

Health Canada / Santé Canada
Your health and safety... our priority / Votre santé et votre sécurité... notre priorité

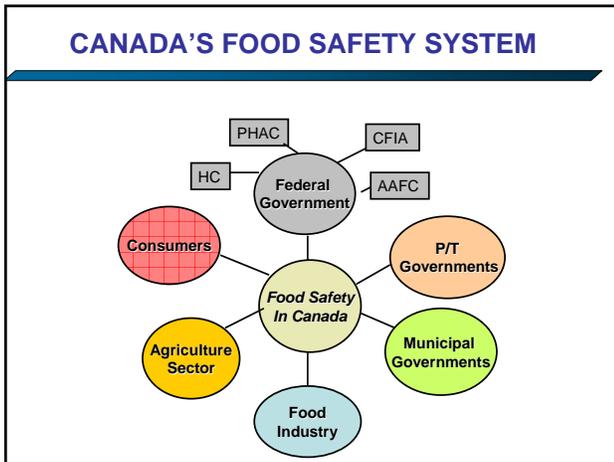
WEIGHT OF EVIDENCE

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OUTLINE

- Food Safety System in Canada
- The Concept
- Decision Diagrams
- Sections
 - Intact and Non-Intact Sample Information
 - Clinical Match Evidence
 - Epidemiological Evidence
 - Traceback/Traceforward
 - Health Risk Assessment
 - Risk Management Actions
 - Public Advisory
- Conclusions

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FOOD SAFETY SYSTEM IN CANADA...

Other key federal partners

- **Canadian Food Inspection Agency (CFIA)** responsible for:
 - Enforcing federal food safety standards and policies set by HC under the Food and Drug Act (among the 13 federal and Acts and regulations they enforce)
 - Setting non-safety food standards and policies
- **Public Health Agency of Canada (PHAC)** responsible for:
 - Mobilizing pan-Canadian action to prevent an injury
 - Promote and protect national and international public health
- **Agriculture and Agri-Food Canada (AAFC)** responsible for:
 - On-farm food safety, environment control, innovation
 - Support to the sector for effective and efficient agriculture

... is a shared responsibility

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FOOD SAFETY SYSTEM IN CANADA...

- Food safety and nutritional quality in Canada is a shared responsibility
 - Federal government, Provinces, Territories, Municipalities, Industry, Consumers
 - 37 different governments and agencies; 90 pieces of legislation at federal and provincial/territorial levels deal with aspects of food safety
- Health Canada responsible for:
 - Setting standards for food related to health and safety (regulations, policies, guidelines)
 - Assessing effectiveness of the Canadian Food Inspection Agency (CFIA)
- Food Directorate in Health Products and Food Branch is the federal health authority responsible for establishing policies, setting standards, and providing advice and information on the safety and nutritional value of food

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FEDERAL FOOD SAFETY RESPONSIBILITIES ARE SHARED

Production Processing/Distribution/Retail/Food Service Consumers

On-farm Food Safety Programs Policy and Standards Surveillance/ Early Warning Education and Outreach Inspection and Enforcement Public Health Surveillance

AAFC HC PHAC

CFIA

Primary Responsibilities

AAFC	HC	CFIA	PHAC
<ul style="list-style-type: none"> •Contributes to research and development of on-farm food safety programs 	<ul style="list-style-type: none"> •Establishes food safety policy and standards •Conducts health risk assessments •Informs Canadians about potential risk to their health •Safety of veterinary drugs and pesticides 	<ul style="list-style-type: none"> •Design and delivery of federal food inspection programs •Monitors industry's compliance with Acts and regulations •Undertakes enforcement action as necessary 	<ul style="list-style-type: none"> •Public health surveillance •Leads foodborne illness outbreak investigations with P/T public health officials

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WEIGHT OF EVIDENCE

- A foodborne illness outbreak investigation is complex and multidisciplinary
- As each responsible organization gathers more data and more detailed information, the situation is updated, thus providing strength to the weight of evidence
- Scientific evidence needed to proceed with an action to implement control measures as quickly as possible and prevent further illnesses varies widely, and is usually based on a combination of different factors

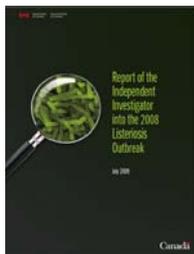


CANADIAN LISTERIOSIS OUTBREAK

In 2008, a national outbreak of foodborne listeriosis resulted in 57 confirmed cases in 7 provinces, with a total of 22 deaths



THE WEATHERILL REPORT



THE WEATHERILL REPORT

Recommendation # 29

- Health Canada, the CFIA and the Public Health Agency of Canada should review, update and publish the criteria for proceeding with a food recall to ensure that the **weight of evidence** takes into account epidemiological information, including suspected illnesses and deaths, geographic distribution, and food sample test results whether packages are opened or unopened

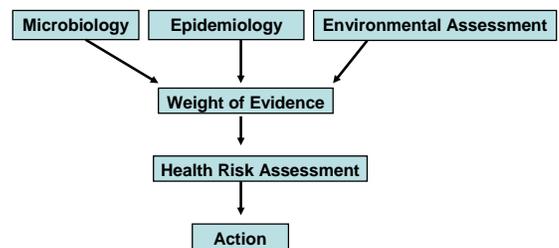


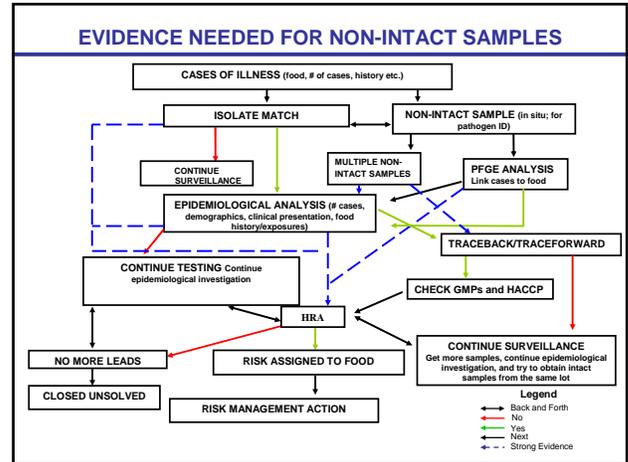
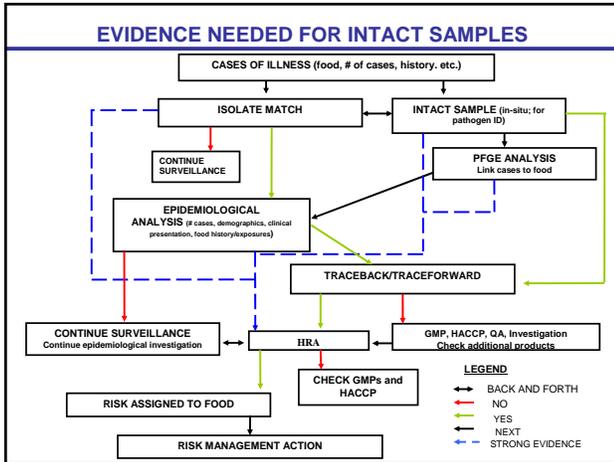
WOE PARTICIPANTS



THE CONCEPT

The simplified process of decision-making is, as follows:





NON-INTACT SAMPLES

- Product with opened packaging or a product removed from original packaging
- Non-intact samples can be found in a consumer's home or in the marketplace (i.e., nursing home)
- Test results could be useful when intact product is not available, or when additional information is needed to determine if a link between product and illness exists
- Test results could result in appropriate action

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INTACT vs NON-INTACT

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NON-INTACT SAMPLES: FACTORS TO CONSIDER

- How was non-intact product handled by the case patient?
- Minimal handling (i.e., opened package cut) or extensive handling (i.e., mixing/stirring)?
- Storage conditions of product?
- Are packaging materials and labels available?
- Can product identity be certain?
- Photographs should be taken

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NON-INTACT SAMPLE PRODUCTS

- Test results could potentially be used in mitigation strategies to prevent further illness
- Product action could be taken: product detention, removal, recall
- Results can provide indicators for further investigation

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INTACT AND NON-INTACT SAMPLE INFORMATION

The following information is gathered by CFIA and Public Health Inspectors

General Information

- (Address, Place of Collection, Photograph, Reason for Collection, etc.)

Food Information

- (Name of Food, Main Ingredient, Food/Ingredient Submitted)

Food/Ingredient Submitted

- (Brand, Lot #, UPC, Best-Before Date, etc.)

Preparation of Submitted Food/Meal

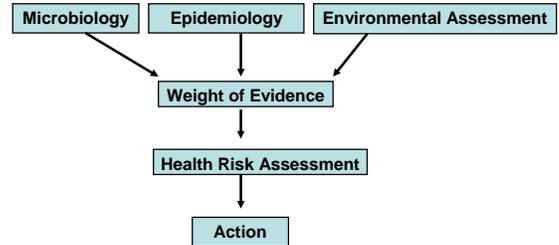
- (Prepared by, Time and Place, etc.)

Hygienic Conditions at the Food Establishment

- (Temperature, Cleanliness, etc.)



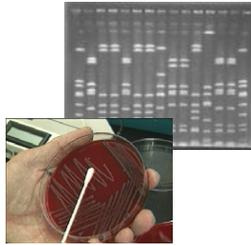
THE CONCEPT



CLINICAL MATCH EVIDENCE

The following clinical match evidence is weighted 'weak' to 'strong'

- Does the organism show suitable diversity by PFGE?
- Are clinical and food isolate PFGE patterns indistinguishable by 2 enzymes?
- What is the historic frequency of the PFGE pattern combination?
- Are other subtyping results available; are they consistent with PFGE?



EPIDEMIOLOGICAL EVIDENCE

The following epidemiological evidence is weighted 'weak' to 'strong' by PHAC

- Is it plausible that a given food item is the vehicle of infection?
- Is a given food item consistently reported across different populations?
- Is the temporal and/or spatial clustering of cases consistent with the availability/distribution of a particular food product?
- Does the information provided indicate a single specific food product as the vehicle of infection?
- How strong is the statistical association between a given food item and the foodborne illness?
- Are PFGE results consistent with epidemiological evidence?



TRACEBACK AND TRACEFORWARD

Traceback / traceforward evidence weighted from 'weak' to 'strong'

Consumer Traceback/Point of Consumption Traceback and Traceforward:

- Does the product identity allow direct tracing to the manufacturer?

Point of Purchase Traceback/Traceforward:

- Can the point of purchase be identified?

Distribution Traceback/Traceforward:

- Can the product identity lead to manufacturer?

Manufacturer Traceback/Traceforward:

- Can the product be traced back to the wholesaler?



HEALTH RISK ASSESSMENT

Information to be considered during a Health Risk Assessment by Health Canada

- Issue Description and Situation Summary
- Hazard Identification (Microbial, Chemical, Allergens, etc.)
- Hazard Characterization (none, low, medium or high)
- Exposure Assessment
- Risk Characterization



HEALTH RISK DEFINITIONS

Health Risk 1 (HR 1)

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

Health Risk 2 (HR 2)

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

Health Risk 3 (HR 3)

- a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence.



POTENTIAL RISK MANAGEMENT ACTIONS AFTER A HEALTH RISK ASSESSMENT

The following risk management actions can be performed by CFIA

Product Action:

- Recall based on Health Risk 1, Health Risk 2 and Health Risk 3
- Precautionary recall if precautionary risk assessment
- No recall but continue investigation if no Health risk assigned

Continue Investigation:

- Trace back and trace forward
- Further sampling and testing - intact products or additional non-intact
- GMPs/HACCP evaluations
- Issue and monitor corrective action reports

Education Risk Management:

- Enhanced consumer education
- Review and enhance industry procedures and requirements



PUBLIC ADVISORY

- Class 1 Recall
- Class 2 Recall
- Canadian Company Initiated Public Warning
- Other Food Safety Issues:
- Other Advisories



EXAMPLE SCENARIOS

SCENARIO 1

- **Cases of Illness:** Many
- **Number of Food Analyzed:** 3; all from the same restaurant
- **Closed or Open Sample:** All opened
- **Epidemiological Evidence:** Strong
- **Food/Clinical Isolate PFGE Match:** No
- **Risk Assessment-possible? (Y/N):** Yes
- **Possible Action:** Yes*-continue testing other possible vehicles



EXAMPLE SCENARIOS

SCENARIO 2

- **Cases of illness:** 1, 2 or many
- **Number of Foods Analyzed:** 1,2 or several
- **Closed or Open Food Sample:** Closed
- **Epidemiological Evidence:** None or weak
- **Food/Clinical Isolate PFGE match:** No
- **Risk Assessment - possible? (Y/N):** Yes
- **Possible Action:** Yes,* recall product, continue investigation-traceforward identify additional products



EXAMPLE SCENARIOS

SCENARIO 3

- **Cases of illness:** 2 (both ate the product from the same lot)
- **Number of Foods Analyzed:** 1
- **Closed or Open Food Sample:** Open
- **Epidemiological Evidence:** Weak
- **Food/Clinical Isolate PFGE match:** Yes
- **Risk Assessment - possible? (Y/N):** Yes
- **Possible Action:** No* product action, continue investigation - find intact sample and test



CONCLUSIONS

- This is a general guidance draft document which provides factors to consider during a foodborne outbreak investigation in order to ensure timely and appropriate actions
- The document contains diverse example scenarios which can be used to understand the decision-diagrams and provide examples of what has been done in the past
- The Document has been submitted to FPTFSC and we are currently looking at the comments



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