MICROBIAL RISK ASSESSMENT & RISK MANAGEMENT

Support to Capacity Building and Implementation of International Food Safety Standards in ASEAN Countries (GCP/RAS/280/JPN)
17-19 September 2012, Royal Princess Hotel, Bangkok

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OUTLINE

• Why should we be interested in food safety?
• Assessing risks
  – a systematic approach
  – An example (*Listeria monocytogenes*)
• Managing risks
  • HACCP: how NASA and space travel helped improve food safety back at home
• The benefits of MRA and RM
• Some valuable resources
• Conclusions (and two suggestions)
Objective

OBJECTIVE 4

• To discuss and identify capacity building needs and identified priorities
### Relevance?

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Why should we be interested in food safety?
FOOD POISON ALERT

2 million cases a year...why no action?
The map shows food poisoning outbreaks in the United States that have been reported in the last few months. The outbreaks involve *Campylobacter jejuni*, *Clostridium botulinum*, *E. coli* (often O157:H7), *Listeria monocytogenes*, norovirus, *Shigella*, *Salmonella*.

The burden of foodborne disease is not well defined in many countries or regions or on a global level. The World Health Organization (WHO), in conjunction with other national public health agencies, is coordinating a number of international activities designed to assist countries in the strengthening of disease surveillance and to determine the burden of acute gastroenteritis. These data can then be used to estimate the following situations: (1) the burden associated with acute gastroenteritis of foodborne origin, (2) the burden caused by specific pathogens commonly transmitted by food, and (3) the burden caused by specific foods or food groups.
# Foodborne Disease in Australia: The OzFoodNet Experience

Martyn D. Kirk,1,2 Ian McKay,1 Gill V. Hall,2 Craig B. Dalton,3 Russell Stafford,4 Leanne Unicomb,2 and Joy Gregory5

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## Estimated incidence of diseases potentially transmitted by food and research summary findings from selected OzFoodNet Studies, 2001–2007.

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of cases reported nationally</th>
<th>Estimated no. of annual infectionsa (95% credible interval)</th>
<th>Estimated percentage of foodborne illnesses (95% credible interval)</th>
<th>Main food vehicles and research findings</th>
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<tr>
<td>Campylobacteriosis</td>
<td>~16,000</td>
<td>223,000 (93,800–362,800)</td>
<td>75 (67–83)</td>
<td>9.6 community cases per case reported to surveillance; infections acquired from chicken (50,000 cases), offal (3500 cases), and pets (8500 cases); low levels of fluoroquinolone resistance among human isolates; molecular typing <em>(flaA)</em> improves risk factor identification</td>
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<tr>
<td>Salmonella infection</td>
<td>~8400</td>
<td>48,700 (15,000–91,300)</td>
<td>87 (81–93)</td>
<td>7.6 community cases per case reported to surveillance; <em>Salmonella</em> Mississippi (~75 cases annually, 80% of cases in Tasmanian residents; drinking untreated was the water main risk factor, exposure to native birds was important); <em>Salmonella</em> Enteritidis (~380 cases annually, ~50 cases locally acquired annually, 75% of cases occurred in Queensland residents, predominantly phage type 26, absent in commercial egg-laying flocks)</td>
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<tr>
<td>Listeria infection</td>
<td>~60</td>
<td>120</td>
<td>98 (92–100)</td>
<td>Host factors were the most important predictor of disease, risky foods were commonly eaten; perinatal case-fatality rate, 25%; nonperinatal case-fatality rate, 25%</td>
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<tr>
<td>Shiga toxin-producing <em>Escherichia coli</em> infection</td>
<td>~80</td>
<td>3800 (1000–33,000)</td>
<td>65 (48–82)</td>
<td>High rate in South Australia because of intensive screening of bloody stool samples (2%-4% of bloody stool samples were stx positive); predominantly serotype O157; animal exposure was an important predictor of disease</td>
</tr>
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</table>
SCIENTIFIC REPORT OF EFSA AND ECDC

The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2010

European Food Safety Authority

European Centre for Disease Prevention and Control
The European Food Safety Authority and the European Centre for Disease Prevention and Control analysed the information on the occurrence of zoonoses and food-borne outbreaks in 2010 submitted by 27 European Union Member States. In 2010, **99,020 salmonellosis cases in humans** were reported and the decreasing trend in case numbers continued. Most Member States met their Salmonella reduction targets for poultry, and Salmonella is declining in these populations. In foodstuffs, Salmonella was most often detected in fresh broiler and turkey meat. **Campylobacteriosis was the most commonly reported zoonosis with 212,064 human cases.** Campylobacter was most often detected in fresh broiler meat. The number of human listeriosis cases decreased slightly to 1,601. Listeria was seldom detected above the legal safety limit from ready-to-eat foods at retail. A total of **4,000 confirmed verotoxigenic Escherichia coli (VTEC) infections** were reported and this number has been increasing since 2008. VTEC was also observed in food and animals. The numbers of human yersiniosis cases have been decreasing in recent years and, 6,776 cases were reported in 2010. Yersinia enterocolitica was isolated also from pig meat and pigs; 133 cases of **Mycobacterium bovis** and 356 cases of brucellosis in humans were also reported. The prevalence of bovine tuberculosis in cattle increased, and the prevalence of brucellosis decreased in cattle, sheep and goat populations. **Trichinellosis and echinococcosis** caused 223 and 750 confirmed human cases, respectively. These parasites were mainly detected in wildlife. The number of **Q fever** cases in humans decreased to 1,414. In animals Q fever was found in domestic ruminants. There were two human cases of rabies in 2010 and the number of rabies cases in animals slightly increased. Most of the **5,262 reported food-borne outbreaks** were caused by Salmonella, viruses, Campylobacter and bacterial toxins and the main food sources were eggs, mixed or buffet meals and vegetables.
Put another way, how much illness in the United States is caused by foodborne pathogens? It sounds like a simple question. Getting a reasonable answer, however, is far from simple. The basic problem lies in the fact that only a small fraction of foodborne disease cases get reported through official (or unofficial) reporting systems. Calculating the “real” rate of foodborne illness requires development of models that use reported cases as a starting point to estimate underlying disease rates. Given the plethora of pathogens that can be transmitted through foodborne routes, this is a complex, and somewhat daunting, process. It is, however, necessary for assessing the safety of foods and developing strategies for disease prevention.
To better quantify the impact of foodborne diseases on health in the United States, we compiled and analyzed information from multiple surveillance systems and other sources. We estimate that foodborne diseases cause approximately **76 million illnesses**, **325,000 hospitalizations**, and **5,000 deaths in the United States each year**. Known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths. Three pathogens, Salmonella, *Listeria*, and *Toxoplasma*, are responsible for 1,500 deaths each year, more than 75% of those caused by known pathogens, while unknown agents account for the remaining 62 million illnesses, 265,000 hospitalizations, and 3,200 deaths.
Estimates of foodborne illness can be used to direct food safety policy and interventions. We used data from active and passive surveillance and other sources to estimate that each year 31 major pathogens acquired in the United States caused 9.4 million episodes of foodborne illness (90% credible interval [CrI] 6.6–12.7 million), 55,961 hospitalizations (90% CrI 39,534–75,741), and 1,351 deaths (90% CrI 712–2,268).

Most (58%) illnesses were caused by norovirus, followed by nontyphoidal Salmonella spp. (11%), Clostridium perfringens (10%), and Campylobacter spp. (9%).

Leading causes of hospitalization were nontyphoidal Salmonella spp. (35%), norovirus (26%), Campylobacter spp. (15%), and Toxoplasma gondii (8%).

Leading causes of death were nontyphoidal Salmonella spp. (28%), T. gondii (24%), Listeria monocytogenes (19%), and norovirus (11%).

These estimates cannot be compared with prior (1999) estimates to assess trends because different methods were used. Additional data and more refined methods can improve future estimates.
Most human extraintestinal Escherichia coli infections, including those involving antimicrobial resistant strains, are caused by the members of a limited number of distinctive E. coli lineages, termed extraintestinal pathogenic E. coli (ExPEC), that have a special ability to cause disease at extraintestinal sites when they exit their usual reservoir in the host's intestinal tract. Multiple lines of evidence suggest that many of the ExPEC strains encountered in humans with urinary tract infection, sepsis, and other extraintestinal infections, especially the most extensively antimicrobial-resistant strains, may have a food animal source, and may be transmitted to humans via the food supply. This review summarizes the evidence that food-borne organisms are a significant cause of extraintestinal E. coli infections in humans.
Royal Society names refrigeration most significant invention in the history of food and drink

13 September 2012

The Royal Society, the UK’s national academy of science, has today named the fridge, pasteurised milk, and the tin can as the three most significant inventions in the history of food and drink. These relatively modern innovations outsored more ancient inventions including the fishing net, the plough, and the cork.

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<td>1. Refrigeration</td>
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<td>2. Pasteurisation / sterilisation</td>
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<td>4. The oven</td>
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<td>6. Threshing machine/combine harvester</td>
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<td>8. Selective breeding / strains</td>
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<td>9. Grinding / milling</td>
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<td>10. The plough</td>
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<td>11. Fermentation</td>
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<tr>
<td>12. The fishing net</td>
</tr>
<tr>
<td>13. Crop rotation</td>
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<tr>
<td>14. The pot</td>
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<tr>
<td>15. The knife</td>
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<tr>
<td>16. Eating utensils</td>
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<tr>
<td>17. The cork</td>
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<tr>
<td>18. The barrel</td>
</tr>
<tr>
<td>19. The microwave oven</td>
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<tr>
<td>20. Frying</td>
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</tbody>
</table>
Changing global factors that affect national food safety systems

- Increasing volume of international trade.
- Expanding international and regional bodies and resulting legal obligations.
- Increasing complexity of food types and geographical sources.
- Intensification and industrialization of agriculture and animal production.
- Increasing travel and tourism.
- Changing food handling patterns.
- Changing dietary patterns and food preparation preferences.
- New food processing methods.
- New food and agricultural technologies.
- Increasing resistance of bacteria to antibiotics.
- Changing human/animal interactions with potential for disease transmission.
Introduction to Risk Analysis

• Food safety is a fundamental public health concern, and achieving a safe food supply poses major challenges for national food safety officials.

• An array of food-borne hazards, both familiar and new, pose risks to health and obstacles to international trade in foods.

• These risks must be assessed and managed to meet growing and increasingly complex sets of national objectives.

• Risk analysis is a systematic, disciplined approach for making food safety decisions.

• Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems.
HAZARDS AND RISKS
Vital distinction

Hazard
The potential for harm
Something adverse can happen

Risk
The likelihood of harm and the consequences
But will something adverse happen
Contrasting approaches

- **Philosophy** (personal belief)
- **Intuitive risk assessment**

- **Objective, evidence driven**
- **Science based Risk Assessment**

HAZARD

A food-borne hazard is defined by Codex as “a biological, chemical or physical agent in, or condition of, food, with the potential to cause an adverse health effect.”
BIOLOGICAL HAZARDS

**Infectious bacteria**
- Salmonella
- Campylobacter
- E.coli (VTEC)
- Vibrio cholerae
- Vibrio parahaemolyticus
- Shigella
- Listeria monocytogenes

**Toxin producing microorganisms**
- Staph. aureus
- Bacillus cereus
- Clostridium perfringens
- Clostridium botulinum
- Fungi (mycotoxins)

**Others Biological hazards:**
- Protozoa
- Parasites
- Prions
RISK

• A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food

Risk Analysis:
• A structured and multi-disciplinary approach to identifying and, where necessary, reducing risk.
Why Risk Analysis?

• Estimate the risk to human health & safety
• To identify & implement appropriate measures to control the risks
• To communicate with the stakeholders about the risks & measures applied
• To support & improve the development of standards
• To address food safety issues that result from emerging hazards or breakdown of Food Control System
• For effective decision making/prioritize programs on food safety based on resources
PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

INTRODUCTION

1. SCOPE

2. DEFINITIONS

3. GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT

4. GUIDELINES FOR APPLICATION
   4.1 General considerations
   4.2 Statement of purpose of risk assessment
   4.3 Hazard identification
   4.4 Exposure assessment
   4.5 Hazard characterization
   4.6 Risk characterization
   4.7 Documentation
   4.8 Reassessment
DEFINITIONS

Risk
A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk analysis
A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment
A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk characterization
The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk communication
The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties.

Risk estimate
Output of risk characterization.

Risk management
The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Hazard
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard characterization
The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of microbiological risk assessment, the concerns relate to micro-organisms and/or their toxins.
GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT

1. Microbiological risk assessment should be soundly based upon science.
2. There should be a functional separation between risk assessment and risk management.
3. Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment and risk characterization.
4. A microbiological risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.
5. The conduct of a microbiological risk assessment should be transparent.
6. Any constraints that affect the risk assessment, such as cost, resources or time, should be identified and their possible consequences described.
7. The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
8. Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
9. A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
11. A microbiological risk assessment may need re-evaluation, as new relevant information becomes available.
PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)

CAC/GL 63-2007

1. **PRINCIPLE 1**: Protection of human health is the primary objective in MRM.
2. **PRINCIPLE 2**: MRM should take into account the whole food chain.
3. **PRINCIPLE 3**: MRM should follow a structured approach.
4. **PRINCIPLE 4**: MRM process should be transparent, consistent and fully documented.
5. **PRINCIPLE 5**: Risk managers should ensure effective consultations with relevant interested parties.
6. **PRINCIPLE 6**: Risk managers should ensure effective interaction with risk assessors.
7. **PRINCIPLE 7**: Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.
8. **PRINCIPLE 8**: MRM decisions should be subject to monitoring and review and, if necessary, revision.
RISK ANALYSIS

normative interactive iterative

Fig. 1 Schematic diagram of risk analysis
Risk Assessment: Scientifically based process

**Hazard identification**
Availability of public health data & a preliminary estimate of the sources, frequency & amount of the agent under consideration

**Hazard characterization**
The qualitative &/or quantitative Evaluation of the nature of the adverse health effects associated With B,C,P hazards (dose response)

**Exposure Assessment**
The qualitative &/or quantitative estimation, Including attendant uncertainties, of the Probability of occurrence & severity of Potential adverse health effects.

**Risk Characterization**
The qualitative &/or quantitative Evaluation of the likely intake of B,P,C agents via food
Risk Management Process Steps

1. Initiation: Identify objectives, the activity to be managed, the stakeholders / risk receptors

2. Scope Definition: Define Boundaries, Identify Needs of Stakeholders

3. Risk Assessment
   3a. Risk Analysis:
       - Hazard Identification
       - Likelihood Analysis
       - Consequence Analysis
       - Risk Estimation/ Ranking
   3b. Risk Acceptability Evaluation: Do we need to reduce risk?

4. Risk Control: Add/ Modify Risk Controls (New programs/ legislation, resource allocation, priority setting)

5. Risk Monitoring: Carry on with Activity / Monitor Controlled Risks / Audit

6. Learning: Broaden Scope, Increase Detail to Reduce Uncertainty

Continuous Improvement Loop

7. Stakeholder Participation
   - Communicate Risks With Stakeholders
   - Consider Stakeholder Needs/ Risks/ Costs/ Benefits in Decisions

Learning Loop

Steps of microbial food safety risk assessment.

Preliminary risk mgmt. activities
- Identify food safety issues
- Develop risk profile
- Estb. Goals of risk mgmt
- Estb. RA policy
- Rank risks

Identification & selection of risk Mgmt. options
- Identify possible options
- Evaluate options
- Select preferred options

Implementation of risk mgmt. decision
- Validate control where necessary
- Implement selected controls
- Verify implementation

Monitoring & Review
- Monitor outcomes of control
- Review controls where indicated
Risk Communication.

• Interactive exchange of information and opinions concerning risks among risks assessors, risk managers, consumers, academicians & other interested parties

• Includes the explanation of risk assessment findings and the basis of risk management decisions

• It helps to provide timely, relevant & accurate information to the stakeholders
Risk Communication:

Steps which require Effective risk communication

Preliminary risk mgmt. activities
- Identify food safety issues
- Develop risk profile
- Estb. RA policy
- Rank risks

Identification & selection of risk Mgmt. options
- Identify possible options
- Evaluate options
- Select preferred options

Implementation of risk mgmt. decision
- Implement selected controls

Monitoring & Review
- Review controls where indicated
Distribution of illnesses by food type in 1,565 foodborne outbreaks caused by a single food type and reported to CDC’s National Foodborne Disease Outbreak Surveillance System, 2003-2008
Relative rates of laboratory-confirmed infections with Campylobacter, STEC O157, Listeria, Salmonella, and Vibrio, compared with 1996–1998 rates, by year

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<td>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</td>
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<td>CAC/GL 78-2011</td>
<td>Guidelines for the Control of <em>Campylobacter</em> and <em>Salmonella</em> in Chicken Meat</td>
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<tr>
<td>CAC/GL 61-2007</td>
<td>Guidelines on the Application of General Principles of Food Hygiene to the Control of <em>Listeria monocytogenes</em> in Ready-to-Eat Foods</td>
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<td>CAC/GL 14-1991</td>
<td>Guide for the Microbiological Quality of Spices and Herbs Used in Processed Meat and Poultry Products</td>
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<td>CAC/GL 73-2010</td>
<td>Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic <em>Vibrio</em> Species in Seafood</td>
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<tr>
<td>CAC/GL 21-1997</td>
<td>Principles for the Establishment and Application of Microbiological Criteria for Foods</td>
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Risk Assessments

- Interagency Risk Assessment for the Public Health Impact of Highly Pathogenic Avian Influenza Virus in Poultry, Shell Eggs, and Egg Products (May 2010)
- Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef (Mar 2002)
- Risk Assessment of *E. coli* O157:H7 in Ground Beef (Sep 2001)
- Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* (non-O157 STEC)
- Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats (May 2010)
- Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat and Poultry Products (Sep 2005)
- Risk Assessment for *Listeria monocytogenes* in Deli Meat (May 2003)
- Risk Assessment for *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products (Oct 2005)

Risk Assessment Example

FSIS Comparative Risk Assessment for Listeria monocytogenes In Ready-to-eat Meat and Poultry Deli Meats

Prepared by

Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service
United States Department of Agriculture

May 2010

BEWARE MISMATCH!!

a) **Prevalence** of *L. monocytogenes* in federally inspected facilities from the all RTE monitoring programs

b) **Incidence** of listeriosis per 100,000 from CDC FoodNet surveillance
Background

- *Listeria monocytogenes* is an important foodborne pathogen, estimated to cause approximately 2,500 illnesses, 2,300 hospitalizations, and 500 deaths each year in the United States. In an effort to understand better the sources of foodborne *L. monocytogenes* infection, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS), working collaboratively, developed a quantitative microbial risk assessment for *L. monocytogenes* that compared the risk of listeriosis among twenty-three categories of ready-to-eat (RTE) foods. The results of the risk assessment, completed in 2003, indicated that deli meats pose the greatest risk for listeriosis, accounting for approximately 1,600 illnesses per year.
Methods

• **Stage I:** Prevalence and Level of *L. monocytogenes* in RTE Meat and Poultry deli meats at retail

• **Stage II:** Growth of *L. monocytogenes* from retail purchase to consumption

• **Stage III:** Deli Meat Consumption
  – Consumer Storage Time and Temperature
  – Serving Sizes and Categories

• **Stage IV:** *L. monocytogenes* Dose-response Relationship
A conceptual model of the stages in this risk assessment and the critical inputs considered within each stage

**Retail occurrence**
- Product type (prepackaged or retail-sliced deli meat)

**Growth**
- Exponential growth rate (EGR)
- Growth inhibitor usage
- Storage time
- Storage temperature

**Consumption**
- Serving size
- Number of servings

**Dose-response**
- Age of consumer (neonatal, intermediate, elderly)

**Outputs**
- Annual illnesses and deaths
- Annual mortality by Age
- Risk of death per serving
Results

• Estimated Deaths and Illnesses by Slicing Location and Growth Inhibitor Use
• Comparison with other food groups
• Sensitivity Analyses
  – Consumer Storage Times / Temperatures
  – Shelf Life
  – Total Number of Deaths
• Relative Impacts of Model Variables
Conclusions

- Based on this analysis, RTE meat and poultry products sliced at retail are approximately **4.88 times more risky** on an annual basis than prepackaged product in terms of deaths from listeriosis. Retail-sliced products are associated with 83% of all *L. monocytogenes* deaths from deli meats. This percentage is largely unaffected by consumer storage time, product shelf life, or total number of *L. monocytogenes* associated deaths.

- This risk assessment shows that the interaction of high *L. monocytogenes* prevalence and concentrations in retail-sliced product together with the lack of growth inhibitors for some product are the primary drivers of the risk of death from listeriosis. Potentially, retail delis have two options available to lower this risk. First, retail delis may wish to consider using product that incorporates growth inhibitors, when available. Second, retail delis can exert controls on the transmission and cross-contamination of *L. monocytogenes* within the retail environment.
Food safety ultimately the producers responsibility, says professor

By Joe Whitworth, 13-Sep-2012

Related topics: Cleaning / Safety / Hygiene, Quality & Safety, Contamination

The ultimate responsibility for food safety lies with producers and not auditors, inspectors or government agencies, according to Doug Powell from Kansas State University.

In a paper published in Science Direct, Doug Powell et al. critiqued the limits food safety audits and inspections and provided recommendations for strengthening the system.

In the "Audits and inspections are never enough: A critique to enhance food safety" paper, they noted there have been many foodborne illness outbreaks linked to food processors that have passed third-party audits and inspections, raising questions about the utility of both.

They identified audit reports as useful if the purchaser who requires them reviews the results, understands the risks addressed by the standards and makes risk-reduction decisions based on the results.

"From past examples, there appears to be a disconnect between what auditors provide (a snapshot) and what buyers believe they are doing (a full verification of product and process)."
Internal and external food safety audits are conducted to assess the safety and quality of food including on-farm production, manufacturing practices, sanitation, and hygiene. Some auditors are direct stakeholders that are employed by food establishments to conduct internal audits, while other auditors may represent the interests of a second-party purchaser or a third-party auditing agency. Some buyers conduct their own audits or additional testing, while some buyers trust the results of third-party audits or inspections. Third-party auditors, however, use various food safety audit standards and most do not have a vested interest in the products being sold. Audits are conducted under a proprietary standard, while food safety inspections are generally conducted within a legal framework. There have been many foodborne illness outbreaks linked to food processors that have passed third-party audits and inspections, raising questions about the utility of both. Supporters argue third-party audits are a way to ensure food safety in an era of dwindling economic resources. Critics contend that while external audits and inspections can be a valuable tool to help ensure safe food, such activities represent only a snapshot in time. This paper identifies limitations of food safety inspections and audits and provides recommendations for strengthening the system, based on developing a strong food safety culture, including risk-based verification steps, throughout the food safety system.
SOME RESOURCES
### ISO 22000:2005

**Food safety management systems -- Requirements for any organization in the food chain**

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The World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) are in the forefront of the development of risk based approaches for the management of public health hazards in food.
Food safety

Meetings on microbiological risks

WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGiSAR)
5 June 2009

2nd Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance, 20-24 October 2008
20 October 2008

Benefits and Potential Risks of the Lactoperoxidase system of Raw Milk Preservation,
28 November - 2 December 2005
28 November 2005

18 March 2004

1 December 2003

The Application of Risk Communication to Food Standards and Safety Matters, a Joint FAO/WHO Expert Consultation, Rome, Italy, 2-6 February 1998
6 February 1998

31 January 1997

Microbiological risks publications

Enterohaemorrhagic *Escherichia coli* in Raw Beef and Beef Products: Approaches for the Provision of Scientific Advice: Meeting Report, MRA Series 18

Microbiological Risk Assessment Series, No. 18

Risk assessment of *Vibrio parahaemolyticus* in seafood, MRA Series 16

Risk assessment of *Campylobacter* spp. in broiler chickens, MRA Series 11 & 12

*Salmonella* and *Campylobacter* in Chicken Meat: Meeting Report, MRA Series 19

Risk Characterization of Microbiological Hazards in Food: Guidelines, MRA Series 17

Viruses in food: scientific advice to support risk management, MRA Series 13

Exposure assessment of microbiological hazards in food: Guidelines, MRA Series 7

*Enterobacter sakazakii* (Cronobacter spp.) in powdered follow-up formulae, MRA Series 15

Microbiological hazards in fresh leafy vegetables and herbs, MRA Series 14

Guidelines for the safe preparation, storage and handling of powdered infant formula

*Enterobacter sakazakii* and other microorganisms in powdered infant formula: meeting report, MRA Series 6

Food safety risk analysis - A guide for national food safety authorities

Risk assessment of cholera-geneic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade, MRA Series 9

*Enterobacter sakazakii* and *Salmonella* in powdered infant formula: Meeting report, MRA Series 10

Avian Influenza: Protecting human health from farm to fork (Video)


Risk assessment of *Vibrio vulnificus* in raw oysters, MRA Series 8

Benefits and Potential Risks of the Lactoperoxidase system of Raw Milk Preservation, 28 November - 2 December 2005

Risk assessment of *Listeria monocytogenes* in ready-to-eat foods, MRA Series 4 & 5

Links related to microbiological risks in food

Microbiological risks and JEMRA

The Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) began in 2000 in response to requests from the Codex Alimentarius Commission and FAO and WHO Member Countries and the increasing need for risk based scientific advice on microbiological food safety issues.

JEMRA aims to develop and optimise the utility of Microbiological Risk Assessment (MRA) as a tool to inform actions and decisions aimed at improving food safety and to make it equally available to both developing and developed countries.

Risk management

Microbiological risk management is a dynamic process, using data inputs and decision-making parameters that may change over time.

As microbiological food safety issues are brought to the attention of risk managers, there needs to be a systematic preliminary process that brings particular issues into focus and guides further action.

Using microbiological risk assessment in food safety risk management is an area that is still developing. For MRA to become a truly useful decision-support tool there is a need for risk managers to understand when and how it can be used.

JEMRA

Joint FAO/WHO expert meetings on microbiological risk assessment

Risk assessments of pathogens
Guidelines for risk assessment of microbiological hazards in food and water
The interaction between microbiological risk assessment and management
JEMRA meetings
JEMRA: Call for data and experts

In response to the World Health Assembly food safety resolution in 2000 and a request from the Codex Alimentarius Commission, WHO and FAO embarked on a programme of activities with the objective of conducting risk assessments for the Codex Committee on Food Hygiene and member countries. The Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) focuses on the following main areas of work: providing risk assessments for selected pathogens (Pathogen Commodity Combination Risk Assessments) to the Codex Alimentarius Commission and to Member States, developing Guidelines for Risk Assessment of Microbiological Hazards in Food and Water and providing expert advice on Risk Management.

http://www.who.int/foodsafety/micro/jemra/en/
1. In response to the World Health Assembly food safety resolution in 2000 and a request from the Codex Alimentarius Commission, WHO and FAO embarked on a programme of activities with the objective of conducting risk assessments for the Codex Committee on Food Hygiene (CCFH) and Member countries.

2. Since 2000 FAO and WHO have continued to develop risk assessments on a number of pathogens/commodities combinations including *Salmonella* spp. in broilers/eggs, *Listeria monocytogenes* in ready-to-eat foods and *Vibrio vulnificus* in oysters. See above links to the different risk assessments.

3. To facilitate the use and uptake of these risk assessments by food safety risk managers, FAO and WHO are developing new user friendly web-based tools allowing the comparison of the risk reduction impact of different interventions along the food-chain. The first published tool is on *C. sakazakii* in Powdered Infant Formula (PIF). Others in the development phase address sampling and *Salmonella* and *Campylobacter* in chickens.

Food hygiene

Basic texts

Fourth edition

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome, 2009
People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to ensure that food is safe and suitable for consumption.

The Codex basic texts on food hygiene promote understanding of how rules and regulations on food hygiene are developed and applied. The General Principles of food hygiene cover hygiene practices from primary production through to final consumption, highlighting the key hygiene controls at each stage. This publication also contains the most internationally used description of the Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application. This fourth edition includes texts adopted by the Codex Alimentarius Commission up to 2009. The texts will be of use to government authorities, food industries, food handlers and consumers, as well as teachers and students of food hygiene.
FOOD HYGIENE (BASIC TEXTS)
Fourth edition

PREFACE

RECOMMENDED INTERNATIONAL CODE OF PRACTICE
GENERAL PRINCIPLES OF FOOD HYGIENE
CAC/RCP 1-1969

PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION
OF MICROBIOLOGICAL CRITERIA FOR FOODS
CAC/GL 21-1997

PRINCIPLES AND GUIDELINES FOR THE CONDUCT
OF MICROBIOLOGICAL RISK ASSESSMENT
CAC/GL 30-1999

PRINCIPLES AND GUIDELINES FOR THE CONDUCT
OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)
CAC/GL 63-2007

GENERAL STANDARD FOR IRRADIATED FOODS
CODEX STAN 106-1983

RECOMMENDED INTERNATIONAL CODE OF PRACTICE
FOR RADIATION PROCESSING OF FOOD
CAC/RCP 19-1979

GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD
HYGIENE TO THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS
CAC/GL 61-2007
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<td>Guidelines for the application of the HACCP system</td>
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Logic sequence for application of HACCP

1. Assemble HACCP team
2. Describe product
3. Identify intended use
4. Construct flow diagram
5. On-site confirmation of flow diagram
6. List all potential hazards
   Conduct a hazard analysis
   Consider control measures
7. Determine CCPs
8. Establish critical limits for each CCP
9. Establish a monitoring system for each CCP
10. Establish corrective actions
11. Establish verification procedures
12. Establish documentation and record-keeping
* Proceed to the next identified hazard in the described process.
** Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan
DEFINITION OF MICROBIOLOGICAL CRITERION

A microbiological criterion for food defines the acceptability of a product or a food lot based on the absence or presence or number of micro-organisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.
GUIDELINES FOR THE CONTROL OF CAMPYLOBACTER AND SALMONELLA IN CHICKEN MEAT

CAC/GL 78-2011

This document provides guidance on Good Hygienic Practices and hazard-based control measures as well as approaches for risk-based control of these two pathogens on chicken meat.


Scientific references supporting hazard-based control measures published up to 2009 are available at the following link:

http://www.who.int/foodsafety/micro/jemra/guidelines/scientific_references_cxg_078.pdf
Food Safety Risk Profile for *Salmonella* species in broiler (young) chickens

Compiled by the CCFH Working Group on Guidelines for control of *Campylobacter* and *Salmonella* spp. in broiler (young bird) chicken meat

June 2007

Food Safety Risk Profile for Campylobacter species in broiler (young) chickens

Compiled by the CCFH Working Group on Guidelines for control of Campylobacter and Salmonella spp. in broiler (young bird) chicken meat

June 2007

http://www.foodsafety.govt.nz/elibrary/industry/Food_Safety-Compiled_Ccfh.pdf
1. Manage grandparent flocks
2. Eggs to hatchery
3. Hatchery
4. Receive day-old chicks to Parent flocks
5. Manage parent flocks
6. Eggs to hatchery
7. Hatchery
8. Receive day-old chicks at grower sheds
9. Grow broiler chickens
10. Depopulate
11. Transport to slaughterhouse
12. Receive at slaughterhouse
13. Ante-mortem inspection
14. Slaughter
15. Dress
16. Post-mortem inspection
17. Chill carcass (air, spray or immersion)
18. Pack whole carcass or portion carcass or other (added value)
19. Chill or freeze
20. Storage
21. Transport
22. Wholesale premises
23. Transport
24. Retail premises
25. Transport
26. Consumer
WHAT IS THE ICMSF?
The International Commission on Microbiological Specifications for Foods (ICMSF, the Commission) was formed in 1962 through the action of the International Committee on Food Microbiology and Hygiene, a committee of the International Union of Microbiological Societies (IUMS). Through the IUMS, the ICMSF is linked to the International Union of Biological Societies (IUBS) and to the World Health Organization (WHO) of the United Nations.

PURPOSE
Our primary goal is to provide timely, science-based guidance to government and industry on appraising and controlling the microbiological safety of foods. The primary objectives of ICMSF include:
1. Provide the scientific basis for microbiological criteria and to promote principles for their establishment and application.
2. Overcome the difficulties caused by nations' varying microbiological standards and analytical methods.
Safe Quality Food
http://www.sqfi.com/

SQF 2000 Code
A HACCP-Based Supplier Assurance Code for the Food Manufacturing and Distributing Industries

6th Edition
AUGUST 2008
## Future challenges to microbial food safety

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<tr>
<td>Globalization</td>
<td>Reduced geographical barriers to spread (of new variants)</td>
<td>Inadequate sanitation: higher pathogen loads Global sourcing Intensified contact structures</td>
<td>Long and complex supply chains Varying hygiene levels</td>
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<tr>
<td>Food price/income level</td>
<td>Less profit margins; decreased investment in food safety</td>
<td>Preference for cheaper alternatives (e.g. less meat and butter; discounters; home brands)</td>
<td>Risk not clear</td>
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<td>Science and technology and industry</td>
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<td>Minimal processing</td>
<td>Adaptation</td>
<td>Less kill steps</td>
<td>Increased risk if not well controlled</td>
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<td>Innovation</td>
<td>New food animal species</td>
<td>Step change food innovation Smart packaging Bacteriophages</td>
<td>Smart labels</td>
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<td>Laboratory methods</td>
<td>Discovery of new pathogens or variants Omics approaches</td>
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<td>Increased observed risk</td>
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<td>Population growth</td>
<td>Polluted environments</td>
<td>Increased demand</td>
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<td>Migration</td>
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<td>Age structure</td>
<td>Increase in elderly More premature babies</td>
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<td>Increased risk</td>
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<td>Climate change and regional differences</td>
<td>Changing ecology</td>
<td>Droughts, floods Competition for land resources Movement of farms to new areas</td>
<td>Processing/distribution</td>
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<td>Water/energy savings cleaning, process and ingredient water quality</td>
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<td>Evolution</td>
<td>Emergence and transfer of virulence factors Antimicrobial resistance</td>
<td>New reservoirs</td>
<td>Increased survival</td>
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<td>Population contact structures</td>
<td>Species jumps (spill-over from epizootics or exploitation of new agricultural areas)</td>
<td>Contact zoonoses (MRSA, Q-fever)</td>
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<td>Consumer behavior</td>
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<td>Food choice</td>
<td>Psychrotrophs Re-emerging pathogens</td>
<td>Exotic/ethnic foods Regional products</td>
<td>No or mild processing, less heat treatment Increased pre-processing and packaging</td>
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<td>Information</td>
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<td>Surveillance</td>
<td>Identification of new pathogens Detection of unexpected events</td>
<td>Effectiveness of current controls</td>
<td>Changes in consumption patterns: who, what, where, why?</td>
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<td>Hygiene campaigns Attitude changes to accept safe technologies</td>
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<td>Targets for pathogen reduction</td>
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<td>Agro/bioterrorism</td>
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bites Sept.17/12

1. Don’t kiss animals and avoid poop: child hospitalized by E coli from cowpat in park, 6 others infected
2. Finland to OK raw milk sales?
3. Arrests over alleged food poisoning scam in NZ
4. Dallas restaurant inspections suffered as City Hall diverted revenue
5. Retailer double talk on produce safety
6. MEXICO denies salmonella in mangos exported to U.S. and Canada
7. JAMAICA looks to raise food safety standards for export market
8. Assessing a new technique for ensuring fresh produce remains Salmonella-free
9. UNITED ARAB EMIRATES: 1 dies, 15 hospitalised due to food poisoning in Sharjah
10. UNITED ARAB EMIRATES: Workers’ restaurants in Abu Dhabi scrutinised over food safety rules
11. CANADA: Health Hazard Alert: Various ground beef products may contain E. coli O157:H7 bacteria
12. BRITISH COLUMBIA: Health Hazard Alert: Certain Ponderosa Mushrooms brand Sliced Lobster Mushrooms may contain Listeria monocytogenes
PRO/MBDS is a special service of ProMED-mail for the Mekong Basin Disease Surveillance (MBDS) group of countries. These countries include The Kingdom of Cambodia, Yunnan province of People's Republic of China, Lao PDR, The Union of Myanmar, The Socialist Republic of Vietnam, and the Kingdom of Thailand.

http://www.promedmail.org/mbds
CONCLUSIONS
(and suggestions)
MICROBIAL RISK ASSESSMENT AND MANAGEMENT
Curriculum Development

• Develop an online set of modules meeting the needs of food safety, risk analysis and other areas relevant to ASEAN capacity building

• Curriculum could be developed by collaboration of University of Sydney and identified ASEAN university/ies

• Simple plan
  • Scope, learning outcomes, content, draft modules, review, finalise, online access
ASEAN Risk Analysis Support Group

• Central resource

• Objectives to support / promote / facilitate
  – Consistency
  – Learning by experience
  – Harmonisation
  – Mentoring
  – Peer review of risk assessments
  – Improved food safety, public health, trade
CONCLUSIONS

• Key terms defined and applied
  – Hazard
  – Risk
  – Risk profiling
  – Risk Analysis
  – Risk Assessment
  – Hazard identification
  – Hazard characterisation
  – Exposure assessment
  – Risk characterisation
  – Risk Management
  – Risk Communication