with FD and PACCB.

The interviews and focus groups provided the opportunity for individuals/organizations involved in the listeriosis outbreak to reflect on the response process, the strengths, and the possible areas for improvement and recommendations. Focus groups brought together individuals with common characteristics (such as laboratory personnel, policy makers, communications personnel, etc.) to discuss best practices and/or particular issues identified during the outbreak. Information included in this report from interviews was validated for its accuracy.

HC collaborated, shared information and consulted with CFIA and PHAC as appropriate during the lessons learned exercise. To ensure an accurate and reliable review process, joint discussion of common areas of enquiry took place with regards to inter-organizational interactions.

## 2.3 Data Analysis

Data analysis and the development of findings and recommendations were carried out in consultation with, and through the direction of, the AC. The information summarized from literature review as well as individual and focus group interviews was organized in accordance with the areas of enquiry identified in **Section 1.2**. To ensure that the lessons learned exercise was coordinated and credible, project teams committed to sharing information, participating in relevant data collection activities and providing timely feedback and validation with respect to findings.

## 3.0 Document Review

The following document review is an overview of existing foodborne illness outbreak policies, documents, reports, procedures, MoU, advisories, articles, and Websites across HC, PHAC, and CFIA. The review focuses on the roles of HC, CFIA and PHAC in food safety management, as well as HC's activities related to policy, laboratory testing and HRAs. As information sharing and/or communication activities are commonly referenced in the reviewed documents, all communications-related documents and procedures are summarized under their respective area of enquiry. A list of document sources can be found in **Appendix 2**.

### 3.1 Roles of HC, CFIA and PHAC in Food Safety Management

In Canada, food safety is an area of shared responsibility within the Government of Canada (GoC). HC is one of the federal departments responsible for helping Canadians maintain and improve their health. In food safety management, ***“HC’s role is to establish policies and set standards for the safety and nutritional quality of food sold in Canada, to assess the effectiveness of the CFIA’s activities related to food safety, and to contribute to the investigation and control of foodborne illness outbreaks”*** (FIORP 2006). One of the key ways HC contributes to the investigation of foodborne illness is by providing laboratory testing services and HRAs.

Other HC food safety roles include the regulation of various foods and the provision of related information to Canadians. Specifically, HC develops regulations for food standards and the



nutritional quality of food. HC also plays a role in developing communications on food safety information and practices.

CFIA, which reports to the Minister of Agriculture and Agri-Food Canada (AAFC), enforces the standards established by HC and carries out inspection of the food industry to ensure that it meets its food safety responsibilities. It also has a role in risk management. PHAC's main food safety role is to respond to public health emergencies and disease outbreaks of national concern, including foodborne illnesses, in collaboration with Provinces and Territories (P/Ts).

To elaborate on the roles of HC, CFIA and PHAC in food safety management, the following subsections describe the steps and responsible groups involved in the foodborne illness outbreak protocol, starting from the first point of contact, laboratory testing, HRA and outbreak investigation to information sharing and communication.

### **3.1.1 Determination and Notification of the Outbreak**

A potential foodborne illness outbreak may come to the attention of health or regulatory authorities by local, provincial and/or federal authorities through either the identification of a foodborne hazard or reports of human illness (surveillance).

Identification of a foodborne hazard can stem from various sources:

- Notification from industry of a potential food safety problem;
- Information about a food safety problem from external sources;
- Food processing deviations identified during inspection activities;
- Laboratory reports that indicate the presence of a hazardous contaminant in distributed food; and/or,
- Consumer complaints concerning a food which may include reports of illness.

Human health surveillance activities occur at the local/regional, P/T, federal and international levels. Increased or unusual cases of human illness trigger an outbreak or food safety investigations to determine the source of the outbreak and to implement control measures to reduce public health impacts and prevent further spread of the disease. An epidemiological investigation is also initiated to verify the existence of an outbreak.

Identification of human illnesses that are potentially linked to food may originate from the following sources:

- Outbreaks recognized by the local/regional officials through increased reporting of a particular pathogen or complaints of illness linked to a common event or food product;
- Routine surveillance activities at the national or P/T level indicating that a P/T or national outbreak, potentially foodborne in nature, is in progress; and/or,
- International outbreaks possibly linked to food, and with the potential to affect Canada, may be identified through PHAC's Infection Disease and Emergency Preparedness (IDEP) Branch<sup>[5]</sup> network activities with international groups [e.g. Centers for Disease Control and Prevention (CDC), media, notification from foreign bodies, etc.].

Within the GoC, the usual first point of contact for issues related to actual or potential foodborne illness outbreaks is the IDEP within PHAC. The food product of interest can then be determined



by CFIA, HC, P/T, local or international officials as being the potential source of a foodborne illness outbreak. Further follow-up is done by CFIA and PHAC.

When a food-related illness outbreak is contained within a local region or P/T, the investigation will be led by an officer from the appropriate P/T group. If a local illness outbreak is potentially linked to a foodborne pathogen, then local/regional officials determine if the food was manufactured and sold locally and then they must notify the appropriate P/T officials and CFIA. The Canadian Integrated Outbreak Surveillance Centre (CIOSC) Enteric Alerts hosted by PHAC is a communication tool used by federal and P/T officials for this purpose. CIOSC is a secure, web-based application that provides information to local, P/T health departments, PHAC and other affiliated organizations involved in public health surveillance and/or outbreak response.

In situations where foodborne illness cases occur in multiple provinces and/or territories, such as the case of the recent listeriosis outbreak, federal officials lead the outbreak and epidemiological investigation. In addition, they provide reference laboratory services, conduct food safety investigations and recall actions.

The relationships between federal partners in food safety management are outlined in the *Memorandum of Understanding between CFIA, HC, PHAC for Common Issues Related to Human Health* (April, 2008).

### **3.1.2 Outbreak Investigation Coordination**

The overarching policy guiding multijurisdictional responses to foodborne illness outbreaks is the *Foodborne Illness Outbreak Response Protocol* (FIORP), last revised in July 2006.

FIORP (2006) states that CFIA is the lead in food safety investigations related to foodborne illness outbreaks. Various groups within HC's HPFB may assist or be involved in the investigations of foodborne illnesses. Both FD and the Veterinary Drugs Directorate (VDD) within HPFB are responsible for providing HRAs to CFIA upon request. PHAC is responsible for public health surveillance and applied epidemiological studies. It also manages national outbreak surveillance and an Emergency Operations Centre (EOC). PHAC may also contribute to food safety investigations through access to their surveillance data.

An ad hoc committee called the Outbreak Investigation Coordination Committee (OICC) may be created at the discretion of any partners involved in an epidemiological or food safety investigation where evidence exists to show a food product is the cause or has the potential to be the cause of an outbreak. If an OICC is formed in a multijurisdictional context, then it is the responsibility of PHAC's IDEP to chair and organize meetings and conference calls as well as record and distribute summaries of discussions, decisions taken and next steps to the various groups involved in the OICC. The OICC is to be dismantled once the outbreak is declared resolved.

### **3.1.3 Laboratory Testing and Response**

Both epidemiological and food safety investigations usually involve laboratory testing. Each investigating organization is responsible for conducting the appropriate laboratory analyses as part of their investigation and mandate. If an OICC is in place, it should coordinate laboratory analyses in order to avoid overlap, duplication and to discuss methodology issues.

HC supports the investigating organizations by providing laboratory testing services through the BMH of HPFB's FD, along with PHAC's National Microbiology Laboratory (NML). BMH is



responsible for evaluating microbial contaminants in foods, identifying their risk to human health and developing standards and policies to minimize risks related to the consumption of these products.

BMH also maintains the LRS, in collaboration with PHAC. The LRS analyses food, environmental and clinical samples for the presence of *Listeria* species throughout the year. Its purpose is to coordinate the collection of laboratory information from human cases of listeriosis with data from studies of *Listeria monocytogenes* contamination of foods, food processing plants and animals into a single comprehensive database to facilitate risk assessment and rapid response to case clusters and outbreaks of disease. While the LRS is a coordinated effort, for the most part HC's laboratory analyzes food samples while PHAC's NML focuses on human clinical isolates (i.e., genetic finger printing). Specifically, BHM investigates the ecology of *Listeria* in foods, characterizes the growth and survival of the organism in foods, develops improved methods for detection and quantification of the organism, and collects data for risk assessments.

BMH's Food Microbiology Research Division (FMRD) studies the safety of foods with respect to infectious and toxigenic organisms, defines the conditions leading to survival, growth and toxin production of these organisms, and recommends measures of control. This Division also develops methods for detecting microorganisms, toxins, viruses and parasites and provides analytical assistance to other departments.

In some cases, the lead investigating organization may not have the necessary capacity or expertise to test for the suspect agent. It would then contact supporting laboratories so that samples may be transferred to a laboratory which has the required expertise and appropriate methodology. A contact list of supporting laboratories is maintained by the IDEP. The contact list is updated regularly, to ensure that it is accurate and current, and then distributed electronically to federal and P/T government representatives involved with the implementation of the protocol. The use of PulseNet<sup>[6]</sup> or other existing laboratory networks facilitates communication among federal and P/T laboratories.

### **3.1.4 Epidemiological Investigation, Health Risk Assessment and Risk Management**

Information gathered during the food safety and epidemiological investigations provides the basis for a risk assessment and the development of risk management strategies to control affected food products. Risk assessment focuses on assessing risks and benefits, while risk management involves identifying and analyzing options, selecting and implementing a strategy and then monitoring and evaluating the results.

BMH's Microbial Risk Assessment Section (MRAS) is responsible for conducting HRAs, which involve formally assessing the health risks posed by bacteria, viruses and parasites in specific foods. Microbiological research or expert opinion may be required to complete a risk assessment and therefore the MRAS works closely with the FMRD and national and international experts.

CFIA is responsible for leading risk management during a food safety investigation and recall, and HC provides advice on policy, procedures and protocols where appropriate. An accelerated HRA may be completed within 24 hours; the full assessment report may take up to 14 days to complete.

The process-related tasks for risk assessment and risk management are detailed in the *Health Canada Decision-making Framework for Identifying, Assessing and Managing Health Risks* (August, 2000), and related responsibilities for federal partners are outlined in the Appendices to



the HC, PHAC and CFIA Memorandum of Understanding for Common Issues Related to Human Health (April, 2008).

### **3.1.5 Information Sharing and Communications**

HC briefs the medical community, public health officials, the food industry and the public on matters related to foodborne illness where appropriate.

#### **3.1.5.1 Communication among Federal Partners**

Efficient information exchange among federal partners contributes to effective responses and management of health risks. As such, FD's *Standard Operating Procedure for Responding to the CFIA during Routine Food Safety Emergency Situations* (2005) identifies a CFIA and FD contact database that is updated regularly. The contact information includes CFIA authorized contacts, FD Stand-by Contacts (off-duty hours) and FD Emergency Response Contacts. Communication between HC and CFIA is also detailed in *the Memoranda of Understanding for Common Issues Related to Human Health* (April 2008), as well as FIORP.

#### **3.1.5.2 Communication with Industry**

As stated in FIORP (2006), during an epidemiological or food safety investigation, the implicated company or, where appropriate, industry is to be kept fully informed, to the extent possible, of developments and should be encouraged to participate in the outbreak investigation.

CFIA is the prime contact with processors and importers operating under federal jurisdiction, as well as the non-federally registered sector. CFIA endeavours to obtain current information from the food establishment, which may be related to the outbreak, in accordance with its legislative authority. Such information includes private company food test results (which have a bearing on the outbreak), employee records of illness and employee test results, accurate Hazard Analysis Critical Control Point (HACCP<sup>[7]</sup>) food processing records noting any deviations, as well as thorough, up-to-date and expeditious food distribution information, among others. The provision of information from, between or among governments is done in accordance with federal, or P/T, access to information and privacy legislation.

#### **3.1.5.3 Communication with the Public**

FIORP provides a guideline on communication with the public. Under this guideline, each organization and level of government has the responsibility for public communications activities within its jurisdiction. Due to the dynamics of an outbreak situation, however, all involved partners have a responsibility to ensure coordinated communications activities and complementary messaging.

If a situation involves more than one province or territory, or has an international dimension, the federal government is considered the public communications lead. Where the federal government has the lead, PHAC's IDEP handles communication with the public as it relates to the public health implications of the epidemiological investigation. Once a food source has been suspected, CFIA has the lead for public communication as it relates to the food safety investigation and any necessary food safety recall activities.

HC provides key support to lead departments in communicating with the public during an outbreak situation. The department is responsible for communicating about areas of HC responsibility, including HRAs and HC's regulations and policies relating to food safety. HC also plays an active role in communicating about food safety and safe food handling outside of



outbreak scenarios both through its own communications activities, and those of its partners, including the Canadian Partnership for Consumer Food Safety Education, of which HC is a founding member.

Notably, HC's FNIHB is responsible for communicating food recalls and alert notices disseminated by the CFIA to First Nations communities south of the 60° parallel, informing community members and retail outlets of potential public health risks associated with the recalled foods. FNIHB Environmental Health Officers (EHOs) routinely disseminate food recall notices and conduct follow-up activities to ensure the information is received and recalled products are removed from the market and facilities in First Nations communities.

## 3.2 Policy

FD, in collaboration with CFIA, has developed a Policy on *Listeria monocytogenes* in RTE foods (Listeria policy) (2004), which includes guidance for a wide range of products on inspection and compliance actions. The purpose of this policy is to provide guidance regarding the inspection and compliance action of RTE foods with respect to their potential to support growth of the organism. This policy is based on HACCP principles.

International experts who participated in the World Health Organization's (WHO) Informal Working Group on Food-borne Listeriosis concluded: "... the total elimination of *L. [Listeria] monocytogenes* from all food is impractical and may be impossible." As such, the current Listeria policy takes into consideration the potential for growth of *Listeria monocytogenes* in a particular food and certain criteria rather than the elimination of this pathogen.

The present Listeria policy directs inspection, sampling priorities and compliance action to high-risk RTE foods. In addition to providing guidance to food safety regulators and decision makers, this policy can also guide governments' inspection staff in their verification activities with respect to the presence of *Listeria monocytogenes* in both the plant environment and finished product. The policy's guidance on inspection, environmental sampling and end-product testing during food processing and production is detailed in the Operational and Sampling Guidelines for *Listeria monocytogenes*.

## 3.3 Laboratory Testing and Health Risk Assessments

### 3.3.1 Laboratory Testing

Laboratory testing for the isolation and identification of *Listeria monocytogenes* is outlined in the *HPFB Compendium of Analytical Methods*.

Analysis of RTE food products for *Listeria monocytogenes* should be conducted according to the Listeria policy (including the method MFHPB-30 or equivalent for Category 1 and 2 foods and either method MFLP-74 or MFHPB-30 for Category 3 foods).<sup>18</sup> It is the responsibility of CFIA to collect the samples and provide laboratory services for analysis of suspect food originating in the federal inspection system (Foodborne Illness Outbreak Response Protocol Partnership among: Provincial/Territorial Governments and Health Canada and the Canadian Food Inspection Agency, 1999). If the suspect food is produced under a P/T inspection authority, it is their responsibility to analyze the food.



Testing food and environmental samples can take on average up to 10 days for isolating the organism and an additional 4 days for molecular typing, not including the time it takes to collect the sample and ship it to HC's laboratory.

Although FD's BMH has no special laboratory facilities dedicated to emergency use only, emergency situations take precedence over non-emergency situations. In the emergency situation where laboratory services cannot be delivered wholly or in part, the Emergency Manager seeks other facilities or equipment as required (e.g. MoU between BMH and PHAC's NML regarding the LRS).

### **3.3.2 Epidemiological Investigation, Health Risk Assessment and Risk Management**

To conduct an HRA, an HC scientific evaluator is contacted, either by phone or e-mail, by the CFIA, other governmental departments (at the national or provincial level) or medical services, regarding a potentially hazardous situation related to the microbiological (or physical) safety of a food product. The situation is described to the scientific evaluator. Depending upon the situation, a determination is made by the scientific evaluator, alone or in consultation with the Division Chief and/or Section Head as appropriate, if an HRA or Request for Advisory Opinion (RAO) is deemed necessary. If deemed necessary, the scientific evaluator notifies the Division Chief and/or Section Head of the situation. The section head then assigns a lead scientific evaluator to the file. If a detailed HRA is not deemed necessary, a response to the question is drafted in writing (verbal is not acceptable), including the situation summary, sent to the requesting party and filed as a RAO/technical inquiry, etc. A number is issued for the HRA/RAO.

A formal request for an HRA plus all the data available (a template for request submission outlines the information needed to launch the assessment) must be provided to the scientific evaluator in writing, either by fax or by e-mail. The HRA is reviewed by a senior scientific evaluator, Section Head and/or the Chief of the Evaluation Division. Once final, the HRA is signed by the appropriate parties. In the case of a potential Class 1<sup>[9]</sup> recall by CFIA, and if necessary, the Chief of the Evaluation Division will notify BMH's Director. If needed, the Director will notify the FD's Director General's Office (DGO).

The HRA is sent by fax or e-mail to the requesting party at the CFIA, other governmental departments (at the national or provincial level) or medical services. The HRA is then immediately sent electronically to the Section head, the Chief of Evaluation Division, and the Evaluation Division secretary, for information and filing. Other individuals that may have been involved in the file, e.g. other scientific evaluator(s) and/or research scientist(s) are also copied.

If the CFIA indicates that, based on HC's HRA, a public announcement (alert, notification or advisory) is considered, FD's DG is notified.

## **4.0 Lessons Learned**

This section is a summary of individual interviews and focus groups with key informants from HC, PHAC and CFIA. Key informants include HC employees involved in the listeriosis outbreak response team as well as personnel from PHAC and CFIA who worked with HC during the listeriosis outbreak. The recurring issues raised during the interviews are organized into seven sections, based on themes related to HC's roles and responsibilities in the overall food



safety system: 4.1 Understanding Roles and Responsibilities; 4.2 Policy and Procedures; 4.3 Laboratory Testing; 4.4 Health Risk Assessment; 4.5 Information Technology; 4.6 Federal Communications; and 4.7; Public Communications.

## 4.1 Understanding of Roles and Responsibilities

### *What Worked Well:*

- **FD's role in food safety management was clearly understood within the organization**

### *Key Findings:*

- **Awareness of FD's roles and responsibilities was limited across federal partners**

The roles of HC's FD in food safety management were understood within the organization. However, awareness of FD's roles across federal partners (i.e. PHAC and CFIA) was limited in the area of communication leads, and in managing grey areas.

On the one hand, some of the senior personnel involved in the outbreak had previously worked on developing the roles and responsibilities documents, so this information was well understood at the senior management level. However, focus group discussions with personnel from the working level highlighted some misunderstanding around the roles of FD and its laboratory during the different stages of an outbreak investigation. For instance, interviewees from other federal departments indicated a lack of awareness of the distinctions between the roles of HC and PHAC laboratories as they relate to the LRS (i.e. food source testing vs. genetic fingerprinting), as well as the link between the LRS and CFIA and P/T laboratories. This misunderstanding from some federal partners could have stemmed from confusion around who should be sampling food commodities early in an outbreak investigation. Furthermore, interviewees felt that more clarity around the broader role of the LRS was needed between federal, P/T and regional partners to ensure a more uniform response to foodborne listeriosis outbreaks.

More generally, interviewees acknowledged some grey zones that stem from the complex nature of an emergency (i.e. a food emergency is not constrained to the response of a single partner), and therefore stressed the importance of clearly communicating the leadership roles of each federal partner in managing an outbreak situation. Specifically, there is a need to further clarify the leads during an outbreak (i.e. lead on sampling, lead on indentifying source of outbreak) and the leads for public communications.

### 4.1.1 Recommendations

- Clarify HC's leadership roles in investigation and laboratory testing with other federal and P/T partners in managing an outbreak, including the role of the LRS;
- Hold a joint meeting/briefing at time of initial outbreak identification to facilitate coordination of start-up process.

## 4.2 Policy and Procedures

### *What Worked Well:*

- **There were policies and processes in place to address the listeriosis outbreak (e.g. the Listeria Policy for RTE foods, FIORP)**



### **Key Findings:**

- **Existing policies should be reviewed on an on-going basis to reflect emerging food safety issues**

#### **4.2.1 Listeria Policy**

FD is responsible for the establishment of appropriate policies, regulations, standards and guidelines related to the safety and nutritional quality of food. As part of this role, FD maintains and updates the Listeria policy on an ongoing basis through collaboration and consultation with other organizations and experts involved in food safety.

Although this role is clear within the FD, many interviewees from this directorate indicated the need to clarify FD's role in policy development, which does not include the assessment or incorporation of other federal partners' operational procedures.

As a matter of good policy design, reviews of policy should be done on a regular basis. This was particularly stressed by interviewees in discussions about food safety policy in complex multijurisdictional environments. For instance, interviewees indicated that clarity in policy is needed around what type of information is required for decision making. It was also noted that information flow between federal and P/T partners should be addressed, possibly as part of existing MoUs between HC, PHAC and CFIA.

In addition, many interviewees noted that as part of the policy review process, the status of listeriosis as a non-notifiable disease should be re-examined [it was only a National Notifiable Disease (NND) between 1991 to 1999<sup>[10]</sup>]. Inclusion of listeriosis on the NND list is a potentially useful step towards improving the reporting and dissemination of surveillance data on listeriosis in Canada. This recommended action is already underway and listeriosis is expected to be put back on the NND list in 2009.

#### **4.2.2 Foodborne Illness Outbreak Response Protocol (FIORP) to Guide a Multi-jurisdictional Response**

Although FIORP was generally considered to be a good foundation document, some issues were raised around its implementation, its role as an information sharing and communications tool, and capacity to reflect advances in science and laboratory methodology.

##### **4.2.2.1 Implementation**

During the outbreak, interviewees felt that all parties involved in the outbreak may not have fully understood the extent and limitations of FIORP, which is implemented only at the onset of a national outbreak.

Interviewees also indicated that FIORP might not have been followed by provincial and local authorities due to lack of awareness of the guiding principles established in FIORP. Although FIORP describes guidelines and operating procedures to help coordinate potential food-borne illness outbreaks with multi-jurisdictional implications, more training among provincial and local authorities may help to raise awareness of the established standards and to improve its implementation at the ground-level. Some interviewees suggested adding specific measures about the implementation of FIORP into the protocol to improve its acceptance among all partners.



#### **4.2.2.2 Inter-organizational Communications**

Many interviewees commented on the need for timely availability of surveillance data from PHAC, better transparency and flow of information, as well as more clear requirements and rigour on information sharing.

Based on these observations, it was suggested by interviewees that the OICC, or a similar body, be invoked earlier in the outbreak determination process to assess the magnitude of the crisis and identify areas of concern (e.g. sampling according to HC protocols.) Due to limitations of FIORP in the determination process (e.g. FIORP is not formally activated until PHAC considers the magnitude of the outbreak to be of national concern), the activation of alternate communication channels would allow for earlier information flow during an emergency. In addition, it was noted that FIORP should be revised to clarify what is or is not an emergency, so that food safety issues are handled consistently across the country. In HC, it was noted by FNHIB that clear information is required to FNHIB's regional offices about the magnitude (e.g. emergency vs. routine) of the recall and follow-up requests it received from CFIA.

Suggested revisions by interviewees related to federal and P/T communications include: the need to revise and strengthen the role of the OICC so that information originating from P/T jurisdictions can flow between federal and P/T partners without impediment or delay; and formalizing the information and advice-seeking process between federal and P/T counterparts. Importantly, the issue of information flow between with FNHIB should also be addressed due to its unique role in disseminating recall information to First Nations Communities in different regions.

#### **4.2.2.3 External Communications**

FIORP does not adequately address communications to the public. Interviewees indicated that the roles and responsibilities with respect to external communications are in need of further clarification, such as specifying the lead for drafting documents (program, operations or communications areas), the lead for public communications, and so on.

As suggested by interviewees, FIORP could be improved by providing a guide for communications to the public and with the international community in emergency situations. For example, a flowchart should be developed identifying the lead and the flow of information, which clearly articulates FD's supporting role to the agencies.

#### **4.2.2.4 Technological Advancements and Laboratory Methodology**

In the past, epidemiological investigations were predominantly used when investigating a public health issue. However, there has been an evolutionary shift towards more technically advanced methods that are not reflected in FIORP.

As senior-level decision making relies on scientific evidence from laboratory testing results, interviewees suggested that FIORP be updated to reflect the more prominent role of laboratories and the technical advances made in methodology (e.g. strain testing.) Also, FIORP should emphasize the need to use and rely on more advanced tools such as PulseNet to enhance information sharing.

### **4.2.3 Recommendations**

- Clarify FD's role in policy development across federal partners;



- Continue to ensure the best science is incorporated into the Listeria Policy (e.g. evaluate and benchmark food process standards, protocols, etc., in other countries and international organizations, such Codex Alimentarius);
- Work with PHAC to re-visit the classification of listeriosis as a NND based on lessons learned from this outbreak; and
- HC (including FNIHB) to work with PHAC and CFIA to review FIORP and address issues of implementation, inter-organizational and external communications, as well as the role of laboratory science and methodology.

### 4.3 Laboratory Activities

#### *What Worked Well:*

- **Staff commitment was well recognized, and all test results were provided on time (e.g. between 10-14 days)**
- **Coordination between federal laboratories for sample testing and transfer, as well as information sharing**
- **MoU between FD and NML for surge capacity**

#### *Key Findings:*

- **Due to increasing pressures for more rapid testing, FD may experience challenges in surge capacity**
- **Tracking information and/or information for identifying patterns in origin or risk factors was sometimes missing**

#### 4.3.1 Staff Ethics and Commitment

During the listeriosis outbreak, the overall competency, professionalism, dedication and commitment of personnel at FD's laboratory and NML were generally praised: for example, upon recall, staff came back from leave in order to handle the outbreak. This was particularly important since the outbreak took place during the summer holiday season and FD's laboratory had to work long hours in order to respond to the test requests. The existing MoU between FD and NML also worked well.

#### 4.3.2 Communication and Coordination with Federal Partners' Laboratories

Coordination among the federal laboratory partners also worked well. During the period required to identify the cluster (i.e. making the linkages between source and illness that would provide the scientific results needed for the next steps), communication, sampling, testing and meetings took place without any problems and very efficiently. Daily conference calls and interpersonal communications enhanced the process. FD maintained constant communication with CFIA and responses were provided in a timely manner when more information or clarification was needed.

However, interviewees indicated a need for stronger communication linkages between HC's laboratory and CFIA's operational personnel (e.g. OFSR) for sharing laboratory tests and results. This could be enhanced by revising the communication chain established in the existing SOP for laboratory communications, including the identification of a primary point of contact for each federal laboratory.



### 4.3.3 Surge Capacity

FD consistently provided test results to CFIA within a period of 10 to 14 days, as required by the HPB Method “MFHPB-30 Isolation of *Listeria monocytogenes* from all Food and Environmental Samples” (January 2001). Moreover, FD’s MoU with the NML, a result of work done to establish the LRS, worked extremely well and allowed FD to expand its capacity to respond to demands imposed by the outbreak.

Although FD experienced no delays in providing test results, observations were made by interviewees regarding FD’s laboratory surge capacity; more specifically, the need of FD’s laboratory to rely on PHAC’s NML for Pulsed-Field Gel Electrophoresis (PFGE) testing. This points to a lack of awareness regarding the purpose of the standing MoU between FD and NML, which was developed to serve as surge capacity to each laboratory in the event of a major catastrophe. It is therefore recommended that FD communicate the existence and purpose of this MoU to all federal partners.

The MoU notwithstanding, this outbreak demanded that FD’s laboratory staff work on a 24/7-basis during the month of August 2008, a service standard that cannot be maintained over a long period of time due to the current size of the Directorate and its laboratory staff.

As a result, FD has identified the need for more training to increase the number of certified individuals to conduct the necessary tests so that demands on current staff can be managed differently in a future urgent situation. As part of this training, consideration should be given to cross-training among federal partners to further manage surge capacity. Such capacity issues may be addressed through re-allocation of existing resources.

Some interviewees suggested exploring options for building capacity through the use of external partners. For example, data collection/analysis could be done outside federal government facilities through provincial and/or regional laboratories to supplement the testing process.

### 4.3.4 Laboratory Sample Acceptance

During the initial stages of the outbreak, FD received both open and closed samples collected by the Public Health Units (e.g. TPH).<sup>[11]</sup> However, some of these samples did not have identifiable information (e.g. manufacturer, lot number, etc.) because information from open samples was missing or unavailable. In this case, interviewees noted that as much information from open samples as possible should be provided in requisition forms. More standardized sampling procedures could also ameliorate the transfer and acceptance of sample information between all partners.

Samples received without full documentation during the outbreak may have presented challenges in providing attribution and increased the time elapsed in linking the RTE products and the illness. This issue was resolved during daily teleconferences between federal laboratories, whereby the need to request missing information (e.g. identifiers for samples) was identified. In future circumstances, unique identifiers should be provided for each sample to avoid confusion and improve traceability. Some interviewees also suggested that a protocol should be established to determine how open and closed samples are prioritized for action, including communications and recalls. As this is an issue with which the international scientific community has also been grappling with, it is recommended that a scientific forum or colloquium be organized to discuss the major issues and come up with recommendations.



In addition, interviewees noted that more dialogue with P/T laboratories could help to determine when symptoms associated to *Listeria* are indicative of an outbreak, which will lead to much more sample testing. For example, it was suggested that P/T laboratories should clearly identify samples as routine or emergency, and where possible, notify PHAC if they become aware that they are working on a cluster of cases, so that federal laboratories can begin activating their emergency response protocols and surge capacity measures sooner.

#### 4.3.5 Recommendations

##### *Surge Capacity:*

- Enhance surge capacity preparedness to address more rapid turnaround demands:
  - Communicate the existence and purpose of FD-NML MoU to all partners;
  - Provide more training to increase the number of certified individuals for testing and consider cross-training to better manage surge capacity issues; and
  - Identify options for building capacity with external partners (e.g. provincial and/or regional laboratories).

##### *Sample Information:*

- Enhance transfer and acceptance of sample information to allow for increased tracking of samples and/or identifying patterns in origin or risk factors:
  - Ensure all samples are accompanied by identifiable information (e.g. Lot numbers and unique identifiers);
  - Work with P/Ts to raise awareness of standardized sampling procedures;
  - Encourage P/Ts to identify samples as routine or emergency, and where possible, notify PHAC when a cluster of cases has been identified;
  - Ensure protocols and SOPs for communication between laboratory and operational areas are revised and updated; and
- Work with CFIA and PHAC, as well as international scientific community, to determine weight of evidence (e.g. open vs. closed samples) needed for action, including communications and recalls.

### 4.4 Health Risk Assessment

##### *What Worked Well:*

- **Deadlines for HRA requests were always met**
- **FD personnel demonstrated competency, professionalism and commitment during HRA**

##### *Key Findings:*

- **Pressure for reduction in turn-around time will require surge capacity preparedness**
- **Multiple requests caused duplication and confusion during HRA information transfer**

#### 4.4.1 Staff Ethics and Commitment

FD provides HRAs to assist CFIA recall decisions. As part of this role, FD ensures that HRAs are quickly delivered to the CFIA. To this end, there is HPFB ADM involvement so that BMH at FD is supported and that HRA requests are properly handled. The competency,



professionalism, availability, even afterhours, dedication and commitment of FD's scientific evaluators was highly praised by federal partners. In turn, CFIA was generally able to communicate in real-time with FD's staff to answer questions or obtain replies to HRA requests.

During the outbreak, collaboration between the HPFB ADM, the FD DG and the BMH Director played a critical role in the delivery of prompt and accurate HRAs.

#### **4.4.2 Request Process**

During the outbreak, five HRAs were requested at various stages of the outbreak. FD's SOP on HRA development specifies that HRA requests must be submitted in writing by fax or e-mail.

However, during the outbreak, interviewees noted that this protocol was relaxed due to the complex nature of the outbreak and time sensitivity required to take action (i.e., verbal requests were provided and accepted), which may have led to erroneous expectations and miscommunication during the initial stages of the investigation. Moreover, requests from multiple CFIA individuals for guidance from FD evaluators caused duplication and confusion during HRA information transfer. Although this situation may have led to temporary misunderstanding, all necessary levels of authority took part in the request process.

As part of its role, CFIA provided all the necessary information for FD to conduct the requested HRAs, including scientific information for food science and microbiology-related testing. However, since HRAs are not required for follow-up recalls, information gathered after completion of an assessment (e.g. data regarding environmental sampling and plant sanitation) was not always available during the follow-up stages of the outbreak. As this information was needed for subsequent risk assessment purposes, the information available from the manufacturer should have been more comprehensive.

A suggested area for improvement to the request process includes reviewing and updating the existing SOP to ensure the requirements for the request process are clear and communicated to other federal partners, including a template for submission of necessary information. Finally, FD should work with CFIA to identify a single point of contact to smooth communication transfer.

#### **4.4.3 Surge Capacity**

The FD provides HRAs based on a 24-hour turnaround for verbal communication of results followed by an e-mail message re-stating the results. As specified in the SOP for HRA development, the service standard to provide the completed HRA is one week from the original request unless additional data is expected (which could extend the period up to 14 days). FD met service standards for the all HRAs requested by CFIA.

However, interviewees from HC indicated additional pressures to reduce the time required for HRA requests and communication. Specifically, CFIA has requested a shorter turn-around period (e.g. 8-hour turnaround for HRAs) based on its operational needs (e.g. inspectors operate on a stand-by basis, and need prompt information for decision-making in the field). Whether an 8-hour turnaround for HRAs is a feasible request remains to be explored based on the development of scientific technology and the current size of FD's scientific evaluation team.

#### **4.4.4 Recommendations**

- Assess surge capacity options to further reduce turnaround times;
- Identify single point of contact within each federal partner for HRA request;



- Communicate HRA SOP requirement (i.e. need for written requests according to a template) to partners.

## 4.5 Information Technology

### *What Worked Well:*

- **Information transfer processes are in place**

### *Key Findings:*

- **Federal partners experienced e-mail and file transfer difficulties**
- **Data collection systems are not standardized across all laboratories**

### 4.5.1 Data Collection

For surveillance and emergency preparedness purpose, organizations at every level (federal, provincial, territorial) use various systems for laboratory data collection. Some interviewees commented that inconsistency of the format and inclusion of laboratory information nationwide might have contributed to slowing down the information transfer and validation process. This was particularly relevant to FNIHB, which reported delays in disseminating food recall information to First Nations communities, due to extra time spent re-formatting food recall notices from the CFIA. The observations indicate a need for more robust and standardized data collection systems for tracking of food safety trends in a multijurisdictional environment. Specifically, it is suggested that FD approach federal, provincial and territorial partners to discuss options regarding standardization of data sharing through common tools, such as PHAC's Canadian Network for Public Health Intelligence (CNPHI<sup>[12]</sup>) and PulseNet.

### 4.5.2 Information Transfer

E-mail and file transfer difficulties were evident during the outbreak; for example, interviewees noted that HC's limit on the size of allowable e-mail attachments made it difficult to exchange information with CFIA. In response, CFIA opted for providing only summarized information, highlighting important parts, instead of sending faxes with numerous pages. To solve this issue, HC's e-mail capacity should be increased for key operational personnel at FD, and officials need to indicate this early with IT personnel.

### 4.5.3 Recommendations

- Increase HC's e-mail capacity for key operational personnel;
- Notify IT personnel early of any technical issues; and
- Consider how common tools (e.g. CNPHI, PulseNet) can be used across organizations to facilitate data analysis.

## 4.6 Federal Communications

### *What Worked Well:*

- **Internal communications within HC's FD, and HC at large, including the Issue Management System**
- **Communications between federal partners was continuous during the outbreak**



### **Key Findings:**

- **Collaboration with FNIHB could be enhanced**
- **Continuous communications between all federal partners could be enhanced during routine and everyday business.**
- **FD could benefit from formal participation in the EOC, once activated by PHAC**

#### **4.6.1 Internal Communications**

Internal communications within FD went well. At HPFB, and HC at large, there is an Issue Management System in place through which each Directorate assigns resources to deal with issues as part of regular coordination. During the outbreak, senior managers were informed of the issue. The Issue Management System proved beneficial in facilitating technical expertise to deal with the situation at hand and receiving support from senior management.

#### **4.6.2 Inter-organizational Communications**

Cooperation and communication among the three federal partners was generally well done. Interviewees found that knowing contacts in each other's organizations facilitated coordination, information sharing and communications among federal personnel. This is especially true when senior level individuals have previous experience and/or long-term working relationships with other federal partners.

Although communication among the three federal partners was continuous during the outbreak, interviewees suggested that inter-organizational communication could be strengthened in more routine and everyday business by establishing stronger communication lines and protocols among policy, program and operational areas, both at the senior management and working level. Measures to improve communication between senior management of the three federal partners are already underway through the inclusion of PHAC in monthly meetings between the HPFB ADM and CFIA Vice-Presidents (VPs).

Federal partner contact knowledge at senior management level should also be transferred to FD's electronic and physical corporate memory so it becomes available to the organization as a whole and to safeguard contact knowledge against staff turnover. FD should establish "single windows" of communication with all partners as well as physical communication channels (e.g. specific telephone lines for outbreak notification and enquiry purposes). This requires engagement with provincial and territorial bodies to establish lines of communications that can promote information transfer.

Communication with HC's FNIHB headquarters was identified as an area for improvement. During the outbreak, FNIHB's Environmental Public Health Division first received notification from CFIA to conduct follow-up activities through a Regional Environmental Health Manager. Although working with one region for both information and follow-up requests is effective for outbreaks at the local level, this was not effective for an outbreak of national scale. As such, a better link with FNIHB is required to avoid any unnecessary delays in relaying information to First Nations communities. More generally, HC should work to raise awareness of the roles of FNIHB in food safety management.

#### **4.6.3 Recommendations**

- Work with federal partners to ensure consistent communication between federal partners in both routine and high profile situations;



- Establish a three-way protocol to clarify and streamline CFIA, HC and PHAC food safety communications;
- Improve the effectiveness of federal communications by establishing:
  - a single channel for communications (e.g. individual or group within each federal partner);
  - better coordination of briefing personnel among federal partners;
  - transferring federal partner contact knowledge at senior management level to FD's electronic and physical memory; and
- Discuss and better integrate the role of FNIHB into multijurisdictional food safety protocols (e.g. FIORP), particularly with respect to inter-organizational communications.

## 4.7 Public Communications

### *What Worked Well:*

- **Contribution to the development of communications and informational tools about health and food safety (e.g. It's Your Health – Listeria and Food Safety Advisory)**

### *Key Findings:*

- **HC's roles, as well as those of other federal partners, were not clearly communicated to and/or understood by stakeholders and the public.**
- **Food safety communications could have been more targeted and proactive.**

### 4.7.1 Public Advisories

FD contributes to the development of information tools on health and food safety, such as the advisory "It's Your Health – Listeria and Food Safety", which was originally published in 2005 to provide recommendations for high risk groups. However, interviewees indicated that the advisory's effectiveness, penetration, uptake and impact on the outbreak were difficult to assess because the advisory has not been evaluated before.

HC could better evaluate the advisory's effectiveness by using annual Public Opinion Research (POR) strategies already in place. This would provide a sound basis to determine if publication of information on a Website is sufficient and if other media venues (e.g. e-mail, listserv, conferences, etc.) should be explored in order to reinforce advisories. These efforts should be coordinated with PHAC and should focus on addressing vulnerable populations.

### 4.7.2 Understanding of Federal Roles and Responsibilities by Stakeholders

Several interviewees felt that HC was perceived to be the lead in public communications due to an assumption that HC is the national expert on health-related issues. This assumption led to confusion on who should be the lead spokesperson to stakeholders and the public.

In addition, the lack of understanding by stakeholders of HC's role in food safety management was compounded by a lack of information regarding the roles and responsibilities of each federal partner. There was also some misunderstanding around the fact that federal partners report to two different Ministers, HC and AAFC, which provide separate communications.



To address any misperception of HC's role in food safety management, it is important to clarify and communicate the multifaceted involvement of federal and P/T partners in managing an outbreak. This is particularly important in the early stages of emergency communications.

FD and HC communications personnel should also coordinate with their counterparts at the federal level to identify the communications lead for various information types. These efforts should include a discussion on the type information to be disseminated during an outbreak or any other event that commands high media and public scrutiny.

#### **4.7.3 Risk Management and Risk Communications**

As noted in interviews and focus groups, there have been several questions regarding risk communications as they relate to risk management, especially when an outbreak leads to deaths. To address these questions, Canadians should be provided with facts and scientific information as part of an overall narrative crafted by communications personnel. This narrative should address and build on two main areas: the need for scientific certainty before making decisions and the need to maintain stakeholders abreast of information related to food safety.

An issue to address in public communications could be the way in which scientific information is understood by the media and the public, for instance, the media has difficulty understanding the level of scientific certainty necessary before a recall is issued and the incubation period related to the pathogen (for *Listeria* it is 3 to 70 days, with the median incubation estimated at 3 weeks). There is also the issue that the public sees risk differently from a technical expert: what scientists feel is important may not be as relevant from a media and public perspective.

A general sentiment from interviews and focus groups was that there is heightened public awareness of food safety issues as a result of recent outbreaks worldwide, and this development is making public communications related to risk management and mitigation very challenging. Therefore, risk mitigation strategies should be matched with public and professional expectations so that a balanced approach can be used and stakeholders can feel informed and satisfied with the role of the federal government. These strategies should identify, according to the type of emergency, the target groups (e.g. vulnerable populations and groups involved with these populations, such as medical practitioners, nursing homes, risk counselling groups, etc.), the information to be provided to each target group (e.g. clinical guidelines for healthcare professionals) and the lead among federal partners for each type of outreach.

To achieve these goals, it was suggested that FD approach federal partners to discuss risk management and risk analysis related to high-profile issues (i.e. how much information should be available and evaluated ahead of the decision to inform the public so that recommendations are valid and scientifically-based? when should a public advisory go out?). Information should be provided to the public in a timely fashion as an urgent situation evolves and updated information should be used to ease heightened public concerns about food safety. This discussion could take place around the development of scenarios based on lessons learned exercises and should lead to concrete guidelines for risk communications.

#### **4.7.4 Role of Communications Personnel**

Communications personnel from HC believed that their participation should be sought earlier in the process as they need time to become familiar with the issue at hand so that they can be prepared to respond to potential communications challenges.



As part of this effort, communications personnel should be provided with accurate information to deliver to the public. Also, a timetable should be established on when to obtain information from other sources (e.g. case numbers from P/Ts in different time zones) and when to release them to the public. Clear guidelines should be provided and a lead among the federal partners should be identified to address these issues.

Finally, there is a need to train communications support personnel and provide guidance, especially due to the high turnover in this area, so that personnel become familiar with the subject area being addressed during an outbreak.

#### **4.7.5 Nationwide Coordination of Communication of Outbreak Information**

Coordination among all federal partners' communications personnel was well done and the involvement of HC in the regional crisis response teams was valuable. However, there was some misunderstanding among regional offices as to the lead organization providing them information and when to expect information updates. HC communications personnel should approach federal partners and regional offices to develop guidelines and protocols with clear federal leads.

Coordination across different time zones was a challenge, in particular when providing case updates. Routine calls with P/T partners at 13:00 followed by evening updates by PHAC did not achieve the expected level of coordination; for example, information provided to the public stemming from this process would sometimes contradict information provided by the provinces working on their own time zone. This situation was exacerbated by the tacit agreement that information needed to be released to the public as soon as it became available (e.g. discovery of new cases) and by the difficulty experienced in obtaining information held at different levels (federal, provincial, territorial). HC communications personnel should work with federal, provincial and territorial partners to develop a protocol that determines standard times for communication to the public.

Finally, in order to enhance nationwide coordination, communications personnel identified the need for a facility where they could hold face-to-face meetings. An EOC is considered limited in this respect as information may not be shared among partners due to network firewalls. Moreover, face-to-face meetings are preferred due to the nature of communications work. It was recommended that a working group should be established to discuss these issues and work on coordination. This would allow for the development of guidelines that should be applied in this type of crisis. Agencies as well as Ministers involved in this outbreak should be part of the working group.

#### **4.7.6 Technical Briefings, Conferences and Communication Packages**

Technical briefings are part of the communications outreach strategy; however, interviewees observed that more efficiency is needed to reduce the number of versions of a document and streamline the overall process for briefing preparation. Protocols and operational guidelines should be developed to streamline the approval process for communications to the public in order to avoid the excessive work (and multiple versions) experienced during this outbreak.

It was also emphasized that clear roles should be established for each federal partner delineating their contribution to the communication tool as many times communications personnel need to work outside their jurisdiction in a crisis situation. Interviewees indicated that coordination among federal partners should also be sought so that scientific personnel committed to technical



briefings can operate on a rotation-by-federal-partner; this will ensure that demands on lead personnel can be shared across all the organizations.

In addition, packages should be developed to have “at the ready” with information that is simple and accurate. These packages could then be provided to the media and the public during an outbreak to smooth the flow of information and so that the media and public are not left wanting or waiting. These packages should be reinforced with the message provided during technical briefings and conferences, while spokespersons and ministers should be made aware of the critical role they play in delivering the right information to the media and the public.

#### **4.7.7 Recommendations**

- Work with federal communications counterparts for mutual understanding of leadership responsibilities for communications to P/Ts, stakeholders and the public;
- Improve coordination of external communications:
  - Involve HC communications personnel early on in the process;
  - Review and update existing policies relating to crisis communications and conduct exercises around food safety scenarios to support staff taking on their specific roles in communicating with Canadians during a crisis;
  - Improve and streamline technical briefing process by developing a joint protocol for communications products (e.g. consumer advisories, Web-post of information pages) that require input and approval from multiple departments; and
  - Establish a protocol that determines standard times for communication to the public.
- Emphasize the communication of information on roles and responsibilities of federal partners to stakeholders and the public;
- Work with PHAC to enhance the communication of food safety practices to vulnerable populations:
  - Use POR to evaluate the effectiveness of HC’s public advisories and online information;
  - Explore options (e.g. e-mail, listserv, conferences, etc.) to enhance the communication of advisories to vulnerable populations, including work with relevant stakeholders (e.g. P/T, Non-Governmental Organizations).



# APPENDICES

## Appendix 1.

### Chronology of Federal Actions taken for the Listeriosis Outbreak

#### Thursday, July 10

The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) in Winnipeg, as part of routine practice, receives several human isolates of *Listeria monocytogenes* (*L. mono*) from the Ontario Ministry of Health and Long-Term Care (MOHLTC) for genetic fingerprinting.<sup>[13]</sup>

#### Friday, July 18

PHAC's NML in Winnipeg finds that two isolates from Ontario's MOHLTC have matching genetic fingerprints. Results are reported to Ontario's MOHLTC by NML. The genetic fingerprints are placed on PulseNet, a shared national database for laboratories. The database allows the bacteria's genetic fingerprints to be compared and shared rapidly across Canada.

The NML continues to receive routine isolates of *L. mono* from provincial public health laboratories throughout July.

#### Thursday, July 24

Health Canada's Bureau of Microbial Hazards (HCBMH) in Ottawa, receives eleven routine food samples from Toronto Public Health (TPH).

#### Tuesday, July 29

The Ontario MOHLTC notifies PHAC's Centre for Foodborne, Environmental and Zoonosis Infectious Disease (CFEZID) of an increased number of listeriosis cases. Ontario issues an alert to public health units across Canada via the Canadian Network for Public Health Intelligence (CNPHI).<sup>[14]</sup> PHAC's NML provides analysis of the genetic fingerprints of 20 cases of listeriosis from the previous three months across Canada, and posts the information through PulseNet. At this point, no other information is known and the local public health unit investigations continue throughout Ontario.

#### Wednesday, July 30

PHAC's CFEZID, the Ontario MOHLTC and Ontario public health units participate in a teleconference on technical issues. At this time, there is no clustering of listeriosis cases containing the same genetic fingerprint.

Ontario's local public health units are, nevertheless, asked to send isolates from human *L. mono* cases to NML via their provincial laboratories for further genetic fingerprint testing. Ontario remains the lead, with support from federal departments and agencies.

From July 30 to August 5, PHAC's NML continues testing additional human isolates, which are routinely sent, of *L. mono* received from the provincial laboratories during this time period. HCBMH is also receiving and analyzing food samples and isolates during this time.

#### Tuesday, August 5

PHAC's CFEZID contacts the Ontario MOHLTC regarding the samples and is informed that listeriosis cases continue to be reported and no suspect food source is yet identified.

HCBMH notifies TPH that three of the eleven food samples received July 24 were positive for *L. mono*.



This was done within the standard timelines (7-10 days) for the isolation of *listeria* from foods.

### **Wednesday, August 6**

TPH informs the Canadian Food Inspection Agency's (CFIA) Toronto Regional Office of two listeriosis illnesses reported at a Toronto Leisureworld nursing home. TPH also informs the CFIA of three positive *L. mono* results reported on August 5, indicating the presence of *L. mono* in lunch meats served at the Leisureworld facility. The positive samples were of unidentified deli meat from sandwiches served at the nursing home earlier in July and collected by TPH during the week of July 21st.

### **Thursday, August 7**

Following notification from the CFIA's Toronto Regional Office, the CFIA's Office of Food Safety and Recall (OFSR) initiates a food safety investigation to determine if a food safety-related hazard exists. The CFIA's OFSR requests information from TPH and from HCBMH regarding sample collection practices and testing methodology for the positive samples collected by TPH.

HCBMH informs the CFIA that the samples received from TPH were from previously-opened products retained and handled by nursing home staff as part of the facility's own internal practices. Because the samples were not collected in a scientifically-controlled environment, they could not be considered aseptic – the possibility of cross-contamination from other food, surfaces, instruments, etc. at the time of sample collection could not be ruled out. *L.mono*-positive samples of unopened product would be required for a health risk assessment and product action.

In working to locate unopened samples, the CFIA receives confirmation from TPH that Maple Leaf meats were used in the sandwiches that tested positive for *L. mono* made at the Toronto Leisureworld facility. The CFIA collects and reviews records from the Toronto Leisureworld's supplier, Sysco Canada, to identify the specific Maple Leaf products served at the facility.

### **Friday, August 8**

The CFIA's Toronto Regional Office determines that the meat from the sampled sandwiches originated at Maple Leaf Est. 97B (Toronto) based on records obtained from the supplier Sysco, Canada. The CFIA meat hygiene program inspector responsible for daily inspections at Establishment 97B requests information from Maple Leaf plant officials to further confirm the identity of the specific positive product. CFIA field staff begin the search for deli meats with the same product code and production date as the samples that tested positive for *L. mono*. The purpose of this sampling was to establish a positive link between Maple Leaf product and the *L. mono* strain found in the Toronto Leisureworld product and to rule out the possibility of cross-contamination at the nursing home.

The CFIA's Toronto Regional Office contacts Maple Leaf to obtain product distribution records in order to identify additional search locations for product, however, the CFIA is unsuccessful as the Maple Leaf's sales office had closed for the weekend. The CFIA requests that Maple Leaf continue tracing product purchase orders with the instruction to contact the CFIA's Ontario Area Recall Coordinator (ARC) if the product is found. The CFIA's Greater Toronto Area Laboratory was on standby for product testing over the weekend; however, the ARC was not contacted by Maple Leaf.

### **Monday, August 11**

The CFIA receives the product distribution records from Maple Leaf requested August 8. The three largest product distributors are contacted immediately, however, none of the distributors have samples of the Maple Leaf product codes under investigation in their possession. CFIA's Ontario ARC team broadens the search by contacting other facilities in the Leisureworld chain to determine if they have the product under investigation on hand.

### **Tuesday, August 12**



CFIA Ontario ARC staff locates an unopened package of Maple Leaf product, with a best before date that would place it as a possible product of interest at a Mississauga Leisureworld facility. A sample of this product is collected by CFIA's Toronto Regional Office staff for testing to determine if the product contained *L. mono* and could be linked to the production at Maple Leaf's Est. 97B, thus ruling out the possibility of cross-contamination at the Mississauga Leisureworld facility.

The CFIA is notified by the Halton Region Health Department of two additional listeriosis illnesses in hospitalized patients at Joseph Brant Memorial Hospital in Burlington and of test results on two samples of Maple Leaf deli meats served at the hospital that tested positive for *L. mono*. However, it is reported by the Halton Region Health Department that the two patients had not consumed deli meats in the hospital and samples collected by Halton Region Health Department did not contain critical information linking to the product codes under investigation. Since there is no scientific link established between the cases at the Toronto Leisureworld and Joseph Brant Memorial Hospital, the CFIA initiates a separate food safety investigation.

### **Wednesday, August 13**

CFIA food specialists continue to review production and distribution records at Est. 97B to identify the specific kind of product (e.g., product codes, best before dates, etc.) that tested positive for *L. mono* from the Toronto Leisureworld facility and Joseph Brant Memorial Hospital. Based on common distribution information and product codes, the CFIA team identifies a possible link between the five *L. mono*-positive samples of deli meats (three from the Toronto Leisureworld and two from Joseph Brant Memorial Hospital): the products may all have originated from production lines 8 and 9 in Maple Leaf's Est. 97B.

CFIA's OFSR initiates a teleconference with PHAC, Health Canada, the MOHLTC and Ontario public health units to review laboratory and epidemiological information collected to date. Call participants are notified by MOHLTC that additional listeriosis cases had been reported by public health units in Simcoe, Peterborough and Etobicoke. Investigations by those public health units identified Maple Leaf brand products as a possible source of the illnesses.

PHAC's CFEZID and CFIA are informed by the Health Canada lab that five food samples from open packages collected by public health officials (re-testing the three Toronto Leisureworld samples received July 24 and testing the additional two from the hospital received August 1) are the same strain as found in human isolates identified by PulseNet Canada. The isolates from the human cases reported from Joseph Brant Memorial Hospital also matched this strain.

The information presented in this teleconference (i.e. the fact that these were tests on open samples and lack of evidence of patients' exposure to contaminated product) was insufficient to prove that the product was contaminated at the source of production. A definitive scientific link between a specific Maple Leaf product and the listeriosis illnesses could not be made based on scientific evidence at that time.

Epidemiological information provided to PHAC at this time by the various parties involved in the investigation did not clearly identify a linkage between reported illnesses and Maple Leaf products. It was the consensus of all teleconference participants that further hazard and exposure information was required before HC or CFIA could initiate a risk assessment leading to a recall. No public notification or recall was deemed appropriate by any of the attending groups.

PHAC's NML notifies laboratories across Canada via PulseNet that genetic fingerprinting shows a clustering of cases with a similar strain in more than one province. PHAC's CFEZID is informed by PHAC's NML that BC and Alberta had *L. mono* isolates that match the outbreak strain in Ontario. In response to this information, PHAC CFEZID contacted BC and Alberta to ask for epidemiological information on these matching cases. The case reported by Alberta was determined to be a Saskatchewan



resident.

A large-scale sampling plan to cover all *Sure Slice* brand products (with best before dates of August 1 to September 30) produced on the two suspect Maple Leaf production lines is developed. This plan is forwarded to Toronto Regional Office (ARC) for distribution to CFIA, MOHLTC and public health units. The sampling is conducted by the CFIA with assistance from public health units across Ontario over the following two days.

#### **Thursday, August 14**

CFIA regional staff and Ontario public health units collect samples of Maple Leaf *Sure Slice* products from locations across Ontario over the next two days and submit them to the CFIA's Greater Toronto Area laboratory for testing.

Conference calls led by the CFIA continue with PHAC, Health Canada, MOHLTC and public health units to share information. Progress on the execution of the sampling plan to collect samples of *Sure Slice* products to submit to the CFIA's Greater Toronto Area Laboratory is discussed by the CFIA. No public notification or recall was deemed appropriate by any of the attending groups.

PHAC CEFIZD follows up with Saskatchewan regarding their case. A public health alert is drafted and a questionnaire put together to facilitate the standardization of inter-provincial data collection.

#### **Friday, August 15**

PHAC takes the lead coordinating role in the epidemiological investigation for the Listeriosis outbreak, as per the *Foodborne Illness Outbreak Response Protocol*, since it had become apparent that the illnesses are distributed nationally. This involves the standardization of data collection, centralization of data to enable national reporting and analysis to identify linkages between cases in different provinces. PHAC sends a Public Health Alert to request that all public health units use a standardized questionnaire to obtain information on cases infected with the outbreak strain of *L. mono*.

CFIA and Ontario public health units continue to collect samples of *Sure Slice* products and submit them to the CFIA's Greater Toronto Area Laboratory for *L. mono* testing.

Conference calls led by the CFIA continue with PHAC, Health Canada, MOHLTC and public health units to share information. No public notification or recall was deemed appropriate by any of the attending groups.

#### **Saturday, August 16**

At 5pm, the CFIA's Greater Toronto Area Laboratory confirms a positive result for *L. mono* in a sample from an unopened package of Maple Leaf *Sure Slice* Roast Beef collected August 12 at the Mississauga Leisureworld facility and produced in Establishment 97B. The CFIA's technical risk assessors immediately undertake an assessment of the information to determine the risk posed by the product. The assessment determines that *Sure Slice* Roast Beef and Corned Beef (the latter having been produced on the same production line at 97B immediately following the Roast Beef) meet the criteria set by Health Canada for a 'Health Risk I' concern (i.e., there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse consequences or death).

The CFIA prepares a health hazard alert to the public and provides information to Maple Leaf to initiate a voluntary recall of two specific product codes of *Sure Slice* Roast Beef and Corned Beef products.

#### **Sunday, August 17**

At 2am, a health hazard alert is issued by CFIA advising the public not to consume or serve specific Maple



Leaf *Sure Slice* Roast Beef and Corned Beef products.

Maple Leaf Foods issues a press release to announce the voluntary recall of specific Roast and Corned Beef products sold under the *Sure Slice* name.

### **Monday, August 18**

Epidemiological data from the British Columbia case identifies a potential link to the cases in Ontario.

Conference calls led by the CFIA continue with PHAC, Health Canada, MOHLTC and public health units to share information on the recall of Maple Leaf product. PHAC chairs the epidemiological data portion of the call.

### **Tuesday, August 19**

Conference calls initiated by the CFIA continue with PHAC, Health Canada, MOHLTC and public health units to share information. PHAC chairs the epidemiological investigation portion of the call.

At 11am, the CFIA's Greater Toronto Area Laboratory reports two more positive results on samples of Maple Leaf products produced on line 9 at Est. 97B. These samples were among the samples collected August 14-15 by CFIA and various Ontario public health units. The positive results were of Maple Leaf product (*Sure Slice*) not included in the August 17 recall (different best before dates than the products recalled on August 17). A health risk assessment for all Maple Leaf *Sure Slice* meats produced on lines 8 and 9 in Est. 97B is immediately requested from Health Canada (with support from PHAC) by the CFIA technical risk assessors. The assessment is completed later that day. The assessment determines that *Sure Slice* products produced in Establishment 97b meet the criteria set by Health Canada for a precautionary 'Health Risk I' concern.

At 6pm, Maple Leaf agrees to voluntarily recall all products produced on the affected lines at the plant. CFIA and Maple Leaf work together to identify all 23 products and codes (*Sure Slice* brand and other products) that were manufactured on the two production lines.

The health risk assessment is done by Health Canada, with support from PHAC that evening. The assessment determines that *Sure Slice* products produced in Establishment 97B meet the criteria set by Health Canada for a precautionary 'Health Risk I' concern.

The CFIA's OFSR provides the risk assessment information to Maple Leaf.

The CFIA's OFSR issues a health hazard alert advising the public not to serve or consume any of the 23 products produced on lines 8 and 9 at Est. 97B. While the health hazard alert indicates that these positive samples were collected as part of an ongoing investigation, it was noted that no link between the recalled products and reported illnesses had been established by PHAC's NML and that the investigation into the source of the listeriosis cases was ongoing. A PHAC contact to whom enquiries about the epidemiological investigation should be directed was listed in the press release.

### **Wednesday, August 20**

Maple Leaf issues a press release to announce the recall notice/advisory for the 23 products. The CFIA meat inspection program requires that Maple Leaf implement a hold and test protocol whereby no meat product produced at Est. 97B is made available to the consumer before test results are negative for *L. mono*. Maple Leaf suspends all production at Est. 97B.

With the assistance of the Ontario public health units, CFIA officials begin recall effectiveness checks to verify the recalled products' removal from the marketplace. Hospitals, nursing homes and independent grocery stores are subjected to an enhanced verification process (100% verification coverage), while chain



stores are subject to recall effectiveness checks at a normal rate of verification.<sup>[15]</sup>

The CFIA begins receiving media inquiries regarding the recalls. Between August 20 and August 30, the CFIA's OFSR responds to over 200 such requests from television networks, radio stations and local and national newspapers.

PHAC issues a statement from the Chief Public Health Officer informing Canadians about the public health investigation.

HCBMH receives three isolates for genetic fingerprinting from the CFIA regional office in Greater Toronto area.

Conference calls initiated by the CFIA continue with PHAC, Health Canada, MOHLTC and public health units to share information. PHAC chairs the epidemiological investigation portion of the call.

#### **Thursday, August 21**

PHAC requests all provinces and territories to review all cases of listeriosis from August 1, 2008.

The CFIA issues a notice to news outlets to ensure media are reporting the recalled product codes correctly, following reports that the media were omitting salient details of the affected products.

CFIA and Health Canada laboratories continue to test recalled products and results show a large number of samples that are positive. Level and contaminations and genetic fingerprinting were not available at this point.

Maple Leaf continues its efforts at Est. 97B to determine the cause of the contamination.

The CFIA designs a sampling plan, in consultation with Health Canada, for products produced on other lines at Est. 97B.

#### **Friday, August 22**

PHAC activates its Emergency Operations Centre to Level 2 (Increased Vigilance).

PHAC, Health Canada and CFIA hold a joint press conference in Ottawa to alert the public about the food safety investigation and to answer questions from the media.

Health Canada conducts a health risk assessment on products (beyond the *Sure Slice* products assessed on August 19) produced on lines 8 and 9, which were recalled by Maple Leaf on August 20. The assessment determines these products meet the criteria set by Health Canada for a 'Health Risk II' concern (i.e., the use of, or exposure to, violative product may cause adverse health consequences or the probability of serious adverse health consequence is remote).

CFIA and Royal Touch Foods issue a health hazard alert warning the public not to serve or consume Shopsy's deli-fresh Classic Reuben sandwich because the product contained Maple Leaf Corned Beef that may be contaminated with *L. mono*.

Daily conference calls led by the CFIA continue with PHAC, Health Canada, MOHLTC and Ontario public health units to share information. PHAC chairs the epidemiological investigation portion of the call.

#### **Saturday, August 23**

Based on additional information received from Est. 97B, Health Canada upgrades the health risk assessment issued on August 22 (regarding products produced on lines 8 and 9 beyond the *Sure Slice*



products assessed on August 19) from a 'Health Risk II' to a 'Health Risk I' concern.

The Minister of Agriculture and Agri-Food holds a press conference in Ottawa announcing that genetic testing, completed by the Health Canada food laboratory, of recalled Maple Leaf products show that two out of three samples test positive for the same outbreak strain of *L. mono*. The third sample is a close match to the outbreak strain, but with a slight variance. Results are shared with PHAC's NML to compare genetic fingerprints from the human samples being tested.

Maple Leaf holds a press conference to respond to the determination by PHAC that the outbreak is linked to Est. 97B. The company announces that it has decided to voluntarily expand its recall to include all products produced in that facility, while emphasizing that there is no evidence of contamination beyond production lines 8 and 9.

PHAC's NML receives 15 isolates of *L. mono* (received in two shipments) obtained from unopened meat samples from the CFIA laboratory for genetic fingerprinting. These were sent to PHAC's NML instead of HCBMH due to capacity issues and as per the Memorandum of Understanding between PHAC's NML and HCBMH.

The CFIA requests a health risk assessment from Health Canada on the entire production of Maple Leaf Est. 97B. The CFIA notifies Maple Leaf that this assessment is being initiated as part of ongoing communication between the two parties that day.

#### **Sunday, August 24**

Health Canada responds to the request for a health risk assessment, indicating that all products produced in Establishment 97B meet the criteria for a 'Health Risk I' concern.

The CFIA issues an expanded health hazard alert warning the public not to serve or consume any meat products produced at Est. 97B because these products may be contaminated with *L. mono*.

Maple Leaf issues a second press release regarding the voluntary recall for all Est. 97B products and lists the affected products on its corporate website.

The Minister of Health holds a news conference in which technical spokespeople from the CFIA, PHAC and Health Canada respond to questions regarding the outbreak and recall.

CFIA identifies that some Est. 97B product had been shipped to another Maple Leaf facility in Laval, Québec, through an inter-facility transfer of work-in-progress process. The CFIA OFSR initiates a secondary food safety investigation at that facility, Est. 271B.

#### **Monday, August 25**

The CFIA and Lucerne Foods issue a health hazard alert warning the public not to serve or consume certain *Safeway* brand and *Take Away Café* brand sandwiches because these products contained one of the previously-recalled Maple Leaf products that may be contaminated with *L. mono*. This alert is one of more than 20 secondary recalls of products associated with the recalls of Est. 97B products issued by the CFIA August 25 – September 5 (Appendix One).

The CFIA continues to conduct recall effectiveness checks to determine that all recalled product was successfully removed from the marketplace. Approximately 29,000 checks were conducted from August 20 to September 14.

MOHLTC changes its reporting methodology to include all deaths among the listeriosis cases linked to the outbreak from those that had listeriosis as the underlying cause of death. Twelve deaths (eleven in Ontario



and one in BC) from the *L. mono* outbreak are now being publicly reported by PHAC.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

PHAC assumes responsibility for hosting a teleconference for all provincial/territorial public health and environmental health officials and federal food safety partners (Health Canada and CFIA) to discuss the epidemiologic and environmental investigation. PHAC prepares and distributes to provinces, territories and key partners a brief epidemiologic report.

A final conference call led by the CFIA includes Health Canada, MOHLTC and Ontario public health units to share information.

A news conference is held in which technical spokespeople from the CFIA, PHAC and Health Canada respond to questions regarding the outbreak and recall.

### **Tuesday, August 26**

Investigation of listeriosis cases by public health officials continues, but changes to the number of confirmed cases are related to laboratory test results for suspect cases. The number of confirmed listeriosis cases with the outbreak strain is listed as 29, with 15 deaths.

PHAC prepares and distributes to provinces, territories and key partners an updated brief epidemiologic report.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

PHAC hosts a teleconference with Council of Chief Medical Officers of Health and the CFIA to discuss the epidemiological investigation and further public health actions, including testing guidelines for listeriosis.

CFIA requests a health risk assessment from Health Canada for products processed by other food processing establishments either using recalled Maple Leaf meat or meat products produced using the same equipment as that used in Maple Leaf Est. 97B. Over the following days, CFIA and Health Canada work to clarify the types of products to be assessed.

From August 26 to 31, PHAC's NML reports to CFIA's OFSR that 42 of the 44 recalled isolates (from samples collected by CFIA and Ontario's public health units on August 14 & 15) submitted between August 23 and 27 have the outbreak pattern.

PHAC's NML reports the results of 1 of 15 CFIA closed food *L. mono* isolates submitted to NML on August 23. The *L. mono* isolate matches the genetic fingerprint of the product from Maple Leaf's Est. 97B.

PHAC's NML continues to receive and perform genetic fingerprinting on all suspect cases. NML continues to report results to provinces and territories.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

### **Wednesday, August 27**

No change to the number of confirmed cases or deaths.

Secondary recalls are continuing to occur to capture wider distribution of the recalled meats from Maple



Leaf. The secondary recalls are of processed meat product utilizing meat (i.e. a pre-packaged sandwich) produced at Maple Leaf Est. 97B. (See Appendix One).

From August 27 to September 18, Health Canada continues to receive and analyze food and environmental samples for *L. mono*.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

CPHO participates in CTV National interview.

The Health Canada Listeria 'It's Your Health' document, was slightly modified and re-posted.

PHAC's NML reports the results of the remaining 14 of 15 closed food *L mono* isolates submitted to NML on August 23. The *L. mono* matches the genetic fingerprint of the recalled product from Maple Leaf's Establishment 97B.

PHAC's NML receives an additional 29 isolates of *L. mono* obtained from closed meat samples from the CFIA laboratory for genetic fingerprinting.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

#### **Thursday, August 28**

No change to the number of confirmed cases or deaths.

Health Canada conducts a health risk assessment indicating that products processed by other establishments that contain recalled Maple Leaf meat meet the criteria for a 'Health Risk I' concern.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

CPHO video posted to PHAC website and YouTube.

CPHO grants Canada AM interview.

Secondary recalls of product produced utilizing meat product from Maple Leaf Est. 97B continue.

The CFIA, Health Canada and PHAC discuss Maple Leaf's environmental investigation, employee issues and food product testing associated with Est. 97B.

Maple Leaf submits a corrective action plan to mitigate deficiencies identified by the CFIA investigation team to the CFIA for review and approval.

PHAC's NML holds a teleconference with the Canadian Public Health Laboratory Network (CPHLN), which includes P/T representatives, to discuss issues such as laboratory practices for *L. mono*. NML convenes an expert committee to discuss *L. mono* laboratory testing guidelines.

Daily conference call hosted by PHAC with P/T colleagues, Health Canada and the CFIA to share information.

#### **Friday, August 29**

No change to the number of confirmed cases or deaths.

PHAC's NML has a teleconference with provincial and territorial Chief Medical Officers of Health to



finalize the *L. mono* clinical laboratory testing guidelines and to discuss recommendations for testing at-risk populations and the general public. The results of this discussion are distributed amongst the clinical community. The *L. mono* laboratory testing guidelines are posted on the PHAC website on the evening of August 29.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

Public health notices are placed in 123 Canadian daily newspapers between Aug 29-Sept 1.

Secondary recalls are continuing to occur to capture wider distribution of the recalled meats from Est. 97B.

PHAC prepares an updated brief epidemiologic report and distributes it to provinces, territories and key partners.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

### **Saturday, August 30**

The number of confirmed listeriosis cases is listed as 31, with 16 deaths associated with the outbreak strain.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

CPHO grants an interview with the Toronto Star.

Fact sheet: Listeriosis – Protecting Your Pregnancy posted on PHAC website and distributed to Agency distribution lists and to national organizations such as the Society of Obstetricians and Gynaecologists and Canadian Paediatric Society, who distributed it to their distribution lists.

PHAC's NML reports the results of 4 of 29 isolates of *L. mono* from unopened food samples submitted to NML by the CFIA on August 27. All match the outbreak fingerprint.

### **Sunday, August 31**

The number of confirmed listeriosis cases is listed as 33, with 17 deaths associated with the outbreak strain.

PHAC's NML reports the results of the remaining 25 of 29 CFIA closed food *L. mono* isolates submitted to NML on August 27. Twenty three isolates match the outbreak fingerprint, and two are a different species of *Listeria* (with a different genetic fingerprint).

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

### **Monday, September 1**

The number of confirmed listeriosis cases is listed as 38, with 19 deaths associated with the outbreak strain.

PHAC prepares and distributes to provinces, territories and key partners an updated brief epidemiologic report.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak.



Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

### **Tuesday, September 2**

No change to the number of confirmed cases or deaths.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

The Minister of Agriculture and Agri-Food Canada holds a press conference to discuss the listeriosis outbreak and investigation. The Chief Public Health Officer and senior HC and CFIA staff participate in the press conference to provide updates and answer questions.

### **Wednesday, September 3**

No change to the number of confirmed cases or deaths.

Teleconference with Health Canada, CFIA, and PHAC's NML to discuss Maple Leaf's environmental investigation at Est. 97B.

Teleconference between the CFIA's laboratory and PHAC's NML to discuss laboratory results.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

In a live press conference, the Prime Minister calls for an independent inquiry into the listeriosis outbreak.

The Minister of Agriculture and Agri-Food Canada holds a press conference to discuss the listeriosis outbreak and investigation. The Chief Public Health Officer and senior HC and CFIA staff participate in the press conference to provide updates and answer questions.

### **Thursday, September 4**

No change to the number of confirmed cases or deaths.

Teleconference with Council of Chief Medical Officers of Health and the Chief Public Health Officer. They discuss policy issues, consumer recommendations and public health advice.

PHAC's NML hosts a technical briefing for the media.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information continue.

PHAC hosts a technical briefing on the surveillance systems used to detect and track listeria and other food-borne pathogens.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

Fact sheet: Listeriosis– Protecting the Health of Senior Citizens posted on PHAC website and distributed to senior organizations and home care associations and was distributed at the Seniors Aging Conference being held in Montreal.

### **Friday, September 5**

No change to the number of confirmed cases or deaths.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share



information continue.

The CFIA issues an advisory to operators of federally-registered establishments processing ready-to-eat meats to ensure meat slicers are completely dismantled and cleaned, collect environmental samples to test for the presence of listeria, and to review cleaning and disinfecting procedures with the CFIA inspector to ensure proper sanitation of the slicers. The advisory also instructed operators to inform the CFIA Inspector of all details of the required activities and of test results. Associated CVS tasks (for sanitation of meat slicing equipment) are issued to CFIA inspectors on September 9, 2008.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

### **Saturday, September 6**

No change to the number of confirmed cases or deaths.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information.

The Minister of Agriculture and Agri-Food Canada hosts a news conference to discuss the outbreak. Technical spokespeople from the CFIA, PHAC and Health Canada respond to questions.

Prime Minister Harper announces an investigation into the *L. mono* outbreak.

### **Sunday, September 7**

No change to the number of confirmed cases or deaths.

Daily conference calls hosted by PHAC with P/T colleagues, Health Canada and CFIA to share information.

### **Monday, September 8**

No change to the number of confirmed cases or deaths.

PHAC's Emergency Operations Centre is de-activated to Level 1 (Normal Readiness)

Teleconferences with P/Ts to discuss the epidemiology of the outbreak are reduced from daily to every other day.

PHAC prepares and distributes to provinces, territories and key partners an updated brief epidemiologic report.

Fact Sheet: Listeriosis – Protecting Those with Weakened Immune Systems - was distributed by PHAC to TB and HIV/AIDS distribution lists.

In anticipation of the resumption of production at Establishment 97B, the CFIA begins week-long on-site review to assess the facility's suitability for resumption of operations. Four corrective action requests are identified by the CFIA inspectors and are subsequently addressed by Maple Leaf.

PHAC's NML receives 8 isolates of *L mono* obtained from the food processing environment at Est. 97B. (The genetic fingerprinting results of these isolates are reported to CFIA on September 18. 7 of 8 match the outbreak strain.)

### **Tuesday, September 16**

Maple Leaf provides the CFIA's Ontario Area Office with a summary of its proposed action plan in anticipation of the restarting of operations at Est. 97B. The Maple Leaf document includes the results of



the company-led investigation to identify the cause of the listeria contamination. The Maple Leaf Foods investigation into the source of the contamination is inconclusive; however, it provides five likely sources, including the cooked meat slicers.

### **Wednesday, September 17**

In correspondence from the CFIA's Executive Director for Ontario, Maple Leaf receives CFIA's approval to restart operations at Est. 97B.

A detailed directive from the CFIA's Area Program Manager is provided to the CFIA's inspector in charge of Est. 97B with the sampling plans and conditions for the re-start of operations.

Following multiple revisions and consultation with Health Canada on start-up requirements, the CFIA approved Maple Leaf's corrective action plan and Est. 97B resumed production on September 17. CFIA daily inspection presence continues in the facility.

### **Wednesday, October 8**

Maple Leaf notifies the CFIA that four end product samples from Est. 97B had tested positive for *L.mono*. None of the affected product had been released for sale. Increased *L. mono* testing continues in the facility.

Health Canada issues a precautionary "Health Risk I" assessment for product manufactured the week prior to the positive results. The CFIA issues a Class I recall to the distribution level to ensure the product is not made available to consumers. A subsequent health risk assessment conducted by Health Canada determined that the product posed no health risk.

### **Friday, October 17**

A health risk assessment conducted by Health Canada determined that the products manufactured on Line 7 at Est. 97B following start-up of the plant in September (September 19 to October 7, 2008) are suspect, and, if distributed to the consumer, they would be considered to represent a **Health Risk I** situation.

### **Monday, October 20**

CFIA announces that Est. 97B products with satisfactory *L. mono* test results could be released for distribution. Test and hold protocols continue at Est. 97B as does enhanced inspection presence.



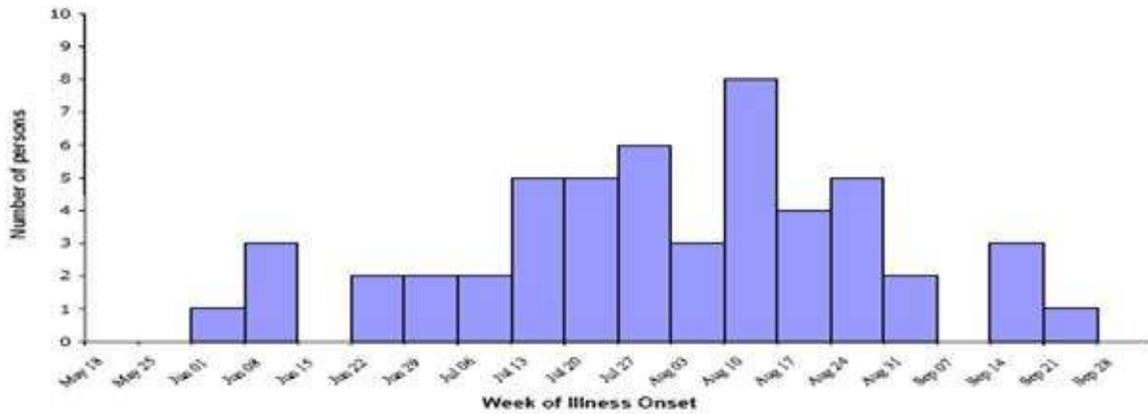
**Appendix 1, Table 1 - Listeria Recalls Related to Maple Leaf Est. 97B**

<b>Date</b>	<b>Product</b>	<b>Company</b>	<b>Primary/ Secondary</b>	<b>Classification</b>
17-Aug-08	Roast / Corned Beef	Maple Leaf Foods Inc.	Primary	Class I - Consumer
19-Aug-08	Meat products Line 8 and 9	Maple Leaf Foods Inc.	Secondary	Class I Consumer
22-Aug-08	Classic Reuben, Corned Beef	Royal Touch Foods Inc.	Secondary	Class I - Consumer
24-Aug-08	All Meat Products	Maple Leaf Foods Inc.	Secondary	Class I - Consumer
25-Aug-08	Sandwich	Atlantic Prepared Foods Limited	Secondary	Class I - Consumer
25-Aug-08	Sandwiches	Lucerne Foods	Secondary	Class I - Consumer
25-Aug-08	Deli	Metro Ontario Inc. (Formerly A&P Canada)	Secondary	Class I - Consumer
27-Aug-08	Subs	Sobey's Corporation	Secondary	Class I - Consumer
27-Aug-08	Croissant / Meat & Cheese Platter	Costco Wholesale Canada Ltd	Secondary	Class I - Consumer
28-Aug-08	Deli	Delta Country Market	Secondary	Class I - Consumer
28-Aug-08	Sandwiches	Loblaw Brands Limited	Secondary	Class I - Consumer
28-Aug-08	Sandwiches	Glen Fine Foods	Secondary	Class I - Consumer
28-Aug-08	Sandwiches	Sobey's Corporation	Secondary	Class I - Consumer
28-Aug-08	Deli Meats	White House Meats	Secondary	Class I - Consumer
29-Aug-08	Pepperoni Pizzas	Wal-Mart	Secondary	Class II - Retail/HRI
29-Aug-08	Sandwiches	Safeway Canada	Secondary	Class I - Consumer
29-Aug-08	Deli	Country Traditions Frozen Food	Secondary	Class I - Consumer
29-Aug-08	Deli	Metro Richelieu Inc.	Secondary	Class I - Consumer
29-Aug-08	Deli Meats	Coop Atlantic	Secondary	Class I - Consumer
29-Aug-08	Cold Cut Ends	Metro Ontario Inc. (Formerly A&P Canada)	Secondary	Class I - Consumer
29-Aug-08	Sandwiches	Sobey's Corporation	Secondary	Class I - Consumer
30-Aug-08	Sandwiches	King Bean Wholesalers	Secondary	Class I - Consumer
04-Sep-08	Bologna	Canex Retail Supermarket	Secondary	Class I - Consumer
05-Sep-08	Sandwiches	Metro Ontario Inc. (Formerly A&P Canada)	Secondary	Class I - Consumer



### Appendix 1, Table 2 – PHAC Listeriosis Epidemiological Curve

**Infections with the outbreak strain of *Listeria monocytogenes* by symptom onset date or estimated date\* as of 3 October 2008, Canada**



\* SOME ILLNESS ONSET DATES HAVE BEEN ESTIMATED FROM REPORTING INFORMATION



## Appendix 2. List of References

- Bureau of Microbial Hazards general information (e.g. pamphlet, Website)
- Food Directorate Emergency Response Plan – Non-Routine Emergencies (January, 2006)
- Food Safety and Nutrition Policy Development in the Food Directorate - A Reference Manual.
- Frequently Asked Technical Questions on “Policy on *Listeria monocytogenes* in Ready-To-Eat Foods”. HC Website.
- Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks. (August 2000)
- Health Canada, The Public Health Agency of Canada and Canadian Food Inspection Agency, “Canada Foodborne Illness Outbreak Response Protocol (FIORP) to Guide a Multi-jurisdictional Response.” (July 21, 2006). HC Website.
- Health Products and Food Branch Standards and Guidelines for Microbiological Safety of Food. (Apr., 2008)
- Health Products and Food Branch Compendium of Analytical Methods. HC Website.
- Introduction to the Bureau of Microbial Hazards. HC Website
- “It’s Your Health - *Listeria* and Food Safety.” August, 2008. Website.
- Listeriosis Reference Service. HC Website.
- Memorandum of Understanding Between Health Canada (Bureau of Microbial Hazards) and the Public Health Agency of Canada (National Microbiology Laboratory) for the Listeriosis Reference Service
- Memorandum of Understanding between Health Canada and the Public Health Agency of Canada and the Canadian Food Inspection Agency for common issues related to Human Health (April, 2008)
- MFHPB-30 Isolation of *Listeria monocytogenes* from all Food and Environmental Samples (January 2001).
- OAG 1994 report Chapter 13 – Federal Management of the Food Safety System
- OAG 1999 report Chapter 15 – Management of a Food-borne Disease Outbreak
- PHAC and HC Strategic Risk Communications Framework and Handbook (November, 2004).
- Policy on *Listeria Monocytogenes* in Ready-to-Eat Foods (July, 2004)
- Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods (FAO/WHO, 2004)
- Standard Operating Procedures for Health Risk Assessments (July 4, 2003, revised August 22, 2007)
- Standard Operating Procedures for Responding to the CFIA during Routine Food Safety Emergency Situations. (2005)



- Summary of Methods in the Compendium That Detects the Presence of *Listeria* SPP and *Listeria Monocytogenes* (January 2005).

<sup>[1]</sup> To improve outreach services to Canadians, PACCB was created as a stand-alone branch from the Public Affairs, Consultation and Regions Branch on July 14, 2008.

<sup>[2]</sup> “It’s Your Health – *Listeria* and Food Safety.” Health Canada. Updated August 2008. <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/listeria-eng.php>

<sup>[3]</sup> Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods. Food and Agriculture Organization and World Health Organization. 2004. <http://www.fao.org/docrep/010/y5394e/y5394e00.htm>

<sup>[4]</sup> Note that First Nations and Inuit Health Branch personnel were consulted in the development of the report to ensure their perspectives were incorporated.

<sup>[5]</sup> FIORP has not been updated since PHAC’s Infectious Disease and Emergency Preparedness Branch was reorganized in 2007. The FIORP provides the first point of contact at the federal level as the Centre for Infectious Disease Prevention and Control at PHAC.

<sup>[6]</sup> PulseNetUSA, a national molecular subtyping network for foodborne disease surveillance in the USA, was established by the CDC in 1996 to facilitate subtyping bacterial foodborne pathogens for epidemiologic purposes. PulseNetUSA is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). PulseNet participants perform standardized molecular subtyping (or “fingerprinting”) of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE). PFGE can be used to distinguish strains of organisms such as *Escherichia coli* O157:H7, *Salmonella*, *Shigella*, *Listeria*, or *Campylobacter* at the DNA level. DNA “fingerprints,” or patterns, are submitted electronically to a dynamic database at the CDC. These databases are available on-demand to participants, which allows for rapid comparison of the patterns. The PulseNet network is now being replicated in different ways in Canada (i.e. PulseNet Canada), Europe, the Asia Pacific region, Latin America and the Middle East. These independent networks allow public health officials to share molecular epidemiologic information in real-time, and enable rapid recognition and investigation of multinational foodborne disease outbreaks. Routine communication between the various international PulseNet networks allows for early warnings on foodborne disease outbreaks to participating public health institutions and countries. PHAC’s NML in Winnipeg plays the leadership role in coordinating PulseNet Canada.

<sup>[7]</sup> Hazard Analysis and Critical Control Point (HACCP) is an internationally recognized food safety system that is used to help ensure the manufacture of safe food products. HACCP is designed to prevent, reduce or eliminate potential biological, chemical and physical food safety hazards, including those caused by cross-contamination. During the development of an HACCP system, potential hazards are identified and control measures are implemented at specific points in the manufacturing process.

<sup>[8]</sup> Category 1 products include those that have been causally linked to documented outbreaks of listeriosis and/or have been placed into the “high risk” category in the HHS/USDA risk assessment (HHS/USDA, 2003). Category 2 contains all other RTE foods which are capable of supporting the growth of *Listeria monocytogenes* and have a shelflife exceeding 10 days. Products in Category 2 receive the second highest priority for inspection and compliance activities. Category 3 contains two types of RTE foods: those supporting growth with a less than 10 day shelf-life and those not supporting growth. These products receive the lowest priority in for inspection and compliance activities.

<sup>[9]</sup> Class 1, Class 2 or Class 3 levels of recall are determined by CFIA for a particular product once the level of risk has been assigned to the product by HPPFB. The level of risk indicates the relative degree of health hazard presented by the product to be recalled; the level of recall applied will be such as is deemed appropriate to offset the risk.



Class 1 recalls are linked to situations where there is reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

<sup>[10]</sup> PHAC's Center for Infectious Disease Prevention and Control maintains a list of notifiable diseases to enhance dissemination of surveillance data on notifiable diseases in Canada. The list is reviewed and updated by a federal/provincial/territorial working group to determine which communicable diseases should or should not be on the list. [http://dsol-smed.phac-aspc.gc.ca/dsol-smed/ndis/index\\_e.html](http://dsol-smed.phac-aspc.gc.ca/dsol-smed/ndis/index_e.html)

<sup>[11]</sup> Closed samples refer to the food samples submitted to the laboratory in the original unopened containers. Open samples refer to the food samples submitted to the laboratory that are not in the original unopened containers.

<sup>[12]</sup> PHAC's CNPHI integrates relevant public health intelligence, including strategic or interpreted data, into a common national framework that supports coordination between multi-level jurisdictions. Such coordination is needed to use data for early identification of risks to health, initiate rapid response and build response capacity.

<sup>[13]</sup> Serotyping and genetic fingerprinting together can take up to fourteen days to complete, not including the time it takes to collect the sample (human, food or environmental) and send it to a federal laboratory. The entire process can take as long as three to four weeks. A faster turnaround time is possible once an outbreak investigation is initiated (even then, because of the science and rigorous quality control involved, the genetic fingerprinting process takes four days at minimum).

<sup>[14]</sup> CNPHI is a secure, national web-based information sharing tool.

<sup>[15]</sup> At a normal rate of verification, a randomly-selected sample of accounts (i.e., locations where the recalled product would have been available in the marketplace) is checked. The sample is designed to be statistically sufficient to determine the effectiveness of the recall (with a 99% confidence level).