Listeria monocytogenes Regulation: Past, Present, and Future

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Food and Drug Administration
A Public Health Concern Emerges

“Listeria monocytogenes Regulatory History”
Emergence of a Public Health Concern

- In the 1980’s, a series of outbreaks associated with the consumption of coleslaw, pasteurized milk, and fresh soft cheeses led to recognition of *Listeria monocytogenes* as a foodborne pathogen that affected FDA regulated foods.

Age of *Listeria* Hysteria
Emergence of U.S Policy
Emergence of Policy

- The Known and Unknown
  - Several large and fatal outbreaks of listeriosis had occurred over a short period of time
    - Food was the vehicle
    - Mortality rate was high (approaching 40%)
      - Fetuses were particularly susceptible
  - Incidence of *L. monocytogenes* in food was unknown
Emergence of Policy

– Research on *L. monocytogenes* had been going on for decades.
  • Well known and characterized cause of disease in farm animals and occasional reports in humans
  • Organism’s habits were not known or well understood
  • Good methods for isolating the bacterium from food were not available (took as long as a month)
  • Quantitative methods were non-existent
U.S. Policy Emerges

- FDA policy established in 1985
  - Presence of the organism in a ready-to-eat food using the FDA detection method is a violation of the Federal, Food, Drug and Cosmetic Act, section 402(a) (1) and (4)
  - *L. monocytogenes* is a human pathogen which may be injurious to health and is considered an added substance.
- Interpretation was affirmed by a US District Court *(USA v Union Cheese Co, 1995)*
• In 1985, issued Compliance Policy Guides for pathogens in dairy products (CPG 7106.08)
  – Provided guidance for initiating legal action in cases involving products found to be improperly pasteurized, contaminated with pathogenic microorganisms, or prepared and packed under insanitary conditions
FDA Policy

• FDA Method
  – Originally based on a method for detection using a 250-g sample
  – In 1987, the sample size required for isolation was reduced to two 25-g samples

• Approximate ideal method sensitivity limit
  – 0.04 CFU/g for single 25-g sample
  – 0.02 CFU/g for two 25-g samples
USDA Policy

• In 1987, FSIS considered there to be a strong possibility that meat and poultry products could contain *L. monocytogenes*
USDA Policy

• In 1987, FSIS considered there to be a strong possibility that meat and poultry products could contain *L. monocytogenes* – FSIS expanded its testing/monitoring program for *L. monocytogenes* in meat and poultry products to emphasize cooked and ready-to-eat products
USDA Policy

• In 1987, FSIS considered there to be a strong possibility that meat and poultry products could contain *L. monocytogenes*

• FSIS policy is the same as that of FDA
  – Based on the definition of adulteration: *L. monocytogenes* in ready-to-eat foods is considered an added agent
USDA Policy

• In 1987, FSIS considered there to be a strong possibility that meat and poultry products could contain *L. monocytogenes.*

• FSIS policy is the same as that of FDA.

• In 1989, FSIS modified its policy to require action to be taken on lots for which monitoring samples of intact, retail packages were found to be positive for *L. monocytogenes.*
  
  – Included recall of current lots until test results are known and the agency is assured that corrective action has been successfully implemented.
U.S. Policy

• In 1991, the National Advisory Committee on Microbiological Criteria for Foods recommended control strategies to minimize the presence, survival, and multiplication of *L. monocytogenes* in foods
  – Development of effective surveillance systems for listeriosis
  – Targeted efforts on specific foods
  – Use of HACCP-based programs
U.S. Policy

• In 1991, the National Advisory Committee on Microbiological Criteria for Foods recommended control strategies

• In 1993, FDA produced *Food Code 1993*
  – Recommended best practices to prevent the occurrence and/or spread of *L. monocytogenes* during retail food preparation and production
U.S. Policy

- In 1991, the National Advisory Committee on Microbiological Criteria for Foods recommended control strategies.
- In 1993, FDA produced *Food Code 1993*.
- FDA and FSIS jointly produced recommendations for delicatessen operators describing safe handling procedures for use at retail.
U.S. Policy

- In 1991, the National Advisory Committee on Microbiological Criteria for Foods recommended control strategies.
- In 1993, FDA produced *Food Code 1993*.
- FDA and FSIS jointly produced recommendations for delicatessen operators.
- In 1995, FSIS issued its pathogen reduction program and a proposed rule for HACCP to reduce the incidence of foodborne illness associated with consumption of meat and poultry products.
Public Health Goals

• Healthy People 2010
  – Called for Federal food safety agencies to reduce foodborne listeriosis by 50% by the end of 2005
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    • shy of the goal of 0.25 cases per 100,000 people by the end of 2005
Public Health Goals

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    • Additional targeted measures were needed
Public Health Goals

• *Listeria* Action Plan (2001)
  – Develop and revise guidance
    • Processors that manufacture or prepare ready-to-eat foods
    • Retail and food service and institutional establishments
Public Health Goals

• Action Plan (2001)
  - Develop and revise guidance
  - Educational efforts for consumers and health care providers
Public Health Goals

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  – Develop and revise guidance
  – Educational efforts for consumers and health care providers
  – Review, redirect, and revise enforcement and regulatory strategies, including microbial product sampling
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  – Enhance disease surveillance and outbreak response
Public Health Goals

• **Action Plan (2001)**
  - Develop and revise guidance
  - Educational efforts for consumers and health care providers
  - Review, redirect, and revise enforcement and regulatory strategies, including microbial product sampling
  - Enhance disease surveillance and outbreak response
  - Coordinate research activities
Public Health Goals

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  – Called for Federal food safety agencies to reduce foodborne listeriosis by 50% by the end of 2005
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    • shy of the goal of 0.25 cases per 100,000 people by the end of 2005
    • Additional targeted measures were needed
    • *Listeria monocytogenes* Risk Assessment was initiated as an evaluation tool in support of the goal
Surveillance

- In 1986, listeriosis became a reportable illness in the U.S.
- FDA funded a CDC active surveillance project
  - CDC began contacting all acute care hospitals and their respective laboratories in an area that initially included five states and Los Angeles County
Surveillance - Attribution -

• Active Surveillance Projects (1988-2004)
  – First of multiple case control studies indicated sporadic (non-outbreak) individual cases were associated with:
    • Soft cheese
    • Undercooked poultry
    • Hot dogs not thoroughly reheated
    • Food purchased from delicatessen counters
Surveillance
- Attribution -

- Active Surveillance Project (1988-1990)
  - Sporadic (non-outbreak) individual cases
  - Projected that about 1,850 cases of human listeriosis occur annually
    - About 425 deaths occur each year
    - 5% of the 9,000 food poisoning deaths each year are due to listeriosis
Surveillance

• Monitoring Programs
  – Initially concentrated on cheese and dairy products (both domestic and imported)
  – Coverage was expanded to include other ready-to-eat foods (i.e. sandwiches, prepared salads and smoked fish)
Surveillance

• Monitoring Programs
• Survey of Pasteurized Milk at Retail (2000)
  – 5,519 samples tested
  – One positive – skim gallon
  – 0.03 CFU per gram at end of code
  – Contamination rate of milk 0.018%
Risk Assessment

“Filling in the Knowledge Gap—Increasing Our Understanding of the Risks”
WHO Special Working Group

• In 1988, WHO convened a Special Working Group to deliberate and make recommendations about listeriosis and its connection to food
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- WHO concluded that any food other than one processed in its final container could be expected to be contaminated sporadically with some number of *L. monocytogenes*

- Numerous other studies on the incidence of *L. monocytogenes* in various foods have supported this statement
WHO Special Working Group

- In 1988, WHO convened a Special Working Group to deliberate and make recommendations about listeriosis and its connection to food
  - WHO concluded that any food other than one processed in its final container could be expected to be contaminated sporadically with some number of *L. monocytogenes*
  - WHO also concluded that the technology did not exist to assure a food supply completely free of *L. monocytogenes*
Joint FAO/WHO Expert Consultation

• Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of Salmonella spp. in eggs and broiler chickens and L. monocytogenes in ready-to-eat foods
Joint FAO/WHO Expert Consultation

• Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods
  – Noted that microbiological risk assessments could have a wide range of applications in food safety
    • Develop broad food safety policies
    • Develop sanitary measures that achieve specific food safety goals
    • Elaborate standards for food

[Image of FDA logo]
Joint FAO/WHO Expert Consultation

- Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods
  - Noted that microbiological risk assessments could have a wide range of applications in food safety
  - Provided both general knowledge about listeriosis for member nations and responses to specific risk management questions posed by the Codex Committee on Food Hygiene
Joint FAO/WHO Expert Consultation

• Results
  – Re-enforcement of the importance of growth
  – Examination of the potential impact of different standards
  – Identification of the importance of “compliance” (% of products with elevated levels)
  – Identification of the relative susceptibility of different “at-risk” groups
Joint FAO/WHO Expert Consultation

• Recommendations
  – Evaluate the effect of the type of food on the ability of *L. monocytogenes* to cause disease
  – Identify the key virulence factors within *L. monocytogenes* isolates that lead to diversity in the ability of strains to cause disease
  – Determine the distribution of virulence potentials among *L. monocytogenes* isolated from foods
  – Obtain epidemiological data needed to calculate attack rates, determine the exposure dose, and assess the health and immune status of both symptomatic and asymptomatic individuals
  – Develop estimates of the size of the high risk populations
Estimated percentages of servings and illnesses for different contamination levels in US

<table>
<thead>
<tr>
<th>Level of Lm in food at consumption (cfu/serving)</th>
<th>% servings annually at that level</th>
<th>% cases of listeriosis attributable to that level</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0.04</td>
<td>96.37</td>
<td>0.02</td>
</tr>
<tr>
<td>0.1</td>
<td>1.90</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>1</td>
<td>0.91</td>
<td>0.01</td>
</tr>
<tr>
<td>10</td>
<td>0.43</td>
<td>0.03</td>
</tr>
<tr>
<td>100</td>
<td>0.21</td>
<td>0.13</td>
</tr>
<tr>
<td>1000</td>
<td>0.10</td>
<td>0.60</td>
</tr>
<tr>
<td>10,000</td>
<td>0.05</td>
<td>2.85</td>
</tr>
<tr>
<td>100,000</td>
<td>0.02</td>
<td>13.47</td>
</tr>
<tr>
<td>1,000,000 or greater</td>
<td>0.01</td>
<td>82.89</td>
</tr>
</tbody>
</table>

WHO/FAO 2004
Estimated illnesses if a percentage of servings have high levels of Lm, all other servings have either 0.04 or 100 cfu/g

<table>
<thead>
<tr>
<th>Percentage of servings containing greater than $10^6$ cfu/g Lm</th>
<th>Estimated number of illnesses if criteria is set at 0.04 CFU/g&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Estimated number of illnesses if criteria is set at 100 CFU/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.000000</td>
<td>0.5&lt;sup&gt;b&lt;/sup&gt;</td>
<td>5.7</td>
</tr>
<tr>
<td>0.000001</td>
<td>1.7</td>
<td>6.9</td>
</tr>
<tr>
<td>0.00010</td>
<td>12.3</td>
<td>17.4</td>
</tr>
<tr>
<td>0.00100</td>
<td>119</td>
<td>124</td>
</tr>
<tr>
<td>0.01000</td>
<td>1,185</td>
<td>1,191</td>
</tr>
<tr>
<td>0.10000</td>
<td>11,837</td>
<td>11,848</td>
</tr>
<tr>
<td>1.00000</td>
<td>117,300</td>
<td>117,363</td>
</tr>
</tbody>
</table>

WHO/FAO 2004
# Numbers of Lm associated with outbreaks

<table>
<thead>
<tr>
<th>Food(s)</th>
<th>Number (CFU or MPN/g)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Queso blanco / Queso fresco</td>
<td>$10^3 - 10^4$</td>
<td>Linnan et al., 1988</td>
</tr>
<tr>
<td>Raw milk cheese</td>
<td>$10^4 - 10^6$</td>
<td>Bille, 1990</td>
</tr>
<tr>
<td>Pâté</td>
<td>$&lt; 10^2 - 10^6$</td>
<td>McLauchlin et al., 1991</td>
</tr>
<tr>
<td>Pâté</td>
<td>$8.8 \times 10^3$</td>
<td>Kittson, 1992</td>
</tr>
<tr>
<td>Smoked mussels</td>
<td>$1.6 \times 10^7$</td>
<td>Mitchell et al., 1991</td>
</tr>
<tr>
<td>Pork rillettes (pâté)</td>
<td>$&lt; 10^2 - 1.0 \times 10^6$</td>
<td>Goulet, 1995</td>
</tr>
<tr>
<td>Chocolate milk</td>
<td>$2.9 \times 10^9$</td>
<td>Dalton et al, 1997; Proctor et al., 1995</td>
</tr>
<tr>
<td>Cold-smoked rainbow trout</td>
<td>$&lt; 10^2 - 2.5 \times 10^6$</td>
<td>Ecklow et al., 1996</td>
</tr>
<tr>
<td>Cold-smoked rainbow trout</td>
<td>$1.9 \times 10^5$</td>
<td>Miettinen et al., 1999</td>
</tr>
<tr>
<td>Butter</td>
<td>$&lt; 10^2 - 1.1 \times 10^4$</td>
<td>Lyytikäinen et al., 1999</td>
</tr>
<tr>
<td>Imitation crab meat</td>
<td>$2 \times 10^9$</td>
<td>Farber et al., 2000</td>
</tr>
</tbody>
</table>
FDA/FSIS *Listeria* Risk Assessment

  - Examined systematically the available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat foods that may be contaminated with *L. monocytogenes*
FDA/FSIS *Listeria* Risk Assessment

• Designed to predict the potential relative risk of listeriosis
  – From eating certain ready-to-eat foods
    • Foods within 23 categories considered to be principal potential sources of *L. monocytogenes*
  – Among three age-based groups of people
    • Perinatal
    • Elderly
    • Intermediate-age
Main findings

- Reinforced past conclusions that foodborne listeriosis is a moderately rare although severe disease
- Supports the findings of epidemiological investigations of both sporadic illness and outbreaks
- Risk of listeriosis varies greatly among food categories evaluated
- New case control studies and other advanced epidemiological investigations are needed
- Five factors affect consumer exposure to L. monocytogenes at the time of food consumption
Factors that Affect Consumer Exposure

- Amount and frequency of consumption of a food
- Frequency and levels of *L. monocytogenes* in ready-to-eat food
- Potential to support growth of *L. monocytogenes* in food during refrigerated storage
- Refrigerated storage temperature
- Duration of refrigerated storage before consumption
Predicted Cases of Listeriosis per Serving—Total Population—FDA/FSIS 2003

Total Cases Listeriosis per Serving (log scale)
Risk of Listeriosis

Clusters A and B
- **Very High Risk**
  - Deli Meats
  - Frankfurters (not reheated)

Clusters C and D
- **High Risk**
  - Pâté and Meat Spreads
  - Unpasteurized Fluid Milk
  - Smoked Seafood

- **Moderate Risk**
  - Cooked RTE Crustaceans

Cluster E
- **Moderate Risk**
  - No food categories

Cluster 1
- **Moderate Risk**
  - No food categories

Cluster 2
- **Low Risk**
  - Preserved Fish
  - Raw Seafood

Cluster 3
- **Low Risk**
  - No food categories

Cluster 4
- **Very Low Risk**
  - Cultured Milk Products
  - Hard Cheese
  - Ice Cream and Other Frozen Dairy Products
  - Processed Cheese
Listeria Risk Assessment

• Results
  – Identified those foods that are more likely than others to contain significant levels of *L. monocytogenes* at time of consumption
  – Identified the growth of *L. monocytogenes* as the single most important preventable risk factor for listeriosis
  – Produced dose-response curves for foodborne *L. monocytogenes* infection for three age groups
Dose-Response Curves for Three Populations—FDA/FSIS 2003

![Dose-Response Curves for Three Populations Graph](image)

- Intermediate-aged
- Elderly
- Neonatal
Additional U.S. Risk Assessments

- *Listeria monocytogenes* in smoked seafood (FDA, underway)
- *Listeria monocytogenes* in cheese (FDA and Health Canada, underway)
Various Approaches Around the World

“Regulatory approach and food safety laws differ from country to country.”
Current U.S. Regulatory Programs

- **Zero tolerance** for *L. monocytogenes* in cooked and ready-to-eat food based on analytically-based standard
- **Good Manufacturing Practice regulations** are enforced and sanitary inspections conducted
- **Discretionary enforcement authority** is used to selectively sample and test for *L. monocytogenes*
- **Active surveillance** for listeriosis is pursued
- **Outbreaks of listeriosis** are thoroughly investigated
Other Countries

- Major U.S. Trading Partners have established regulatory limits relative to *L. monocytogenes* in ready-to-eat foods
  - Many European countries have adopted the EU regulation
    - **Content of *L. monocytogenes* may not be more than 100 CFU/g in ready-to-eat products at their expiry date.**
Other Countries

• Major U.S. Trading Partners have established regulatory limits relative to *L. monocytogenes* in ready-to-eat foods
  – Many European countries have adopted the EU regulation
    • Content of *L. monocytogenes* may not be more than 100 CFU/g in certain ready-to-eat products at their expiry date
  – Canada has taken an approach that allows up to 100 CFU/g in certain ready-to-eat foods, such as ice cream, that will not support the growth of *L. monocytogenes*
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  - Canada has taken an approach that allows up to 100 CFU/g in certain ready-to-eat foods, such as ice cream, that will not support the growth of *L. monocytogenes*
  - Australia guidelines provide an action limit of 100 CFU/g for ready-to-eat foods that do no support the growth of *L. monocytogenes*
Impact of Various Regulatory Strategies
Incidence of Listeriosis

- Considering differences in national surveillance systems, the incidence of listeriosis is similar among most developed countries.
- Listeriosis is not a reportable disease in all countries.
<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence (Cases per 1,000,000 people)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>1.7</td>
</tr>
<tr>
<td>Australia</td>
<td>3.0</td>
</tr>
<tr>
<td>Belgium</td>
<td>4.7</td>
</tr>
<tr>
<td>Denmark</td>
<td>7.2</td>
</tr>
<tr>
<td>England/Wales</td>
<td>3.5</td>
</tr>
<tr>
<td>Finland</td>
<td>7.0</td>
</tr>
<tr>
<td>France</td>
<td>3.2</td>
</tr>
<tr>
<td>Germany</td>
<td>6.2</td>
</tr>
<tr>
<td>Greece</td>
<td>0.3</td>
</tr>
<tr>
<td>Iceland</td>
<td>6.9</td>
</tr>
<tr>
<td>Ireland</td>
<td>1.6</td>
</tr>
<tr>
<td>Italy</td>
<td>0.6</td>
</tr>
<tr>
<td>Japan</td>
<td>0.7</td>
</tr>
<tr>
<td>Netherlands</td>
<td>3.8</td>
</tr>
<tr>
<td>Norway</td>
<td>3.8</td>
</tr>
<tr>
<td>Portugal</td>
<td>1.4</td>
</tr>
<tr>
<td>Scotland</td>
<td>2.9</td>
</tr>
<tr>
<td>Spain</td>
<td>1.5</td>
</tr>
<tr>
<td>Sweden</td>
<td>7.5</td>
</tr>
<tr>
<td>Switzerland</td>
<td>7.4</td>
</tr>
</tbody>
</table>
International Harmonization

• Codex Committee on Food Hygiene (CCFH)
  – In 1989, *L. monocytogenes* included on CCFH agenda
  – In 1993, CCFH discusses control strategies and quantitative tolerances
    • Member countries had set tolerances for specific classes of foods
  – In 1998, CCFH established a *L. monocytogenes* working group
  – In 2003, CCFH developed a guidance document on hygienic controls
Applying Science to Improve Public Health

“Adapting policies to take advantage of the best science available today and in the future.”
Applying the Best Science Available

- Examination of the current science is one of the tools FDA uses to evaluate the effectiveness of its current and proposed policies, programs, and regulatory practices.
Re-examination of *Listeria monocytogenes* Policy

- Increasing demands for foods with extended shelf lives, increasing consumption of ready-to-eat foods may be providing a heightened likelihood of exposure to *L. monocytogenes*
Re-examination of *Listeria monocytogenes* Policy

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- Population segment highly susceptible to listeriosis has increased and is expected to continue to increase
Re-examination of *Listeria monocytogenes* Policy

- Increasing demands for foods with extended shelf lives, increasing consumption of ready-to-eat foods may be providing a heightened likelihood of exposure to *L. monocytogenes*
- Population segment highly susceptible to listeriosis has increased and is expected to continue to increase
- FDA is developing a control strategy using the best available science to produce a positive impact on public health
  - Consistent with our food cGMP modernization
  - Exploring improved sanitation and temperature control
  - Encouraging reformulation, post final packaging pasteurization technologies, and changes in distribution and storage practices
Re-examination of *Listeria monocytogenes* Policy

- **Citizens’ Petition (filed on behalf of 15 leading trade associations)**
  - Requests FDA to establish a regulatory limit of 100 CFU/g for foods that do not support growth of *L. monocytogenes*
    - Includes prepared foods held at or below -1°C, with pH values ≤4.4, or with water activity levels less than 0.92
    - Includes prepared foods in which *L. monocytogenes* does not grow
Re-examination of *Listeria monocytogenes* Policy

- Citizens’ Petition (filed on behalf of 15 leading trade associations)
  - Requests FDA to establish a regulatory limit of 100 CFU/g for certain foods
  - Asserts
    - A science-based standard would be established
    - Regulatory limit would permit FDA and the industry to focus on foods for which increased scrutiny would not yield a corresponding benefit to public health*
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment demonstrated:
  - In foods that support the growth *L. monocytogenes*, even a small inoculum present at the point of manufacture can readily reach a level that presents significant risk for illness under “real-world” conditions of distribution and storage.
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment demonstrated:
  - Even a small inoculum can grow to significant concentrations in foods that support growth
  - Most ready-to-eat foods contain either non-detectable or low levels of *L. monocytogenes*
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment demonstrated:
  - Even a small inoculum can grow to significant concentrations in foods that support growth
  - Most ready-to-eat foods contain either non-detectable or low levels of *L. monocytogenes*
  - Levels of *L. monocytogenes* at consumption of ≤100 CFU/g pose a low level of risk to consumer
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment demonstrated:
  - Even a small inoculum can grow to significant concentrations in foods that support growth
  - Most ready-to-eat foods contain either non-detectable or low levels of *L. monocytogenes*
  - Levels of *L. monocytogenes* at consumption of $\leq 100$ CFU/g pose a low level of risk to consumer
  - The relatively low percentage of highly contaminated foods cause a disproportionately high percentage of listeriosis cases
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment
- FAO/WHO Risk Assessment indicated:
  - Public health could be enhanced if using a standard such as 100 CFU/g reduced the small percentage of servings that had high levels
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- FDA/FSIS Risk assessment
- FAO/WHO Risk Assessment indicated:
  - Public health could be enhanced if using a standard such as 100 CFU/g reduced the small percentage of servings that had high levels
  - Public health could be enhanced if products were reformulated so that they no longer supported growth of *L. monocytogenes*
Re-examination of *Listeria monocytogenes* Policy

- FDA/FSIS Risk assessment
- FAO/WHO Risk Assessment
- NACMCF* indicated:
  - Public health could be enhanced if consume-by date labels for refrigerated ready-to-eat foods were established and coupled with a consumer education campaign

*National Advisory Committee for Microbiological Criteria for Foods*
Policy Considerations
Policy Considerations

• Ability of *L. monocytogenes* to grow in foods
  – For foods that support the growth of *L. monocytogenes*, it is difficult to determine and control exposures
  – For foods that do not support growth, levels at consumption will be the same or less than those at retail

“What the consumer actually eats is the exposure that counts”
Policy Considerations

- Ability of *L. monocytogenes* to grow in foods
- Selecting “Stringency”
  - *L. monocytogenes* is an infectious agent
Policy Considerations

- Ability of *L. monocytogenes* to grow in foods
- Selecting “Stringency”
- Understanding microbiological criteria
  - No such thing as “zero-tolerance”
Policy Considerations

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Policy Considerations

- Ability of \textit{L. monocytogenes} to grow in foods
- Selecting “Stringency”
- Understanding microbiological criteria
  - No such thing as “zero-tolerance”
  - Must deal with variability, uncertainty, and desired level of confidence
  - Must provide confidence agreed upon Food Safety Objective or Performance Objective will not be exceeded
    - Account for variability of the process/control measure
    - Account for the variability of sampling and testing methods
Policy Considerations

• Ability of *L. monocytogenes* to grow in foods
• Selecting “Stringency”
• Understanding microbiological criteria
• Adequately protecting and promoting public health
  – Will a less stringent performance objective result in enhanced compliance?
  – Will a less stringent performance objective result in increased risk?
Summary

- Many times policy is created to address an immediate and urgent situation
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• Often this policy needs re-evaluation and updating to take advantage of the increase in scientific knowledge and technology advances
• Managing risk and providing the appropriate risk management strategies is a process that requires constant monitoring, evaluation, and adoption of changes to ensure the best available science is applied and consumers are protected
Thank You!

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