
 Santé Canada Health Canada

2010.2.23 第10回微生物・ウイルス専門調査会

AN OVERVIEW OF MICROBIAL FOOD SAFETY – A HEALTH CANADA PERSPECTIVE

Dr. Jeffrey Farber
Director, Bureau of Microbial Hazards
Food Directorate, Health Products and Food Branch
Health Canada



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Canada, eh?

- Canada is the world's 2nd largest country area wise (including its waters), and 4th largest in land area
- Lowest population density in the world, with only three people living per square kilometre! Almost half of the population in Canada was born in other countries
- French and English are official languages
- Country divided into 10 provinces and 3 territories
- Host of the 2010 Winter Olympics!



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Ottawa

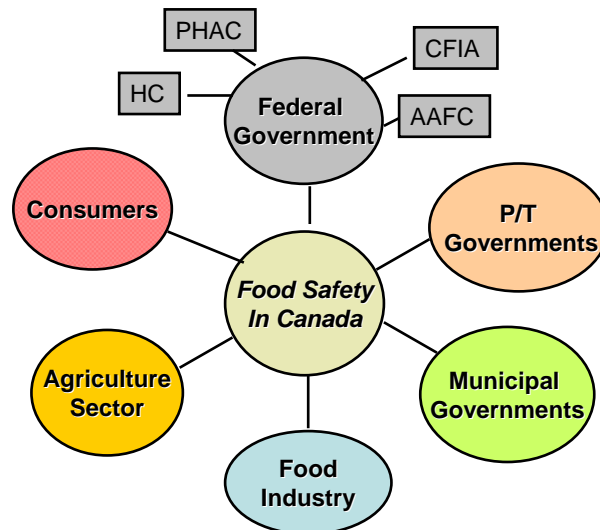
- Ottawa was chosen as Canada's capital city in 1857 by Queen Victoria
- In winter, the Rideau Canal becomes the longest maintained skating rink in the world. It measures nearly 8 kilometres from end to end.
- The temperature in Ottawa measures about 28-30° C in summer and -40° C in winter.
- The Ottawa celebrates 35 major festivals, including Tulip festival and Bluesfest, which are evenly distributed in the four seasons.



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Canada's Food Safety System



Food Safety and Nutritional Quality 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 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

Food Safety and Nutritional Quality 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

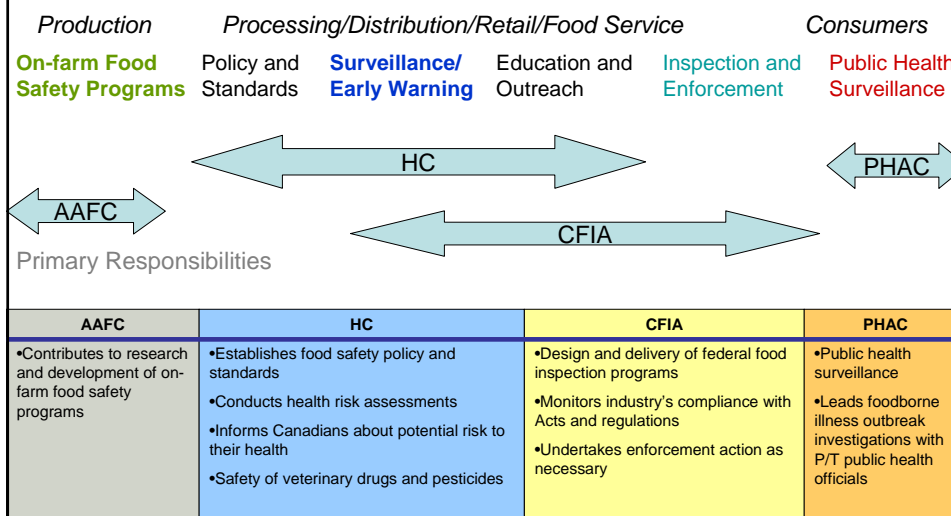


... is a shared responsibility

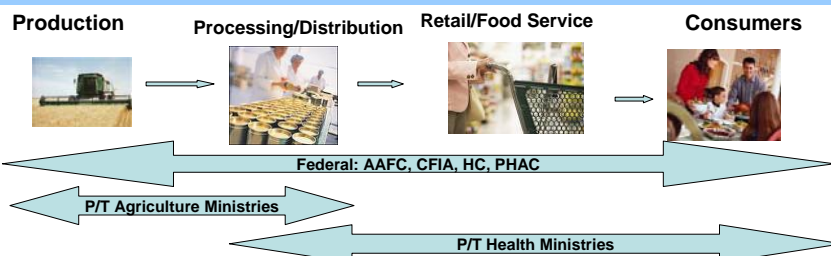
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Federal Food Safety Responsibilities are Shared



Federal and Provincial/Territorial Responsibilities Overlap



Federal

- Enact, administer and enforce food safety laws pertaining to all food sold in Canada
- Enact, administer and enforce trade and commerce legislation for certain commodities traded internationally or inter-provincially (e.g., meat, fish)
- Set standards and policy for federally-registered establishments
- Provide Canadians with public health information, advice and leadership
- Undertake food safety and quality research
- On-farm food safety programming

Provincial/Territorial

- Enact, administer and enforce food safety laws within provincial jurisdictions
- Set standards and policy for provincially licensed establishments
- Provincial health ministries lead and participate in the investigation of foodborne outbreaks

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Food Program – Strategic Framework



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An Overview of How Risk Assessment and Risk Management Approaches Work Between Health Canada and CFIA



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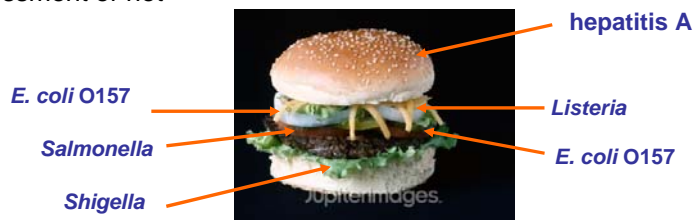
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"Some bloke wants to know if we've carried out a thorough risk assessment?"

Risk Profile

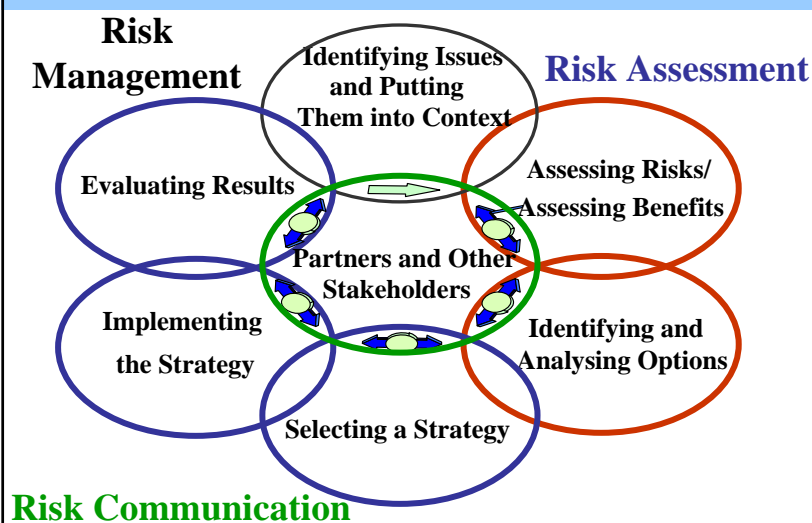
A possible step before Risk Assessment is the development of a **Risk Profile**, which

- food Places the issue within safety content
- Provides as much information as possible to help risk managers clarify their risk assessment questions
- Concludes with a risk management decision to pursue a risk assessment or not



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HC's Decision-Making Framework



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Risk Profile

Microbiological *Mycobacterium avium* subsp. *paratuberculosis*



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Qualitative Risk Assessments

Microbiological

- Health Risk Assessments (HRAs) in response to CFIA and FPT requests
- Sprouted Seeds/Beans
- Unpasteurized fruit juice/cider



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Quantitative Risk Assessments

Microbiological

- *Salmonella* Enterditis in eggs
- BSE infectivity in Canadian beef and beef products and the risk to Canadian consumers of acquiring vCJD



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Health Risk Assessments

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Health Risk Assessments

- Performed by the Evaluation Divisions, Bureau of Microbial Hazards and Bureau of Chemical Safety
- HRAs determine whether a health hazard exists or whether there is potential for a hazard to exist
- Potential health risks are chemicals, foodborne pathogens or injurious extraneous material in food



HRAs – The Process

- A formal request for an HRA, plus all the data available are provided to the scientific evaluator in written format
- Requests are received from CFIA, FPT, etc.
- Is it a Health Risk 1, 2, or 3?



HRAs- The Process

The evaluator reviews the information provided for adequacy and reliability

- The evaluator may request additional information
- A search for similar scenarios in the departmental records, is carried out
- Appropriate experts are consulted as required
- An ongoing two-way dialogue with the client (e.g., CFIA) is common

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HRAs- The Process

A Health Risk Assessment is performed using a modified version of the process described in the Codex Alimentarius document

Principles and guidelines for the conduct of a microbiological risk assessment



HRAs- The Process

- Situation Summary or Purpose
- Analysis of Hazards
 - Hazard Identification
 - Hazard Evaluation
- Exposure Assessment
 - Dose-Response Assessment
 - Hazards Exposure Characterization
- Risk Characterization (Estimation)
- Determination of Health Risk (1, 2 or 3)
- Communication/ Follow up
- Reference/Documentation



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Determination of Health Risk

- Health Risk 1
- Health Risk 2
- Health Risk 3

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Health Risk Assessments

Total of 56 HRA's completed since January 2009

- - 14 designated Health Risk 1
- - 21 designated Health Risk 2
- - 2 designated Health Risk 3
- - 19 designated No Health Risk

1,2,3

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HRAs 2009-2010

- **14 Health Risk 1** - Organisms/ products involved were:
 - *Listeria monocytogenes (Lm)* - smoked ham, sliced ham, cheese, FCS: MLF wieners, sausage
 - *Salmonella* spp. – peanuts, sprouts
- **21 Health Risk 2** - Organisms/ products involved were:
 - *Salmonella* spp. – peanuts, pistachio dessert, tahini, Gourmet salad, sprouts, onion seeds, basil, granola bars, cream cheese
 - *Lm* – deli sandwiches, leeks

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Health Risk 1

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

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Health Risk 2

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

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Health Risk 3

This represents a situation where there is a reasonable probability that the consumption/exposure to a food is **not likely to result in any adverse health consequence**. The situation identified may be an indication of a breakdown in Good Manufacturing Practices; in Good Agricultural Practices; in Good Practices in Veterinary Medicine or some other relevant factor.

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Decision Tree Timeline for Risk Assessment

Written information from CFIA → Preliminary assessment:

Potential HR1 or Potential HR2 or Potential HR3



Is information complete and adequate?

✕ If No ➡ Request additional info (clock stops briefly)

⊕ If Yes ➡ Priority ranking:



Potential HR 1



8h for assessment



Potential HR 2



24h for assessment



Potential HR 3



24h for assessment

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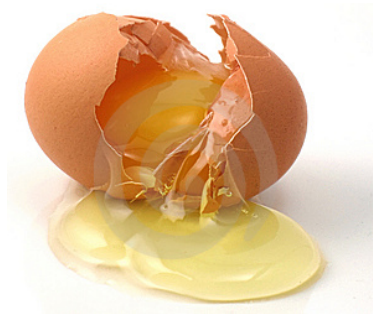
Health Risk Assessment of *Salmonella* Enteritidis in Eggs



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S. Enteritidis in Eggs

In Canada, the incidence of egg contamination with *S. Enteritidis* is on average, 1.7 per million eggs



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Risk Mitigation Strategies for Shell Eggs

Reduction of prevalence of *S. Enteritidis* in regulated flocks

- Test and divert strategy
 - Flock testing is done by environmental sampling for *S. Enteritidis*
 - Testing schemes in place in all provinces, but with different frequencies (recommend the same protocols and methodology across jurisdictions,
 - Recommend diversion of eggs for the lifetime of flocks
 - Positive flocks test should prompt investigation and should be reported to the CFIA
- Vaccination programs
 - Vaccination should never be used as a substitute for cleaning and disinfection between flocks
 - Recommend vaccination if previous flock was positive
 - Flock still subject to *S. Enteritidis* testing

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Reduction of Number of Illnesses from Contaminated Eggs

Educational campaigns

- Development of educational campaigns
- Create an understanding of consumer safety issues



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Recommendations

Reduction of prevalence of *S. Enteritidis* in poultry flocks

- Prevent exposure of day old chicks to *S. Enteritidis*
- Recommend mandatory participation in OFFS programs for regulated laying flocks supplying eggs for the table market

Common requirements for all table eggs offered for sale

- Imported products should meet the same requirements as domestic flocks
- Recommend that surplus hatching eggs are pasteurized
- Eggs from unregulated markets may be pasteurized
- Cracked eggs should not be offered for sale as market eggs



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Egg Production

- All sectors involved in egg production should respect refrigeration of eggs
- CFIA inspects registered egg grading stations to ensure proper sanitation and operation requirements
- Eggs to be processed should not be out of refrigeration for more than 48 hours



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Measuring the effectiveness of the policy

- Goal is to have in place effective policies

Measuring success of the policy:

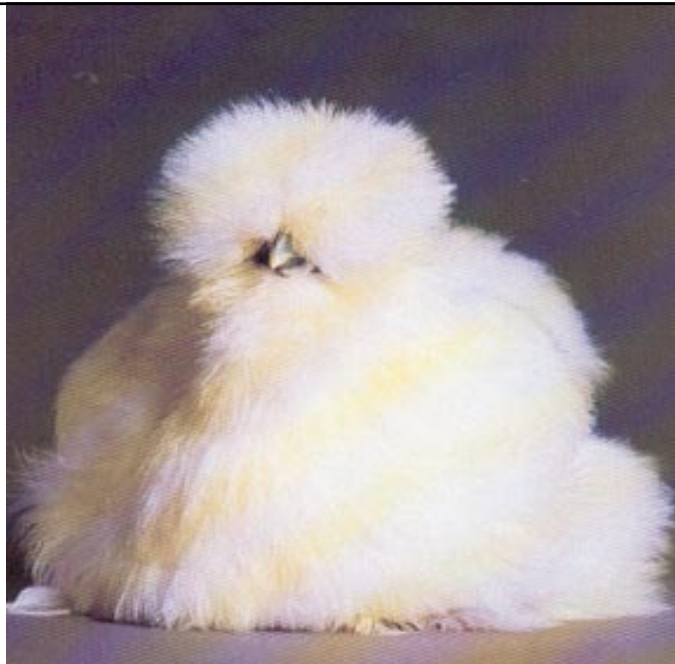
- Monitor prevalence of *S. Enteritidis* in layer flocks, pullets, and hatching chicks
 - prevalence of *S. Enteritidis* expected to decrease
 - changes in methodology and increased flock coverage may initially change the flock prevalence

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Measuring the effectiveness of the policy

- Monitor prevalence of human illnesses
 - limited to outbreaks
 - on-going disease surveillance by PHAC
- Assess proportion of salmonellosis cases that are due to *S. Enteritidis*
 - National Microbiology Laboratory serotyping
 - proportion of *S. Enteritidis* to other serovars
 - role of other commodities, travel-related sources, and outbreaks in data analysis
- Monitor molecular subtypes (phage type and pulsotype) in egg commodities and assess against human isolates and other food commodities
- Assess progress of consumer and producer education program

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Produce Safety in Canada



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Health Canada's Top 10 Produce Research Needs

1. Pathogen survival/factors affecting survival in manure and/or soil
2. Pathogen survival in water/factors affecting survival
3. Internalization of pathogens by produce
4. Effectiveness of hand sanitizers and gloves on farms
5. Effectiveness of cleaning water on pathogen reduction

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Health Canada's Top 10 Produce Research Needs

6. Sampling protocols to detect pathogens
7. Research on interaction of pathogens with produce and growth on produce post harvest
8. Behaviours of pathogens on fresh-cut produce from packaging to consumers
9. Rate of illness from fresh produce in Canada
10. Factors influencing pathogen attachment to produce

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Canadian Produce Outbreaks (2001-2009) Bacteria

Organism	Year	Vehicle	Province	# of cases (deaths)
<i>Salmonella</i>	2001	Mung bean sprouts	Multiple	84
<i>Shigella sonnei</i>	2001	Spinach	BC	31 or 34
<i>Salmonella</i>	2002	Fruit trays	ON	35
<i>E. coli</i> O157:H7	2002	Salad/sandwiches	PEI	17
<i>S. Poona</i>	2002	Cantaloupe	ON	2
<i>Shigella</i> spp.	2002	Greek pasta salad	ON	659
<i>S. Brandenburg</i>	2004	Cucumber	BC	10
<i>S. Javiana</i>	2004	Roma tomatoes	ON	7
<i>S. Enteritidis</i>	2005	Mung bean sprouts	AB/ON	560
<i>E. coli</i> O157:H7	2006	Lettuce	ON	30
<i>S. Oranienburg</i>	2006	Fruit salad	ON	2

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Canadian Produce Outbreaks (2001-2009) Bacteria

Organism	Year	Vehicle	Province	# of cases (deaths)
<i>E. coli</i> 0157:H7	2006	Lettuce	ON	7
<i>E. coli</i> 0157:H7	2006	Spinach	ON	1
<i>S. Oranienburg</i>	2006	Spinach	ON	3
<i>Shigella</i>	2007	Carrots	AB	4
<i>E. coli</i> 0157:H7	2008	Iceberg lettuce	ON	2
<i>E. coli</i> 0157:H7	2008	Spanish onions	ON	235
<i>E. coli</i> 0157:H7	2008	Lettuce	ON	29
<i>S. Litchfield</i>	2008	Cantaloupe	Multiple provinces	9
<i>S. Cubana</i>	2009	Onion sprouts	ON/AB	12

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Canadian Produce Outbreaks (2001-2009) Protozoa

Organism	Year	Vehicle	Province	# of cases (deaths)
<i>C. cayetanensis</i>	2001	Thai basil	BC	17
<i>C. cayetanensis</i>	2003	Cilantro	BC	11
<i>C. cayetanensis</i>	2004	Cilantro	BC	8
<i>C. cayetanensis</i>	2005	Basil	ON	40
<i>C. cayetanensis</i>	2005	Basil	QC	200
<i>C. cayetanensis</i>	2005	Basil	ON	40
<i>C. cayetanensis</i>	2005	Basil	QC	200
<i>C. cayetanensis</i>	2006	Basil/garlic	BC	28
<i>C. cayetanensis</i>	2006	Basil/garlic	BC	28

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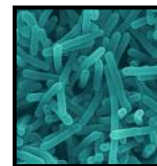
Canadian Produce Outbreaks (2001-2009) Viruses

Organism	Year	Vehicle	Province	# of cases (deaths)
Hepatitis A	2002	Multiple produce	ON	2
Norovirus	2004	Salad	BC	10
Hepatitis A	2007	Leafy greens or carrots	BC	8

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The 2008 Canadian Listeriosis Outbreak due to Deli-Meats

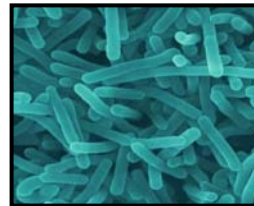
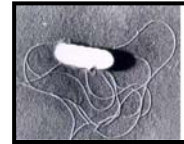
Lessons Learned- A Federal Government Viewpoint



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What is *Listeria monocytogenes* ?

- *Listeria monocytogenes* (commonly called *Listeria*) is a bacterial pathogen that is widely distributed in the environment
- It can be found in soil, vegetation, water, sewage, silage and in the faeces of humans and animals
- It can survive and sometimes grow on foods being stored in the refrigerator
- Foods that are contaminated with this bacterium look, smell and taste normal
- *Listeria* can be killed by following proper cooking procedures



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L. monocytogenes and Listeriosis

- *L. monocytogenes* causes a rare, but serious disease called listeriosis, especially among pregnant women, the elderly or individuals with a weakened immune system
- It is estimated that up to 5% of humans may carry Lm in their intestines without ill effects
- *Listeria* is more likely to cause death than other bacteria that cause food poisoning, i.e., 20 - 30 % of foodborne listeriosis infections in high-risk individuals may be fatal



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Barriers and Challenges to the Control of *Listeria*

- The microorganism is commonly found in the environment, including food processing, distribution, retail environments, and in the home
- Because *L. monocytogenes* is everywhere it can easily enter processing plants via raw foods, humans, equipment, vehicles, shoes, etc.
- Once inside a processing plant, *L. monocytogenes* can establish itself and persist for long periods of time
- It can grow in many foods during refrigerated storage

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Reducing the Risk of Listeriosis

- Avoiding cross-contamination (sanitation)
- Incorporating ingredients that inhibit the growth of *Listeria* (e.g., lactate and diacetate)
- Processes that inhibits growth during shelf life, e.g., low moisture, high acidity, freezing
- Ingredients that can inactivate listeriae (e.g., nisin, growth inhibitor packaging, dipping products)
- Processes that can inactivate listeriae (e.g., cooking, steam heat or hot water)

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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



Geographic Distribution

Province	Confirmed	Probable
Alberta	2	
British Columbia	5	
Manitoba	1	
New Brunswick	1	
Ontario	41	2
Quebec	5	
Saskatchewan	2	
Total	57	2*



* PFGE results were not available for 2 cases

Descriptive Epidemiology

Mean age	75
Median age	78
Age range	29-98
Female	67%
Immunocompromised*	100%
Institutional exposure**	84%

* Prior health status was known for 31 of the 57 cases and all 31 cases had underlying conditions.
 **Residents, inpatients or outpatients of institutions in the 70 days prior to their illness.

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Public Health Actions

- August 17, 2008 - Recall → CFIA and ML Foods warned the public not to serve or consume Sure Slice Roast Beef and Corned Beef, because these products may be contaminated with Lm
- August 19, 2008 - Recall → CFIA and ML Foods warned the public not to serve or consume any RTE deli meat products produced at facility # 97B because they may be contaminated with Lm
- August 24, 2008 - Recall → ML Foods voluntarily recalled all products manufactured at facility #97B in Toronto
- August 24, 2008 - Facility Closure → Toronto ML facility #97B was shut down and disinfection of the entire plant commenced



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2008 Listeriosis Outbreak - Key Facts

- The 2008 listeriosis outbreak was identified following three weeks of higher than expected case reports of listeriosis in Ontario
- On August 6, 2008, the Toronto Public Health Unit informed CFIA of two listeriosis cases at a Toronto nursing home
- Following a food safety investigation led by CFIA, the source of the *Listeria* was linked to Establishment 97B (Maple Leaf Foods Canada) RTE meat products
- Eventually seven provinces were implicated in the outbreak

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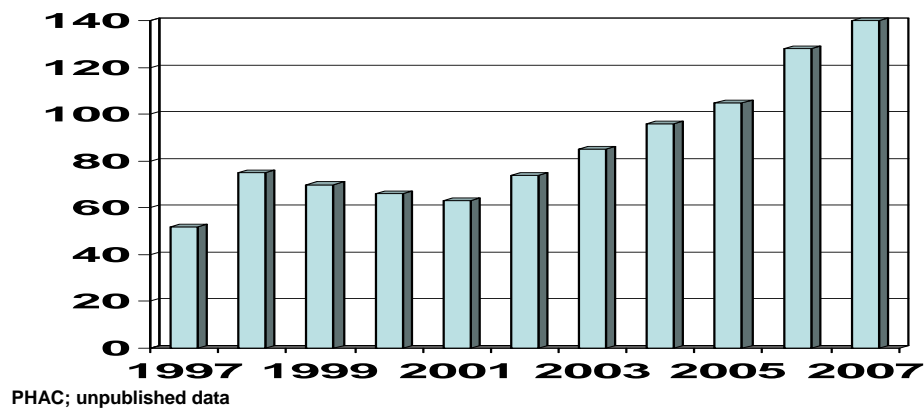
Brief history of listeriosis in Canada

- It was not until several large, common-source outbreaks of listeriosis occurred in North America and Europe during the 1980s that the significance of foods as the primary route of transmission for human exposure to Lm was recognized
- First outbreak in Canada, in 1981 was due to contaminated coleslaw (41 cases, 17 deaths)
- In Canada, there is on average about 100 confirmed cases per year, almost all sporadic



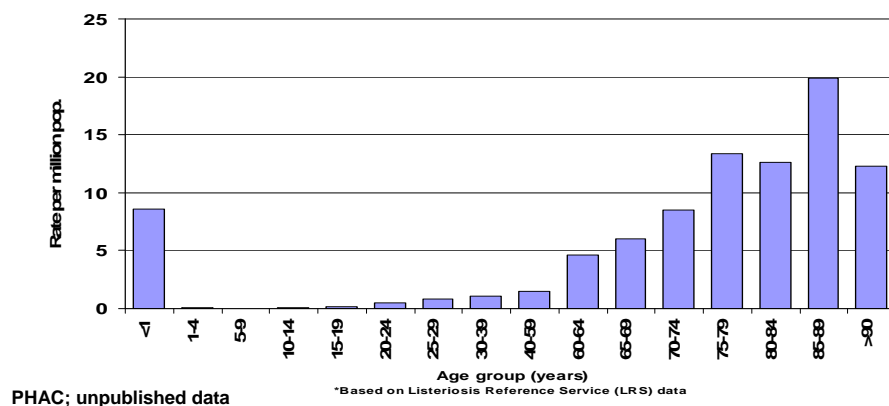
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Listeriosis Cases in Canada (1997-2007)



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Incidence of Listeriosis in Canada (rate per million population) as a function of age group (1995-2004)



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Foodborne Listeriosis Outbreaks in Canada

Year	Province	Source	# Cases (deaths)
1981	Nova Scotia	Coleslaw	41 (17)
1996	Ontario	Imitation crab meat	2
2001	Manitoba	Whipping cream	25
2002	British Columbia	Soft cheese (cheese ripening solution)	47
2002	British Columbia	Soft cheese (storage water)	86
2008	Quebec	Cheese	36(2)
2008	7 provinces	Deli-meat	57 (22)

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Internal Reports



Internal Reviews - Shared Recommendations

What worked well:

- Generally, CFIA, PHAC and HC managed the outbreak well
- Federal partners worked effectively together; effective coordination for sample testing and transfer, information sharing
- Good cooperation and coordination with provinces and territories

Areas for improvement:

- **Improve clarity of roles** - Need to revisit the Foodborne Illness Outbreak Response Protocol (FIORP) to guide a multi-jurisdictional response
- **Capacity** - Need to address capacity (surge and ongoing) issues, particularly demands on technical capacity
- **Communications** – Need to improve communications internally in federal government and externally with key stakeholders, P/Ts and the public

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Early Actions After the Outbreak



Early Actions

Improved Federal Response to Foodborne Illness Outbreaks:

- Actions to improve the overall preparedness and response capacity of the food safety system
 - Improve government coordination by updating FPT protocols
 - Enhance leadership capacity for outbreak response
 - Consolidating Incident Command Structure
 - Pilot test surge capacity
 - Improve risk communication during foodborne emergencies
 - Target communication to vulnerable populations
 - Develop GoC food safety website

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Building on Action Already Taken

The GoC has taken concrete actions to-date:

- Food and Consumer Safety Action Plan has invested money in increased inspection and monitoring, mostly focused on imported products
- Ongoing FPT engagement on food safety and foodborne illness coordination

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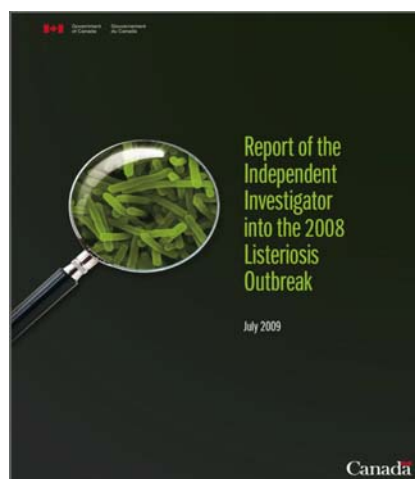
Changes to CFIA Meat and Poultry *Listeria* Directives

The CFIA is implementing major enhanced controls

- Under the new requirements, production facilities must implement food contact surface testing for *Listeria* spp. and/or Lm
- In addition, the CFIA has increased the frequency of its own environmental and end-product monitoring
- The enhanced requirements focus on early detection and control of *Listeria* by introducing new testing and reporting requirements for industry, e.g., positive test results from all FCS must now be immediately reported to the CFIA
- Where applicable, operators must also implement the "Risk based verification sampling of RTE Meat and Poultry Products"
- Companies must perform trend analysis on their test results

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Weatherill Report



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Independent Investigator Report - Overview

- Report focused on:
 - Overview of Canadian food safety system
 - Events surrounding the outbreak
 - Response coordination among FPT partners
 - Handling of communications to the public and medical community
 - Progress made since the outbreak
 - Federal and multi-jurisdictional governance of food safety
- Contains 57 recommendations

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Weatherill Report Recommendation 11

Health Canada should complete the revision of its 2004 *Listeria* Policy, by no later than March 2010 and ensure that:

- the Policy outlines clearly and concisely the expected results for all identified food products where *Listeria* is a potential threat to human health, consistent with international standards
- risk categories of RTE product are retained, although they should be more clearly defined;
- post-processing measures that control Lm are considered when determining product risk categories

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***Listeria* control in Canada**

Update of the HC Lm policy – 2004 vs. 2010

1) The definition of RTE foods in which growth of *Lm* can or cannot occur have been modified and/or developed to be in-line with the International Codex Alimentarius standards:

Growth of *Lm* is assumed not to occur in RTE foods if the pH and a_w values falls within the range below under reasonably foreseeable conditions of distribution, storage and use until the end of its stated shelf-life

- pH < 4.4, regardless of a_w ;
- a_w < 0.92, regardless of pH;
- combination of factors (e.g., pH < 5.0 and a_w < 0.94);
- frozen foods

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***Listeria* control in Canada**

Update of the HC Lm policy – 2004 vs. 2010

The compliance action decision tree, including environmental testing for *Listeria* spp. and end-product testing for *Lm*, has been completely modified and further sub-divided:

– Risk-based:

- Differentiation in the approach depending if the line is producing Category 1 or Category 2 foods (i.e., Figure 1 vs Figure 2)
- Differentiation between FCS testing and non-FCS testing (i.e., Figures 1 & 2 vs. Figure 3)

– Includes more details related to sampling:

- Method recommendation for environmental sample collection (i.e., MFLP-41A & B)
- Specify, at certain steps, to hold products pending test results
- Indication on when to notify the regulatory authority of unsatisfactory results
- Recording of results for trend analysis (which will provide information on frequency of testing and location)
- Indication of how to determine that *Listeria* control is resumed (e.g., hold and test)

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Listeria control in Canada

Update of the HC Lm policy – 2004 vs. 2010

New end-product compliance criteria have been developed to be in-line with the International Codex Alimentarius standards:

Categories	Action level for <i>Lm</i>	Nature of concern	Level of priority
1) RTE foods in which growth of <i>Lm</i> <u>can</u> occur until the end of shelf life	Detected in 125 g (5 x 25 g)	Health Risk 1	High
2A) RTE foods in which a <u>limited</u> potential for growth of <i>Lm</i> to levels not greater than 100 CFU/g can occur until the end of shelf life	> 100 CFU/g	Health Risk 2	Medium-low
2B) RTE foods in which growth of <i>Lm</i> <u>cannot</u> occur until the end of shelf life.			Low

Note: The 2004 version had 3 categories: 1) linked to outbreak and/or rated "high-risk" in HHS/USDA assessment (absence in 50g); 2) support the growth of *Lm* with SL > 10 days (absence in 25 g) and 3) support the growth of *Lm* with SL ≤ 10 days or does not support the growth of *Lm* (action level 100 CFU/g with different level of health risk assigned based on GMP status).

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Nothing microbes do, whether under the duress imposed by antimicrobials or from some less evident pressure, should surprise us. It's their world; we only live in it.

-Sepkowitz. K.A.

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Thank you for listening!



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 Santé Canada Health Canada

