UPDATE: Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods

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The *Listeria* "Problem"

- Improve public health by determining which foods should receive the most regulatory attention

FDA/FSIS Draft *L. monocytogenes* Risk Assessment – Jan 2001

- Carried out in a manner consistent with the guidelines established by Codex Alimentarius, NACMCF, and ICMSF for the conduct of a microbial risk assessment:
  - Transparency
  - Broad scientific and stakeholder input
  - Extensive peer review

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

Selection of Food Categories

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

Exposure Assessment

- Number of *L. monocytogenes* ingested
  - Frequency of contamination of food
  - Extent of contamination
  - Growth before consumption
  - Frequency that food is consumed
  - Amount of food consumed at a serving

Exposure Assessment

- **Additional variables considered to determine the amount of *L. monocytogenes* consumed**
  - **Home refrigerator temperatures**
  - **Percent of frankfurters reheated**
  - **Effect of temperature on growth rate**
  - **Effect of temperature on extent of growth**

Hazard Characterization

- **Probability of illness/mortality as a function of number of *L. monocytogenes* ingested**
  - **Dose-response curve "shape" from mice**
  - **Variation in virulence of *L. monocytogenes* isolates**
  - **Accounting for differences in susceptibility of mice and men - "anchor to health statistics"**
  - **Variation in susceptibility within age groups**
  - **Variation in susceptibility between age groups**

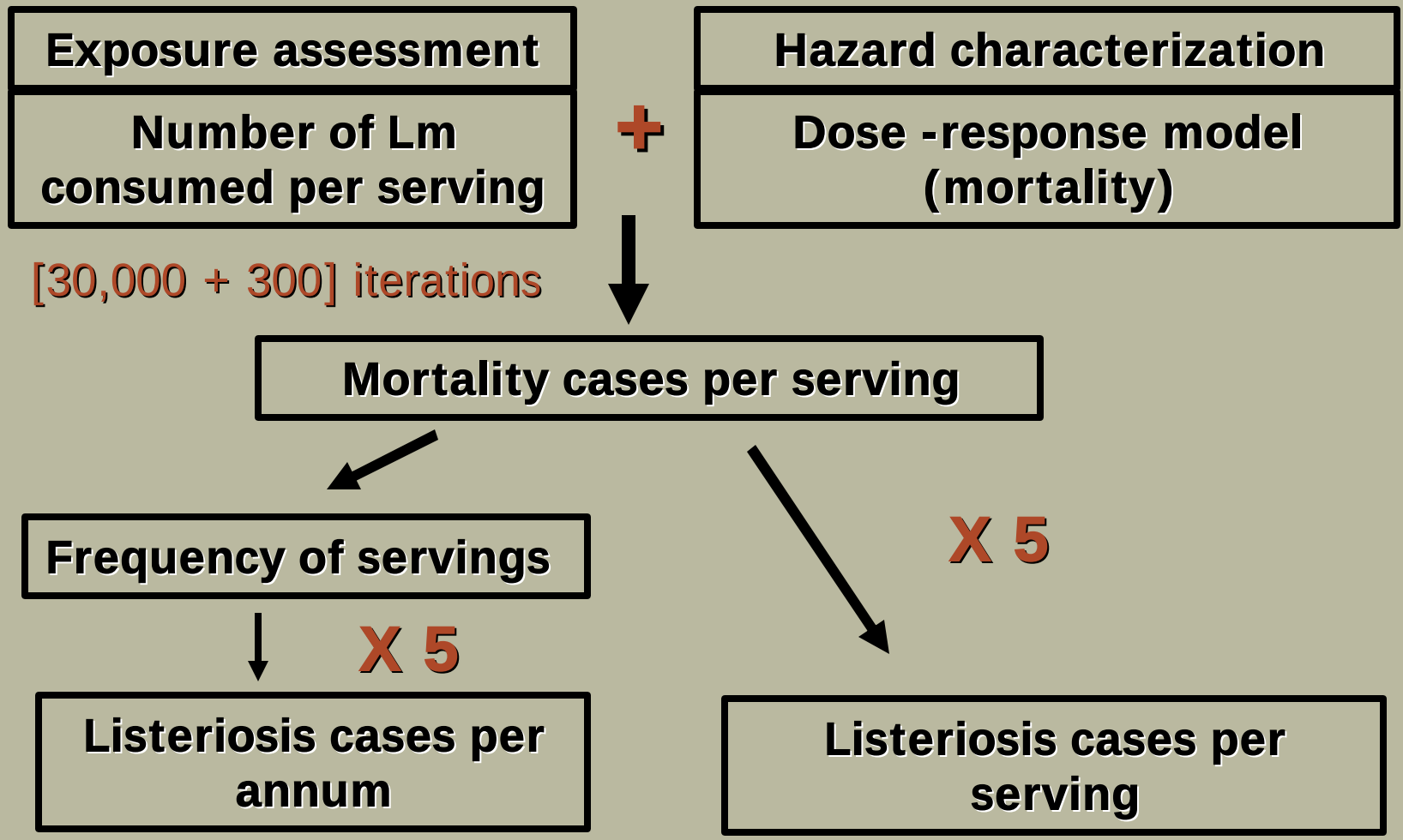
Populations Studied

- **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

Risk Characterization

- Combine exposure assessment and hazard characterization
  - Frequency of death (mortality)
  - Convert to severe cases of listeriosis by multiplying by 5
- Characterize variability and uncertainty

Risk Characterization



Repeat 4,000 times!

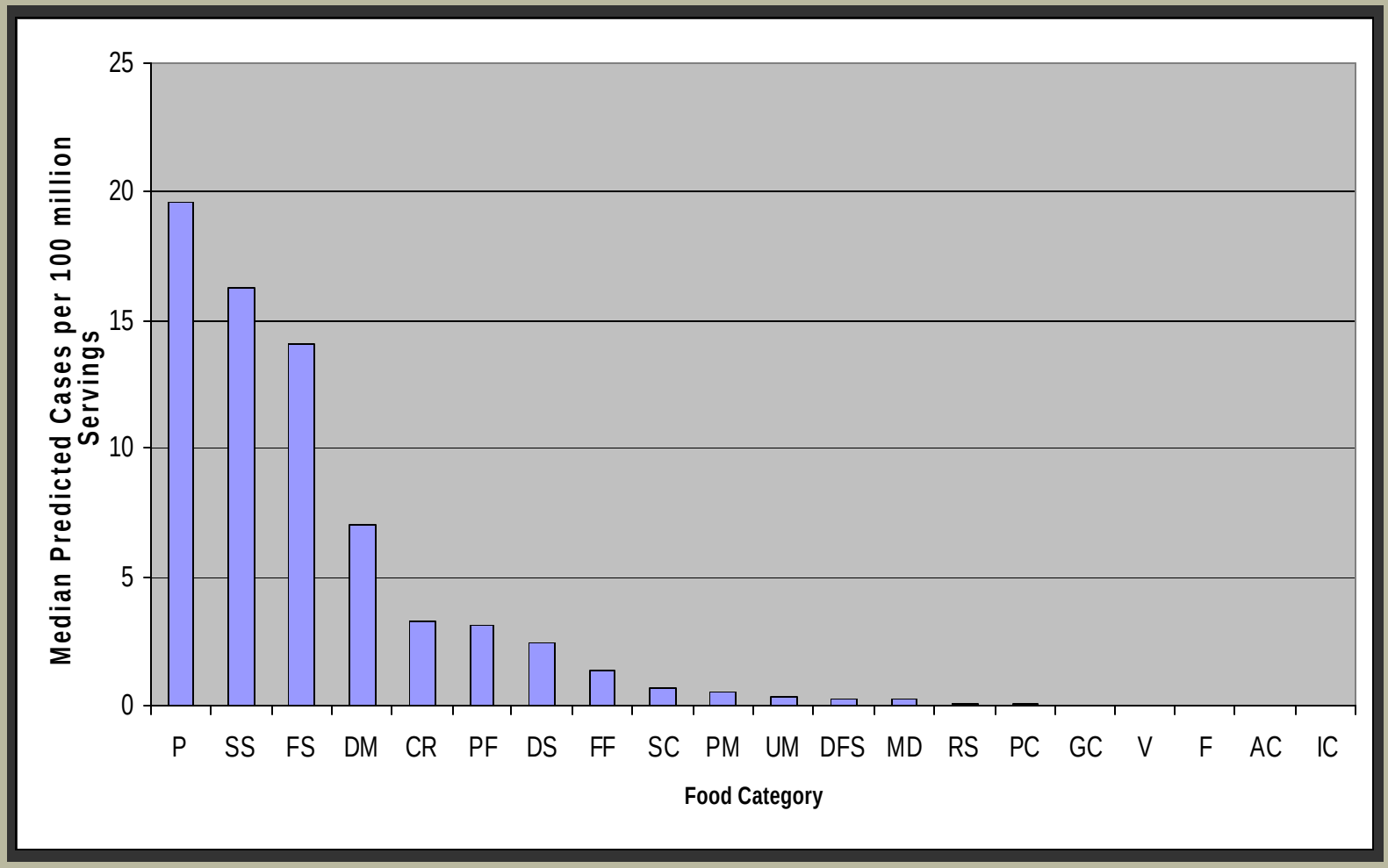
Risk Characterization

- Examined results in light of:
  - Quantitative results
    - Data variability
    - Model uncertainty
  - Consideration of qualitative factors
    - Epidemiological history
    - Food characteristics
  - Extensive discussion of each food category

Initial (2001) Risk Ranking--Per Serving

Food Categories[a]	Subpopulation		
	Intermediate Age[b]	Elderly[b]	Perinatal[b]
EAFOOD			
Smoked Seafood	3	3	3
Raw Seafood	14	14	14
Preserved Fish	7	7	6
Cooked Ready-to-Eat Crustaceans	6	5	5
RODUCE			
Vegetables	17	17	17
Fruits	18	18	18
AIRY			
Soft Mold-Ripened & Blue-Veined Cheese	9	9	9
Goat, Sheep, and Feta Cheese	16	16	16
Fresh Soft Cheese (e.g., queso fresco)[c]	2	1	1
Heat-Treated Natural/Process Cheese	15	15	15
Aged Cheese	19	19	19
Fluid Milk, Pasteurized[d]	10	10	10
Fluid Milk, Unpasteurized[d]	11	11	11
Ice Cream and Frozen Dairy Products	20	20	20
Miscellaneous Dairy Products	12	13	13
EATS			
Frankfurters			
All frankfurters[e]	8	8	7
Only reheated frankfurters[f]	[15]	[15]	[15]
Only non-reheated frankfurters[f]	[1]	[2]	[2]
Dry/Semi-Dry Fermented Sausages	13	12	12
Deli Meats	4	4	4
Pâté and Meat Spreads	1	2	2
OMBINATION FOODS			
Deli Salads	5	6	8

Listeriosis: Predicted Relative Risk per Serving–Total Population (2001)



Initial (2001) Risk Ranking - Per Annum

Food Categories[a]	Subpopulation		
	Intermediate Age[b]	Elderly[b]	Perinatal[b]
SEAFOOD			
Smoked Seafood	6	6	7
Raw Seafood	17	20	17
Preserved Fish	13	13	13
Cooked Ready-to-Eat Crustaceans	9	8	9
PRODUCE			
Vegetables	11	9	11
Fruits	16	14	14
DAIRY			
Soft Mold-Ripened and Blue-Veined Cheese	14	15	15
Goat, Sheep, and Feta Cheese	18	17	18
Fresh Soft Cheese (e.g., queso fresco)[c]	7	11	6
Heat-Treated Natural Cheese and Processed Cheese	10	10	10
Aged Cheese	19	18	19
Fluid Milk, Pasteurized[d]	3	2	2
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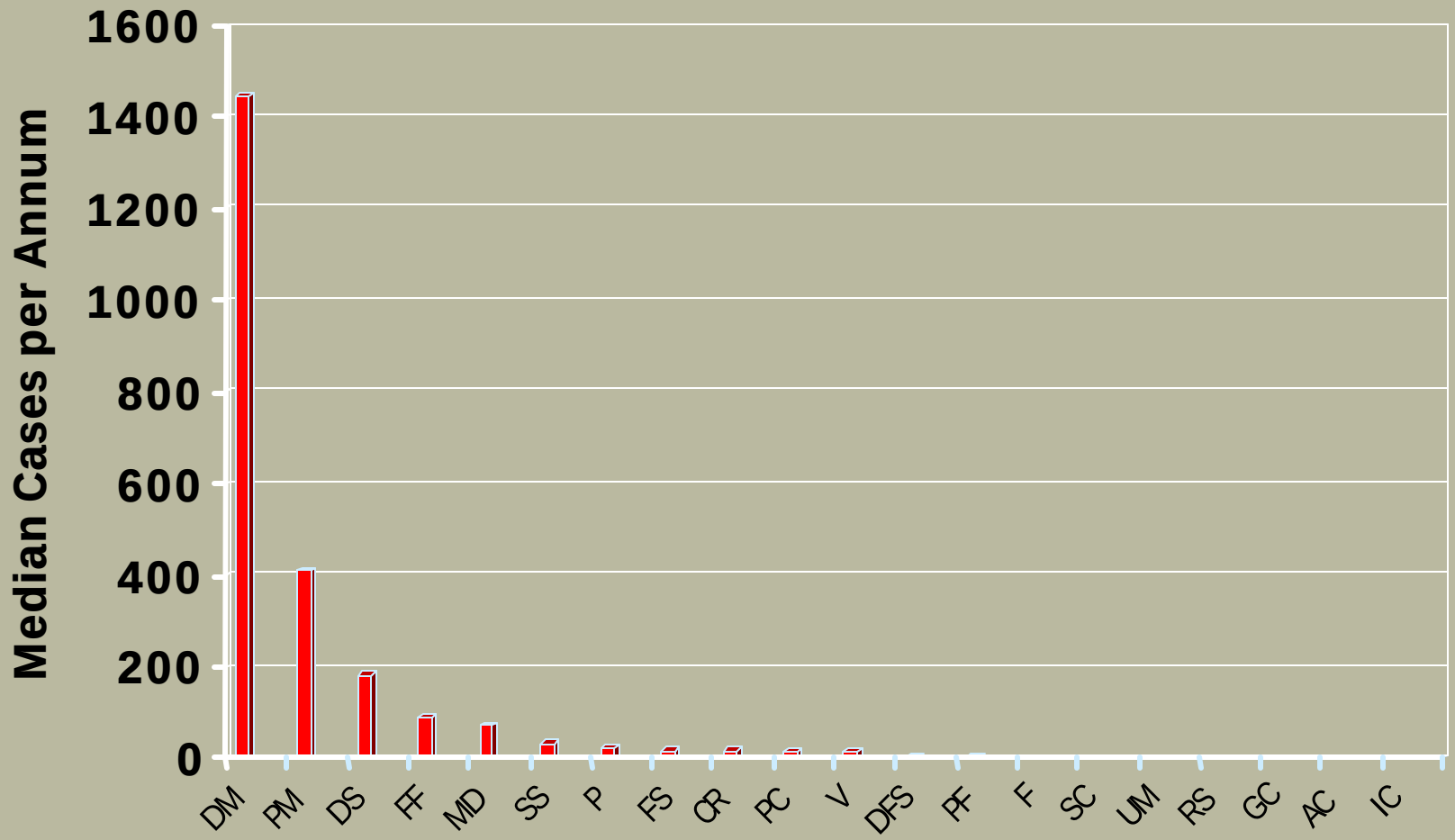
MEATS			
Frankfurters[e]	4	5	4
Dry/Semi-Dry Fermented Sausages	12	12	12
Deli Meats	1	1	1
Pâté and Meat Spreads	8	7	8
COMBINATION FOODS			
Deli Salads	2	3	3

Listeriosis: Predicted Relative Risk per Annum – Total Population (2001)



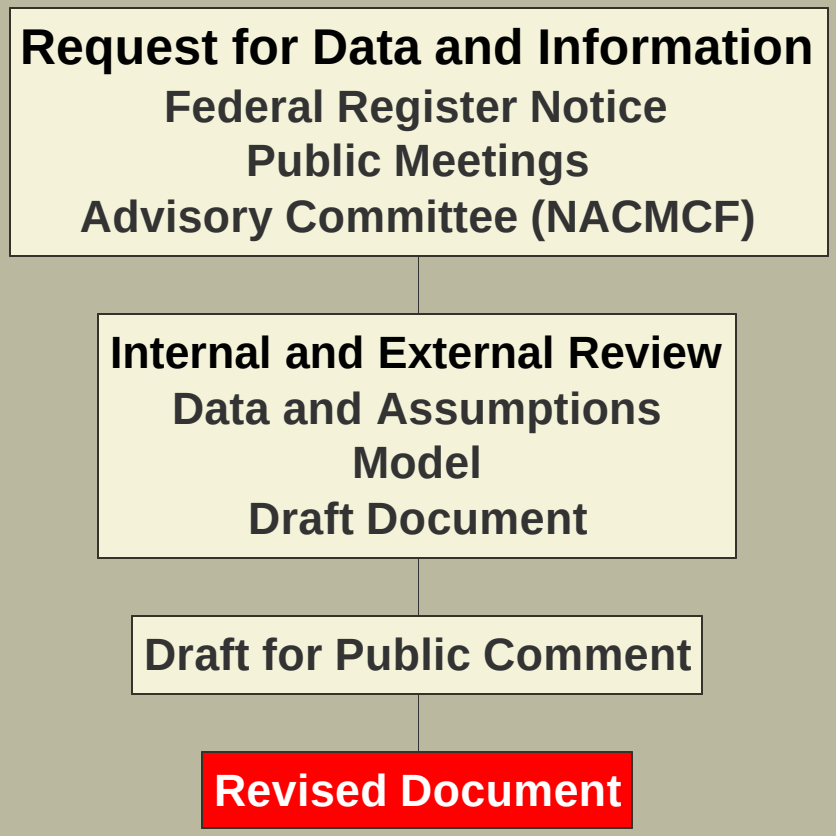
Initial (2001) Conclusions and Interpretation

- **Broad themes reemphasized:**
  - **Disease primarily impacts specific "at-risk" subpopulations**
  - **Disease is rare but severe**
  - **Substantial difference in risk among different food categories**

Initial (2001) Conclusions and Interpretation

- **Major factors that affect risk:**
  - Amount and frequency of consumption
  - Frequency and levels of contamination
  - Ability of food to support growth
  - Refrigerated storage temperature
  - Refrigerated storage time

Technical and Scientific Reviews of the FDA/FSIS Risk Assessment



Process For Finalizing FDA/FSIS LM Risk Assessment

- Draft RA for public comment (Jan 2001)
- Public comment period closes (July 2001)
- Review comments and newly available data
- Develop changes to the model
- Develop revised document
- Internal review and approval
- Issue revised risk assessment and model (planned June/July 2003)
- Public meeting (TBA)
- Future updates of LM RA (as needed)

Public comments

- Submissions to the docket represented
  - Consumer groups, industry, trade associations, expert modelers, manufacturers of food processing equipment, food retailers, marketers for food producers/ processors, and education/scientific societies

Public Comments

- **Revise food categories**
  - **Reorganize cheeses according to percentage moisture**
  - **Split frankfurters into two separate categories (reheated and not reheated)**
  - **Move vegetable and fruit salads to deli salads food category**
- **Weight contamination data according to geographic location, year collected, study size**

Some of the New Data

- AMI survey
  - Home storage of deli meats and frankfurters

Example: Average storage time for pre-packaged deli meats and hot dogs:

- 1 to 3 days (32%)
- 4 to 7 days (37%)
- 8 to 10 days (6%)
- 11 to 14 days (4%)
- Don’t eat these foods (13%)

Some of the New Data (2)

- **NFPA retail study**
  - Frequency and prevalence of LM in deli meats, deli salads, vegetable salads, seafood salads, smoked seafood, soft cheese, and Hispanic-style cheese
  - Total samples: 31705 tested (MD and CA)

Example: Deli Meats

9,199 tested: 82 positive (0.9%)

1 sample 10^3 to 10^4 cfu/g

7 samples 100-1000 cfu/g

2 samples 10-100 cfu/g

10 samples >1-10 cfu/g

20 samples >0.1 –1 cfu/g

42 samples 0.04 – 0.1 cfu/g

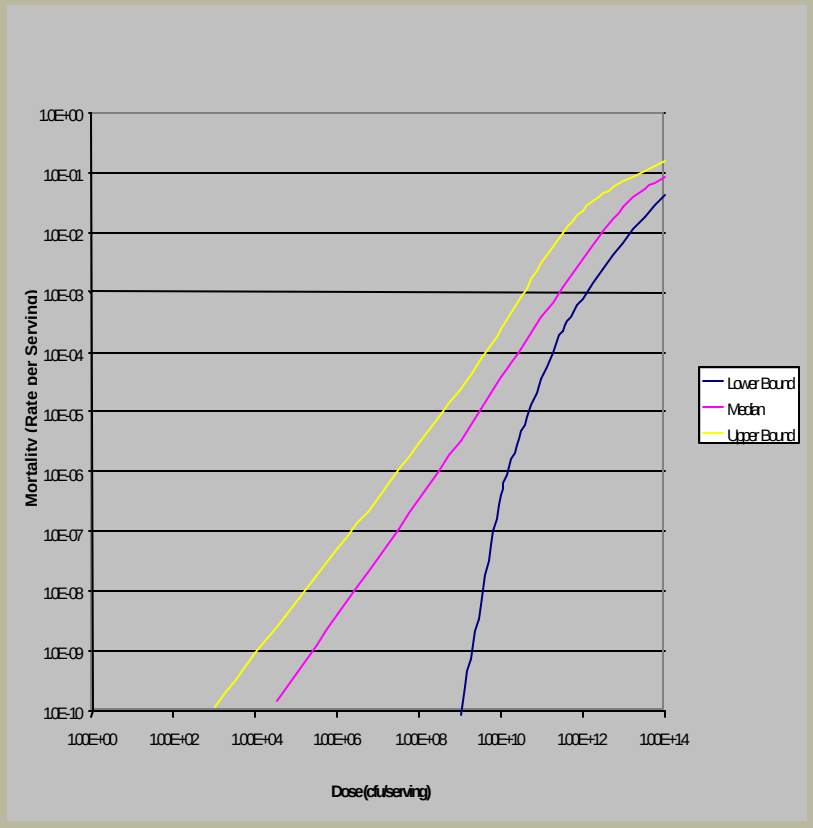
Pre-packed: 77% of the samples (0.4%)

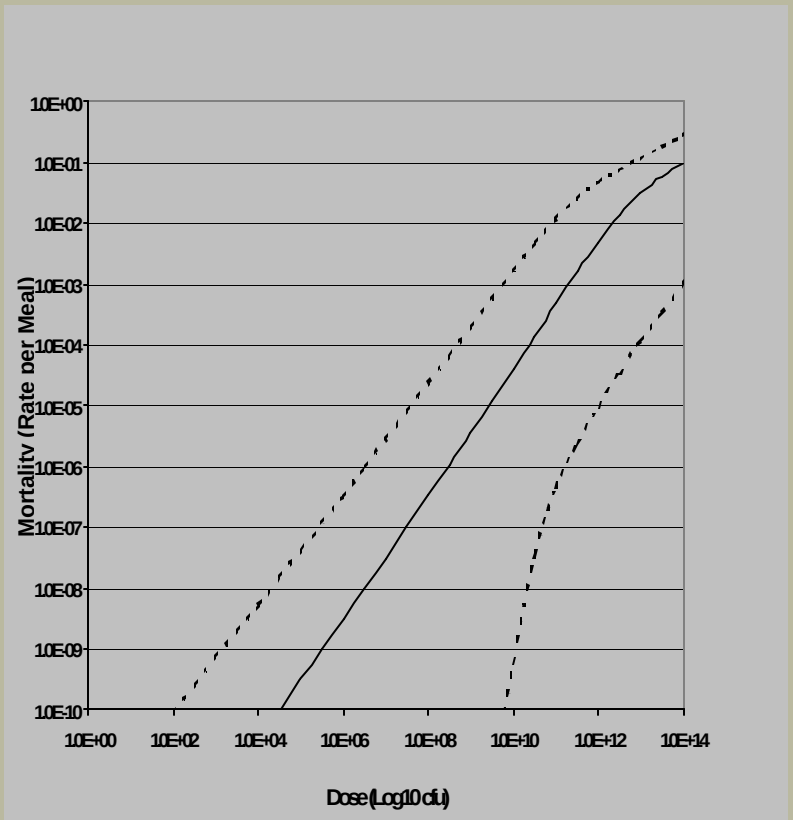
Deli-packed: 23% of the samples (2.7%)

Dose-Response Changes

- Separate mortality to hospitalization ratios calculated for each population
- An additional year of FoodNet data (2000) was included (slightly reduced the total number of predicted cases)
- Scaling factor was selected to adjust the median value for the predicted number of cases to the FoodNet estimates
  - A different scaling factor is used to adjust the exposure assessment to the FoodNet estimates.
  - As a result, the scaling factor is a distribution; the total number of predicted cases is not.

Comparison of DR 2001 and Revised –Elderly Population





2001

Revised

Comparison of 2001 and Revised Results – Deli meats, Elderly

Listeriosis	Median	5th 'ile	95th 'ile
Per annum			
2001	650	9	32,092
Revised	850	165	1,106
Per serving			
2001	2.2×10^{-7}	3.0×10^{-9}	1.1×10^{-5}
Revised	3.0×10^{-7}	5.8×10^{-8}	3.9×10^{-7}

Summary

- The revised model is completed and undergoing scientific and management review
- The revised risk assessment report is being prepared for scientific and organizational reviews
- Deli meats remain among the “highest risk” foods on a per annum and per serving basis

Website

http://www.foodsafety.gov