The 2003 HHS-USDA *Listeria monocytogenes* Risk Assessment as it Relates to Retail Food

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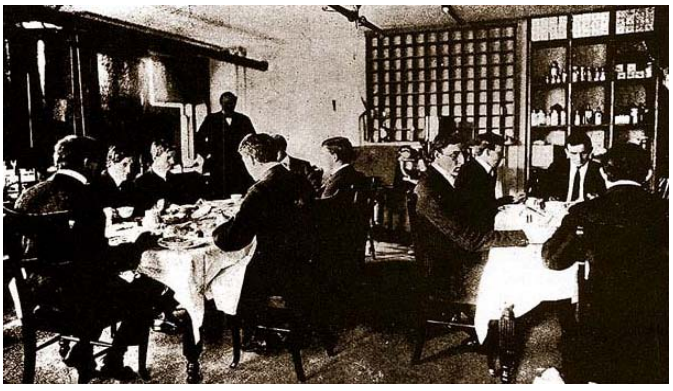
Outline

- Background
- Data and modeling
- Results
- Using the risk assessment
- Conclusions

Background

Early FDA direct approach to risk assessment - 1906

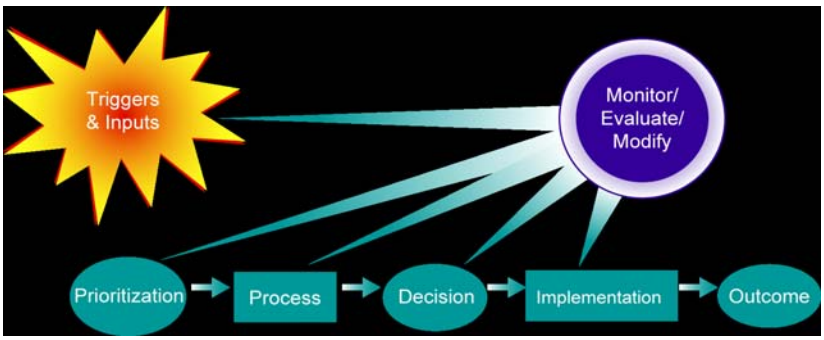


The Dining Room of “The Poison Squad”

Risk Analysis

- Traditionally described as being comprised of three components:
  - Risk management
  - Risk assessment
  - Risk communication

CFSAN's Risk Management Framework



Risk Assessment

The thinking-man's approach to Murphy's Law

Answers four key questions:

- *What can go wrong?*
- *How likely is it to occur?*
- *What are the consequences?*
- *What factors can influence it?*

Benefits of Risk Assessment Approach

- Based on science /scientific methods
- Systematic; helps to organize complex concepts [tell what we know]
- Descriptive; allows one to distinguish the impact of a wide range of data [tell how well we know it]

Risk Assessment: The Five-Step Process

- ⇒ Statement of the Problem
- ⇒ Hazard Identification
- ⇒ Exposure Assessment
- ⇒ Hazard Characterization
- ⇒ Risk Characterization

The *Listeria* "Problem"

Which foods should receive the most regulatory attention in order to improve public health?

Listeria monocytogenes

- ***L. monocytogenes***
  - Widespread
  - Grows at refrigeration temperatures
- **Listeriosis**
  - Severe, life-threatening systemic infections
  - ~ 500 deaths, 2000 additional cases per year in US
  - Immunocompromised
  - Mostly sporadic cases
  - 2-3 weeks incubation (or more)

Populations Studied

- **Perinatal:** 16 weeks after fertilization to 30 days after birth
- **Elderly:** 60 or more years of age
- **Intermediate-age:** General population less than 60 years old, includes healthy people and people more susceptible to listeriosis

Selection of Food Categories

- Potential for Lm Contamination
- Ready-to-eat (with one exception, foods are not cooked or reheated just prior to consumption)
- History of causing listeriosis
- Food contamination and consumption data
- Individual foods grouped into 23 food categories

Food Categories

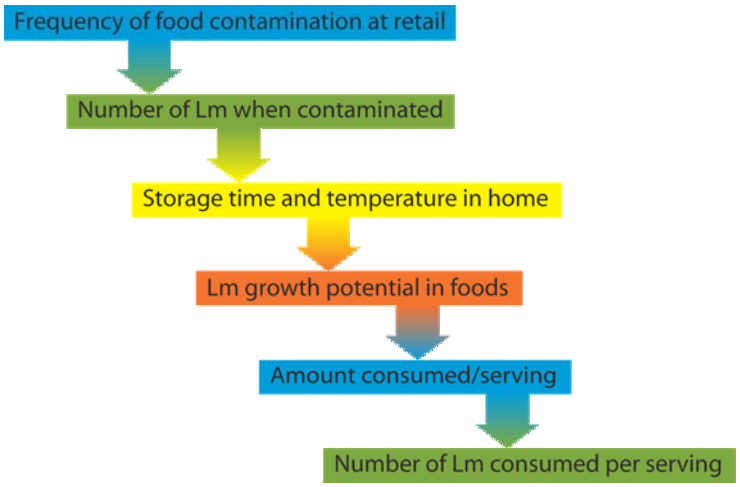
- Seafood
  - Smoked Seafood
  - Raw Seafood
  - Preserved Fish
  - Cooked RTE Crustaceans
- Produce
  - Fruit
  - Vegetables
- Meats
  - Frankfurters, Reheated
  - Frankfurters, Not Reheated
  - Dry/Semi-dry Fermented Sausages
  - Deli Meats
  - Pate and Meat Spreads
- Dairy Products
  - Fresh Soft Cheese
  - Soft Unripened Cheese
  - Soft Ripened Cheese
  - Semi Soft Cheese
  - Hard Cheese
  - Processed Cheese
  - Pasteurized Milk
  - Unpasteurized Milk
  - High Fat and Other Dairy Products
  - Cultured Milk Products
  - Ice Cream and Other Frozen Dairy Products
- Deli-type Salads

Data and Modeling

Sources and Types of Data

- Consumption surveys
- Contamination data
- Growth, survival and thermal inactivation data -- refrigeration, storage and cooking/reheating
- Animal studies -- virulence of Lm strains and susceptibility in subpopulations
- Epidemiological investigations/listeriosis surveillance
- **Almost 500,000 data points examined!!!**

Exposure Assessment

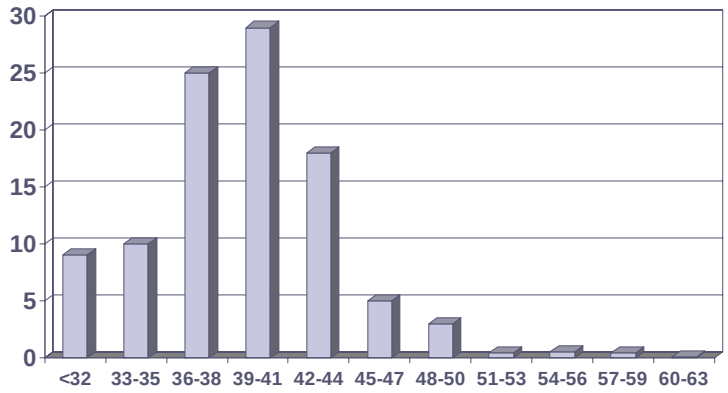


Frequency of Consumption

	Servings/Year-US (millions)	Amount/serving (g)
Smoked seafood	200	57
Soft unripened cheese	4,410	29
Pasteurized milk	87,000	244
High fat dairy products	21,000	13
Fermented meats	1,800	46
Deli meats	21,000	56
Deli-type salads	13,000	96
Pate	120	57

- **Total RTE foods** **340 billion servings/year**

The Real World



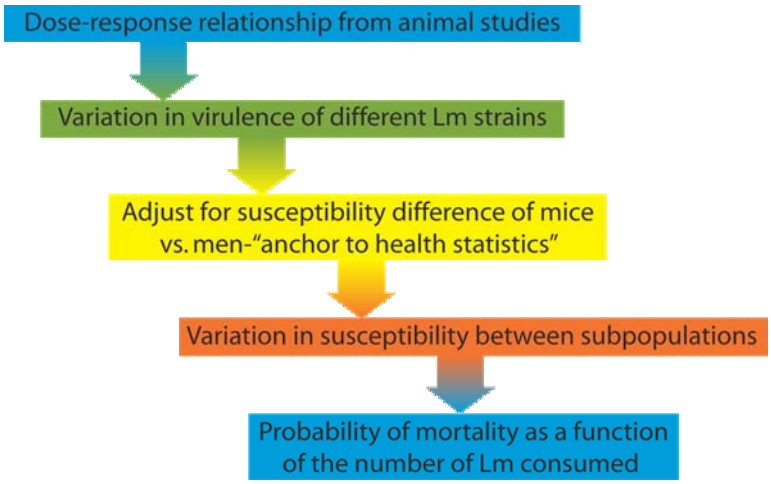
Home Refrigerator Temperatures (°F)

Recent Contamination Data at Retail

	Cfu/g at retail									
	Total	< 0.04	0.1	1	10	100	10^3	10^4	10^5	10^6
All Deli Salads	11,236	10,793	244	47	19	4	2	1		
Smoked Seafood	2687	2573	67	11	19	8	6	1	0	2
Deli Meats	9199	9117	42	20	10	2	7	1		
Soft Ripened Cheeses	1347	1333	12	0	2					
Bagged Precut Leafy Salad	2963	2941	17	1	1	2	1			
Fresh Soft Cheese	2936	2931	2	0	0	3				
Soft mold-ripened Cheeses	2970	2933	30	3	3	1				
Pasteurized Milk	5412	5411	1							

Gombas et al., 2003
IDFA, 2000

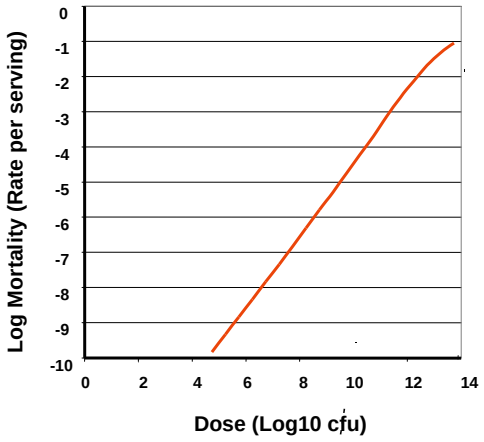
Hazard Characterization



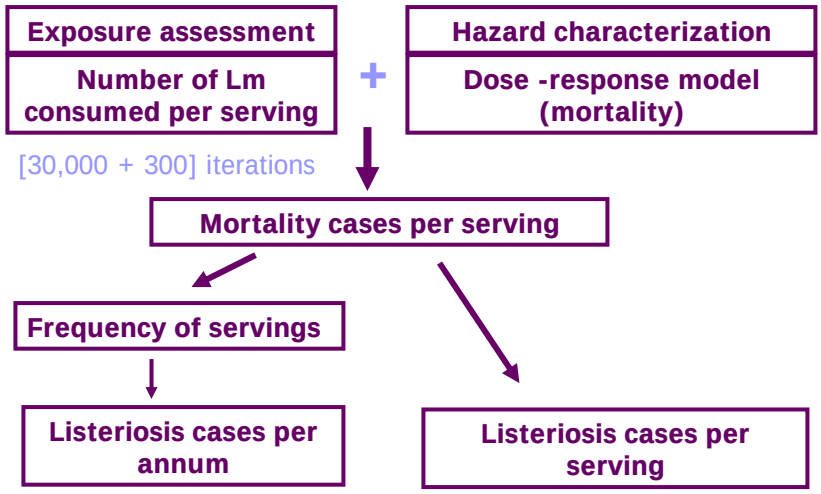
Hazard Characterization

Likelihood of illness after consuming a specified number of *L. monocytogenes*

Example: dose-response curve for the elderly population



Risk Characterization



Repeat 4,000 times!

Risk Characterization

- Risk per serving
  - Risk to individual consumer
  - Basis of most regulatory requirements
- Risk per annum
  - Risk to country
  - Justification for most regulatory requirements

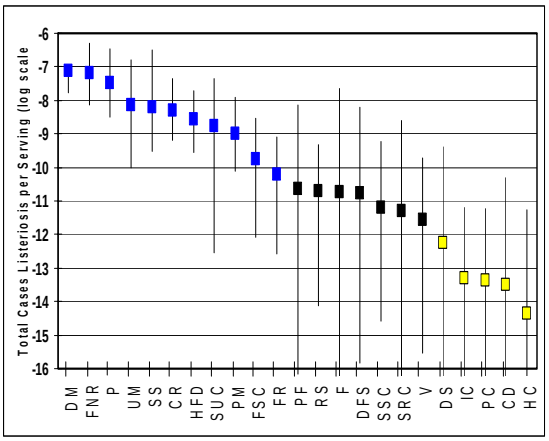
RESULTS

Predicted Median Risk

Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis[a]			Per Annum Basis[b]		
		Food	Cases		Food	Cases
1		Deli Meats	$77x10^{-9}$		Deli Meats	1598.7
2		Frankfurters, not reheated	$65x10^{-9}$		Pasteurized Fluid Milk	90.8
3		Pâté and Meat Spreads	$32x10^{-9}$		High Fat and Other Dairy Products	56.4
4		Unpasteurized Fluid Milk	$7.1x10^{-9}$		Frankfurters, not reheated	30.5
5		Smoked Seafood	$6.2x10^{-9}$		Soft Unripened Cheese	7.7
6		Cooked Ready-to-Eat Crustaceans	$5.1x10^{-9}$		Pâté and Meat Spreads	3.8
7		High Fat and Other Dairy Products	$2.7x10^{-9}$		Unpasteurized Fluid Milk	3.1
8		Soft Unripened Cheese	$1.8x10^{-9}$		Cooked Ready-to-Eat Crustaceans	2.8
9		Pasteurized Fluid Milk	$1.0x10^{-9}$		Smoked Seafood	1.3
10		Fresh Soft Cheese	$1.7x10^{-10}$		Fruits	0.9
11		Frankfurters, reheated	$6.3x10^{-11}$		Frankfurters, reheated	0.4
12		Preserved Fish	$2.3x10^{-11}$		Vegetables	0.2
13		Raw Seafood	$2.0x10^{-11}$		Dry/Semi-dry Fermented Sausages	<0.1
14		Fruits	$1.9x10^{-11}$		Fresh Soft Cheese	<0.1
15		Dry/Semi-dry Fermented Sausages	$1.7x10^{-11}$		Semi-Soft Cheese	<0.1
16		Semi-soft Cheese	$6.5x10^{-12}$		Soft Ripened Cheese	<0.1
17		Soft Ripened Cheese	$5.1x10^{-12}$		Deli-type Salads	<0.1
18		Vegetables	$2.8x10^{-12}$		Raw Seafood	<0.1
19		Deli-type Salads	$5.6x10^{-13}$		Preserved Fish	<0.1
20		Ice Cream and Frozen Dairy Products	$4.9x10^{-14}$		Ice Cream and Frozen Dairy Products	<0.1
21		Processed Cheese	$4.2x10^{-14}$		Processed Cheese	<0.1
22		Cultured Milk Products	$3.2x10^{-14}$		Cultured Milk Products	<0.1
23		Hard Cheese	$4.5x10^{-15}$		Hard Cheese	<0.1

Risk Ranking

- Risk ranking; use for priority setting
  - Surveillance
  - Research
  - New risk assessments



Cluster Analysis

Risk per Serving
Cluster 1 Deli Meats Frankfurters, not reheated Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood
Cluster 2 Cooked RTE Crustaceans High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese
Cluster 3 Deli-type Salads Dry/Semi-dry Fermented Sausages Fresh Soft Cheese Frankfurters, reheated Fruits Preserved Fish Raw Seafood Semi-soft Cheese Soft Ripened Cheese Vegetables
Cluster 4 Cultured Milk Products Ice Cream and Frozen Dairy Products Processed Cheese Hard Cheese

Risk per Annum
Cluster A Deli Meats
Cluster B High Fat and Other Dairy Products Frankfurters, not reheated Pasteurized Fluid Milk Soft Unripened Cheese
Cluster C Cooked RTE Crustaceans Fruits Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood
Cluster D Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters, reheated Fresh Soft Cheese Semi-Soft Cheese Soft Ripened Cheese Vegetables
Cluster E Cultured Milk Products Hard Cheese Ice Cream and Frozen Dairy Products Preserved Fish Processed Cheese Raw Seafood

Two-Dimensional Matrix

Decreased Risk Per Annum →

Decreased Risk Per Serving ↓

A and B	C and D	E	
Very High Risk Deli Meats Frankfurters (not reheated)	**High Risk** Pâtê and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk** No food categories	1
High Risk High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**Moderate Risk** Cooked RTE Crustaceans	**Moderate Risk** No food categories	2
Moderate Risk No food categories	**Moderate Risk** Deli Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk** Preserved Fish Raw Seafood	3
Moderate Risk No food categories	**Low Risk** No food categories	**Very Low Risk** Cultured Milk Products Hard Cheese Ice Cream and Frozen Dairy Products Processed Cheese	4

Putting the Model to Work

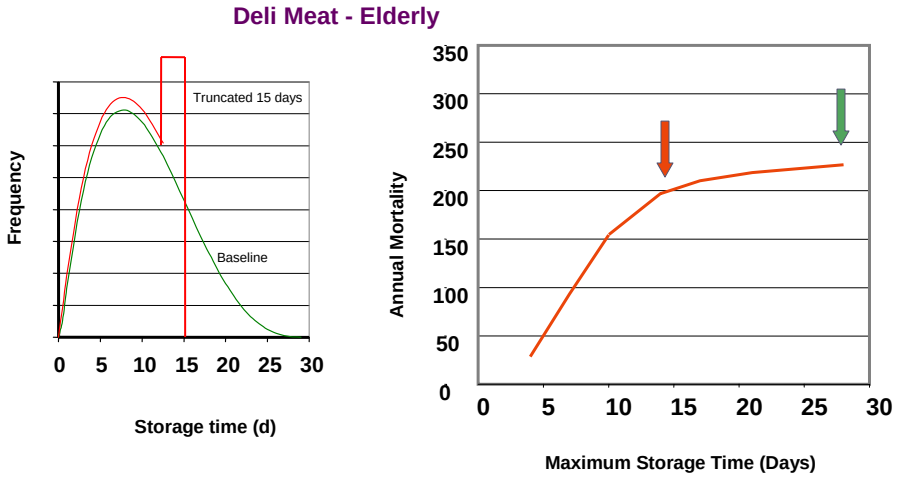
"What-If" Scenarios

- One of the strengths of developing a risk assessment model is the ability for "what-if" scenarios to consider the impact of different potential mitigations

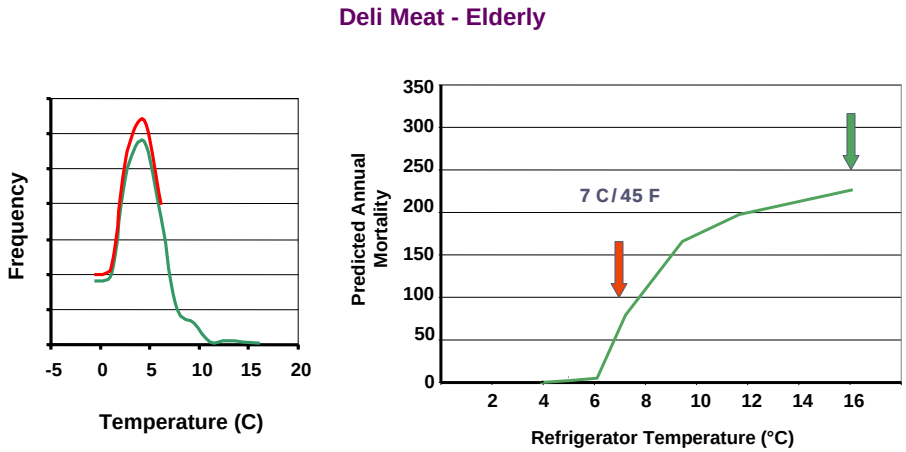
The Model as a Tool— 'What-If' Scenarios

- **Estimate the impact of intervention strategies by changing 1 or more input parameters and measuring change in the model output**
  - **Impact of refrigeration temperature**
  - **Impact of storage time**
  - **Reduction of the Number of Organisms**
  - **Contamination Levels of foods that support growth**
  - **Fresh Soft Cheese made from Unpasteurized Milk**
  - **Frankfurters**
  - **Pasteurized Milk data sets**

‘What-if’ Scenario for Mortality as a Function of Home Storage Time



Mortality as a Function of Maximum Storage Temperature



Conclusions

- Identified “high” and “low” risk foods to enable the best use of regulatory resources to target foods having the greatest likelihood of transmitting listeriosis and food processors to place emphasis on reformulating or specifically treating “high risk” foods to reduce their risk as a vehicle of listeriosis
- Determined the importance of storage temperature and shelf life of foods to enable food processors to place increased attention to these critical factors influencing health outcomes
- Better characterized populations “at increased risk” of acquiring foodborne infections to enable development of more refined educational messages/ programs for different

Food Code

Current Controls for *Listeria*

- Sanitation
- Date-marking
- Cold Holding

Current Date-marking Requirements

- Applies to RTE PHF/TCS foods opened and held, or prepared and held, in a food establishment for more than 24 hrs
- Solely intended to limit the growth of LM, not prevent contamination
- Product should be marked to indicate when it must be consumed, sold, or discarded
- Exemptions exist for certain products
  - Fermented sausages (original casing)
  - Shelf stable, dry fermented sausages
  - Salt-cured products (prosciutto)

Implications of the Risk Assessment for Date-marking

- Certain foods are more likely to be vehicles for LM
- As much as possible, date-marking should target foods that support the growth of *Listeria*
- Several categories of RTE foods that have historically required date-marking do not appear to support the growth of LM

New Date-marking Exemptions based on the *Listeria* Risk Assessment

- Hard or Semi-soft Cheeses
- Preserved Fish
- Cultured Dairy Products
- Deli Salads

LM Action Plan

- Consumer and health care information and education;
- Guidance for processors, retailers, and food service/ institutional establishments;
- Training/ technical assistance;
- Enforcement and regulatory strategies;
- Disease surveillance and outbreak response;
- Research needs

What's Current?

- Used to develop an updated action plan for control of *L. monocytogenes*
- Set inspectional priorities
- Focus research related to intervention technologies and formulation modification
- Identify simple approaches for controlling risk
- Serve as the basis for several additional product/pathway analyses and risk assessments
- Education and outreach (home refrigerator thermometers, Hispanic community, pregnant women)

Consumer Advice

To reduce the risk of illness:

- Use a thermometer to be sure the refrigerator is at 40 degrees F. or below
- Use perishable items that are precooked or ready-to-eat as soon as possible
- Clean the refrigerator regularly

COMMENTS? QUESTIONS ?