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Food Safety and Inspection Service

Simplified Modeling Framework for Microbial Food-Safety Risk Assessments

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Overview:

- Goal of the symposium: The role of mathematics and statistics in food safety
- Topics covered so far include epidemiology, quantitative microbiology, risk assessment
- Topics not covered (in depth): survey stats (consumption patterns, consumer behavior…), economics, censored data, genetics, toxicology, differences between microbial and chemical risk assessment
- Goal: Demonstrate how risk assessment ties together research results from a broad range of disciplines

Overview: Part II

- Briefly describe the Food Safety and Inspection Service (FSIS)
- Overview of food-safety risk assessment
- Describe how risk assessment integrates data and research/models from diverse fields to support decision making
- Describe the current “philosophy” for risk assessments in FSIS
- Provide a range of examples

What is FSIS?

- **Public health regulatory agency in USDA**
  - considers the entire food-safety system (from farm-to-table)
  - collaborates with other federal agencies (e.g., FDA, CDC)
  - collaborates with domestic and international partners
- **Ensure meat, poultry, and egg products are safe**
  - inspection and monitoring of all aspects of processing for good hygienic practices across **all** producers/processor of meat and poultry products.
  - establishing standards (mandatory) and guidelines (voluntary) for production and processing facilities

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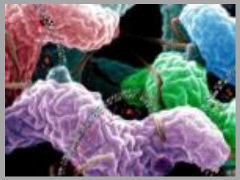
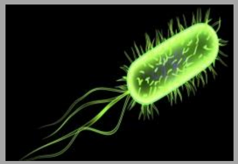
Food Safety Challenge: Existing & Emerging Hazards

- Mitigating established microbial food safety risks
  - *Campylobacter*, *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7
- Preventing emerging food safety risks
  - non-O157 STECs, *C. difficile, toxoplasmosa,* highly pathogenic avian influenza, antimicrobial resistant pathogen strains, bovine spongiform encephalopathy (BSE),…
  - chemical contaminants (e.g., PFCs, heavy metals), veterinary drug residues,…



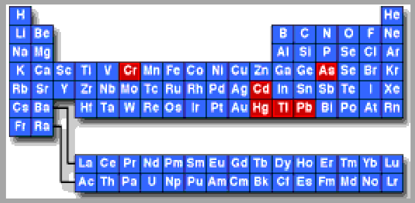
Campylobacter



Listeria monocytogenes

Salmonella

E. coli O157:H7



Arsenic, Mercury, Cadmium

Food-Safety Risk Assessment at FSIS

- Scientific process for estimating the probability of exposure to a hazard and the resulting public health impact (risk);
- Predicts public health benefits (reduction in illnesses) from changes in policies, practices, and operations (can be retrospective).
- Used to facilitate the application of science to policy (decision support tool)

Mathematics of Food-Safety Risk Assessment

- Many food-safety risk assessments reduce to:

$$N_{ill} = N_{servings} P(ill), \text{ where } ill\text{=illness per serving}$$

- The effect of a change (reduction) in contamination (risk) is:

$$\Delta N_{ill} = N_{servings}\left[P_{old}(ill) - P_{new}(ill)\right]$$

- Probability of illness can be factored as:

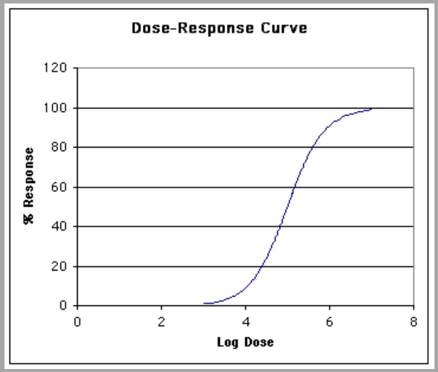
$$P(ill) = P(ill \mid exp)P(exp) + P(ill \mid \overline{exp})P(\overline{exp}), \text{ where } exp\text{=exposure}$$

- Probability of illness depends on level of contamination:

$$P(ill) = \int R(D) f(D) dD, \text{ where } D\text{=dose,}$$

$f(D)$ is dose distribution,

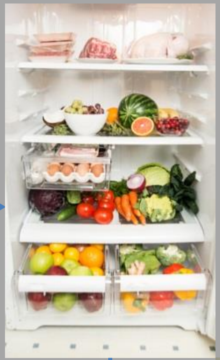
$R(D) = P(ill \mid D)$ is dose-response model



Sources of complexity in risk-assessment models: Need for quantitative microbiology models

Typical point of data collection (where change is likely to occur)

Growth, partitioning, mixing



Growth

Growth or attenuation

Cross-contamination, partitioning, attenuation

Is there a sufficient dose to be a cause illness?

Sources of randomness in risk-assessment models: Variability=true differences that cannot be reduced with the collection of additional data.

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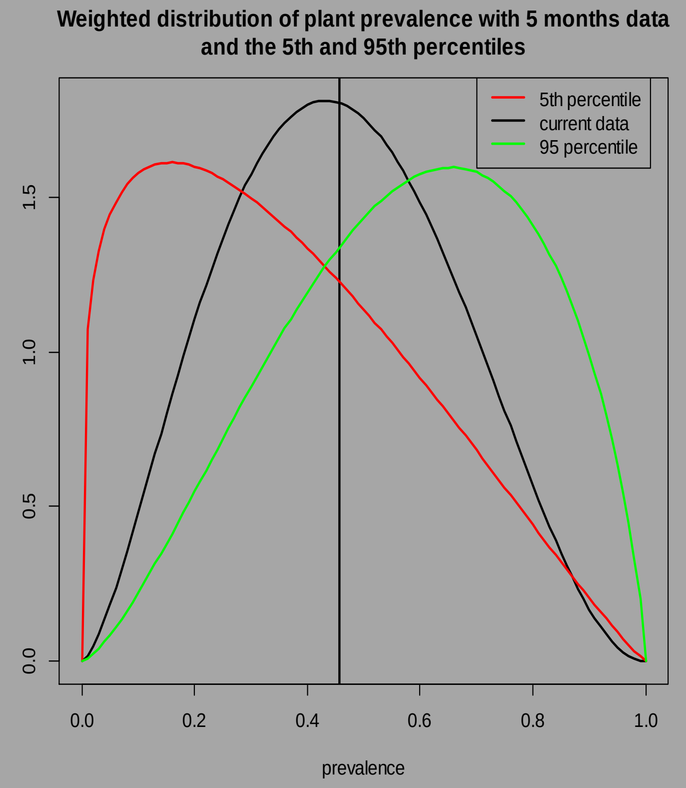
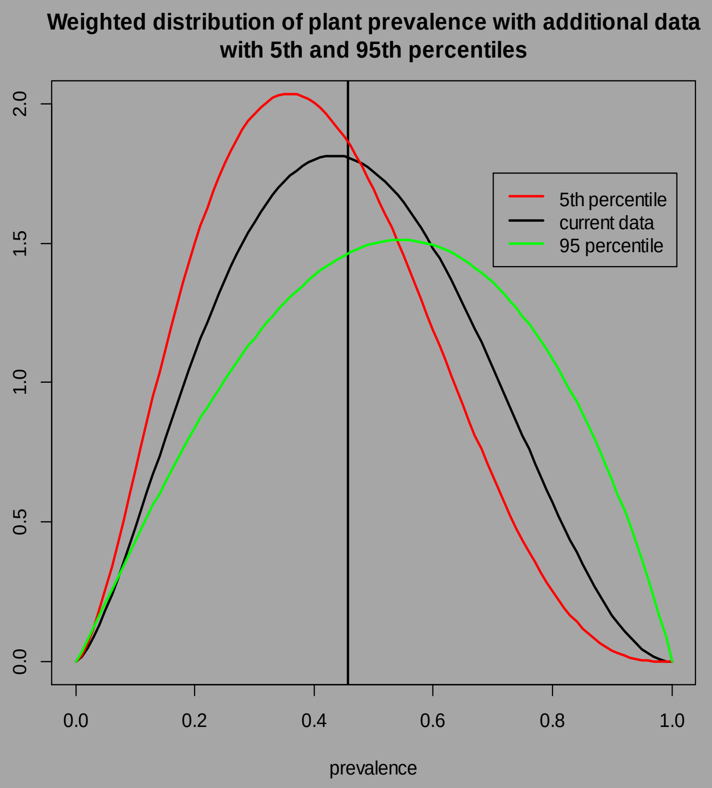
Sources of randomness in risk-assessment models:

Uncertainty = characteristics that can be reduced with the collection of additional data.

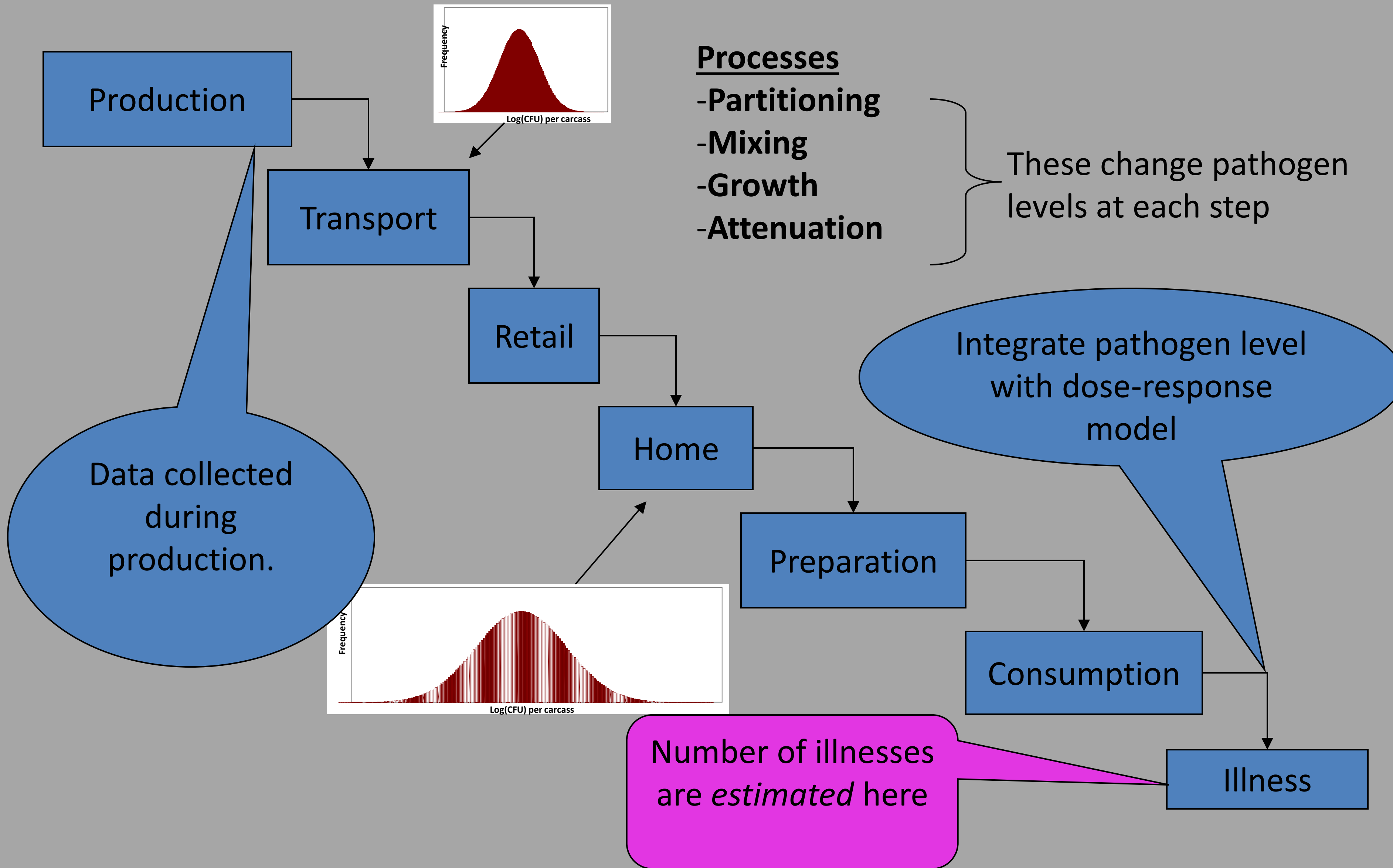
5 months of data



8 months of data



Hypothetical mechanistic risk assessment model



Example 1. Estimate the effect of instituting a inspection program for catfish

- FDA responsible for catfish safety
- Proposed law to move catfish regulation from FDA to FSIS
- Question: What would be the effect of instituting an inspection program for catfish that is similar to other meat and poultry inspection programs?

Figure 1: Basic construction of FSIS catfish risk assessment model

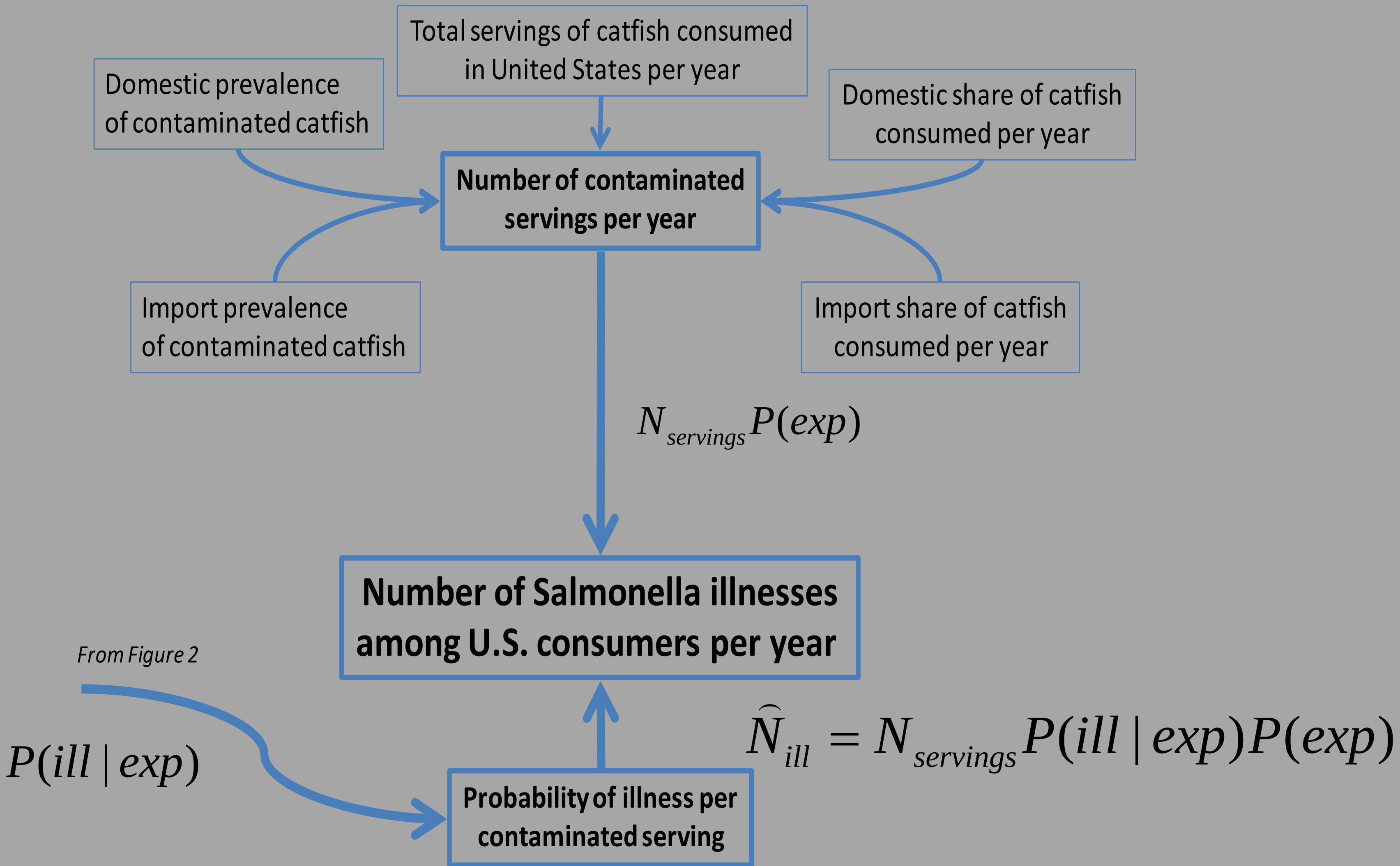
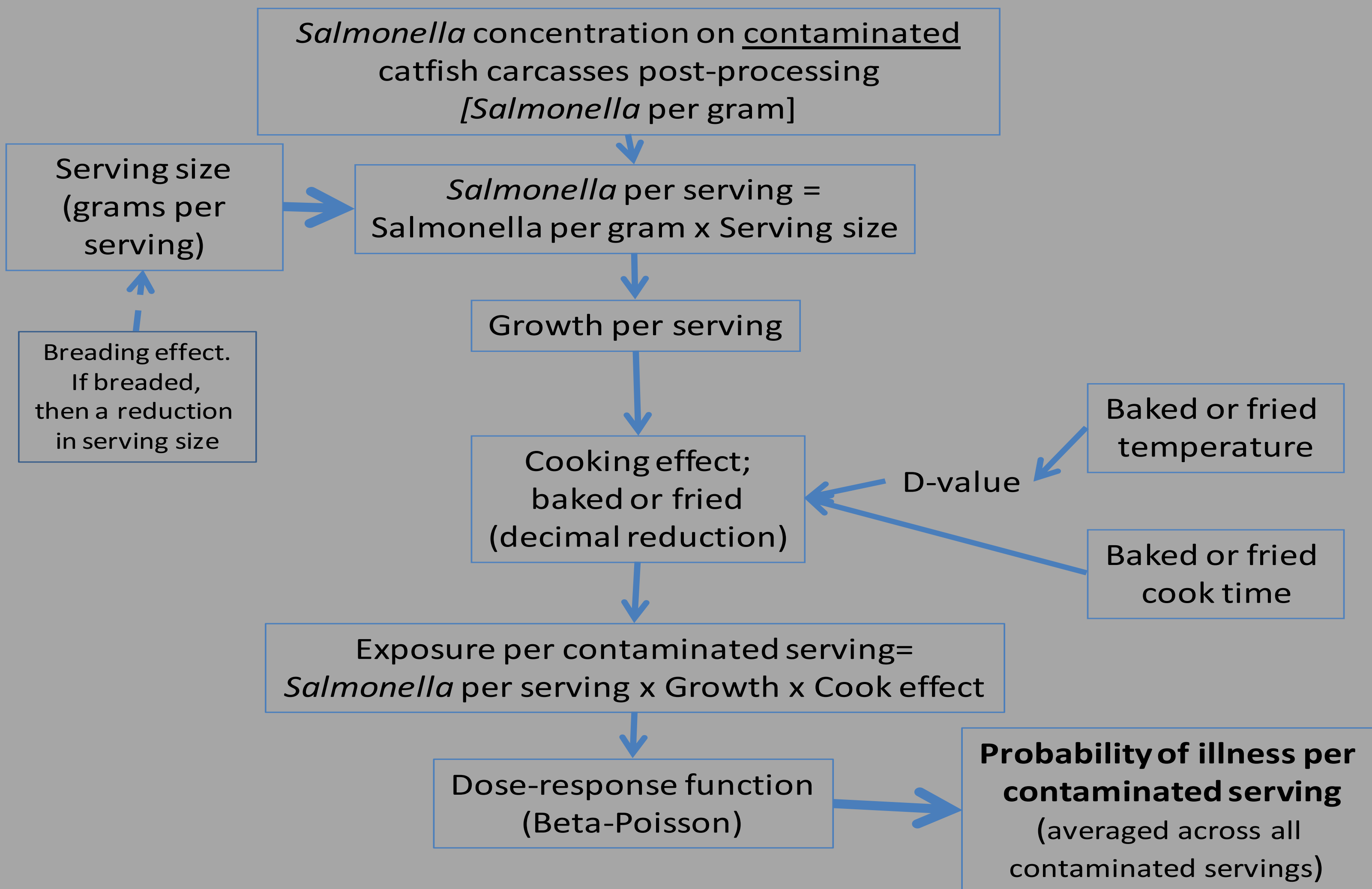


Figure 2: Determination of $P(ill|exp)$



$P(ill|exp)$

Concerns with only using predictive microbiology models

- Users primarily interested in estimates of illness but…
  - predicted illnesses may not match surveillance data
  - models are difficult to calibrate
  - not clear which processes should be modified during calibration?
  - hard to maintain objectivity
- Data intensive
  - how to address data gaps?
  - how long will it take to collect and analyze missing information?
  - how much will it cost?
  - is your agency responsible for the specific part of the food-chain?
- Time consuming
  - typically takes 1 to 2 years to complete
  - changes to proposed policy require modification and recalibration
- Difficult to review and communicate

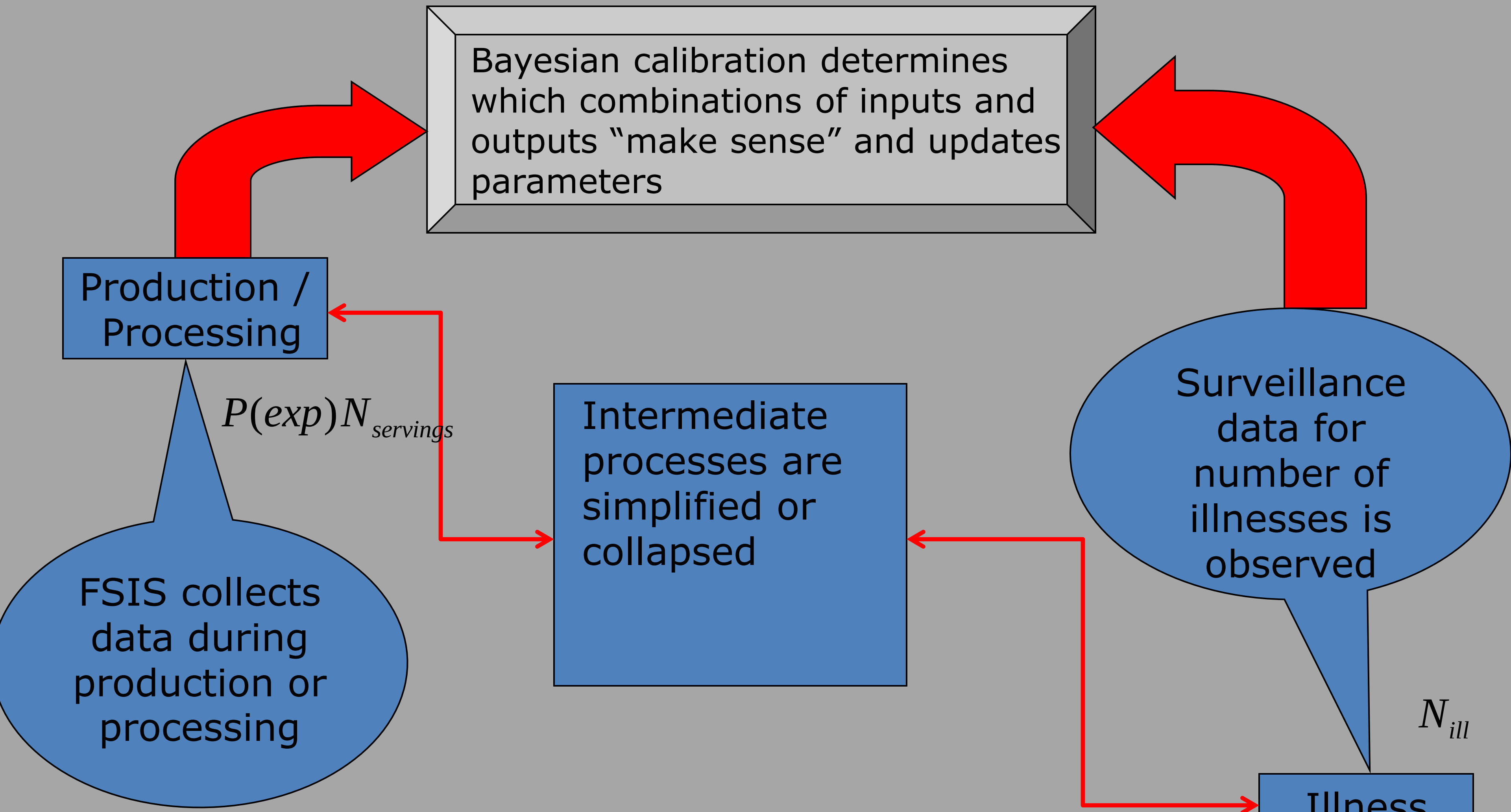
Guiding principles for a simplified risk assessment framework

- **Models should be no more complex than necessary**
- **Fewer data requirements**
  - Data should be relevant to policy question
- **Models should produce uncertainty estimates**
  - 2-d model
  - Reflects both variability and uncertainty
- **Model is flexible**
  - Needs to address many FSIS applications

What is the key piece of information that allows simplification?

- **Microbial contamination generally lead to acute illness**
  - Single meal -> illness
- **Human health surveillance "counts" total illnesses**
  - Pathogen specific
  - CDC FoodNet (US), National Enteric Surveillance Program (NESP)
  - Counts consist of laboratory confirmed cases
- **Outbreak investigation provides attribution estimates**
  - Simple attribution

Schematic for a simplified modeling process



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Example 2: Which FSIS-regulated product is most likely to cause illness?

- Pathogens of interest *Salmonella, E.coli* O157:H7
- Commodities
  - Beef
  - Chicken
  - Pork
  - Lamb (no active sampling program=no exposure data)

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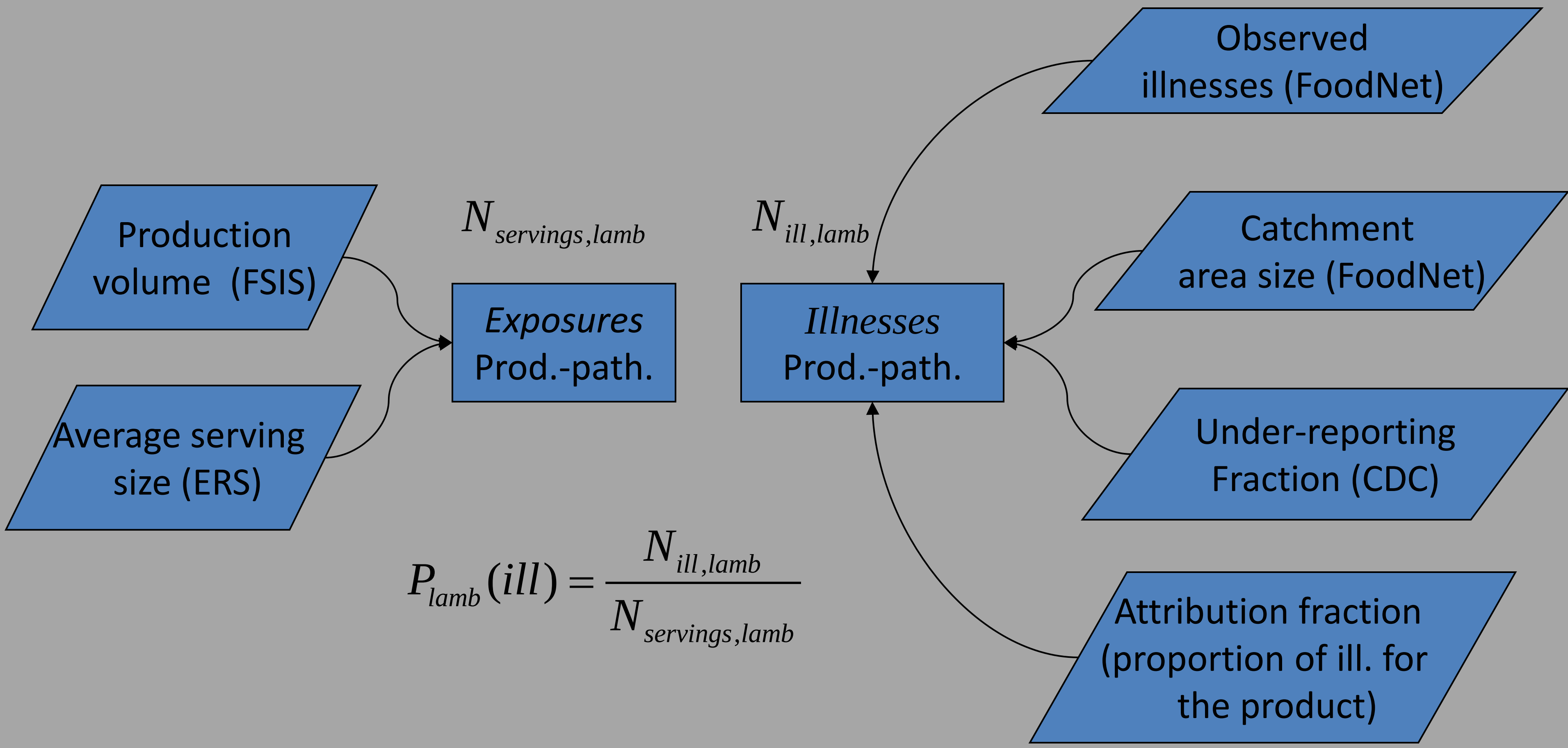
Data Requirements



$$P_{lamb}(ill) = \frac{N_{ill,lamb}}{N_{servings,lamb}}$$

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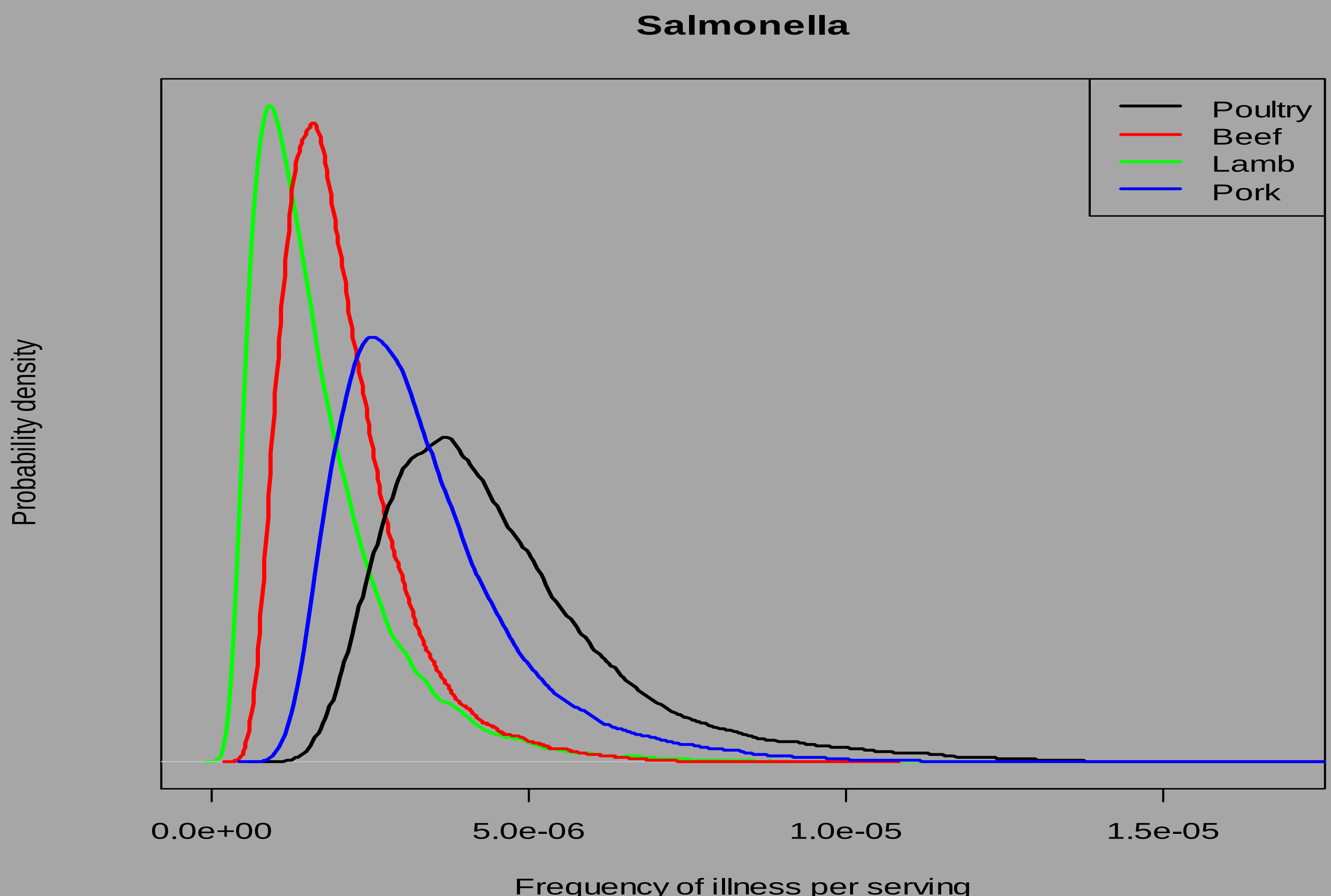
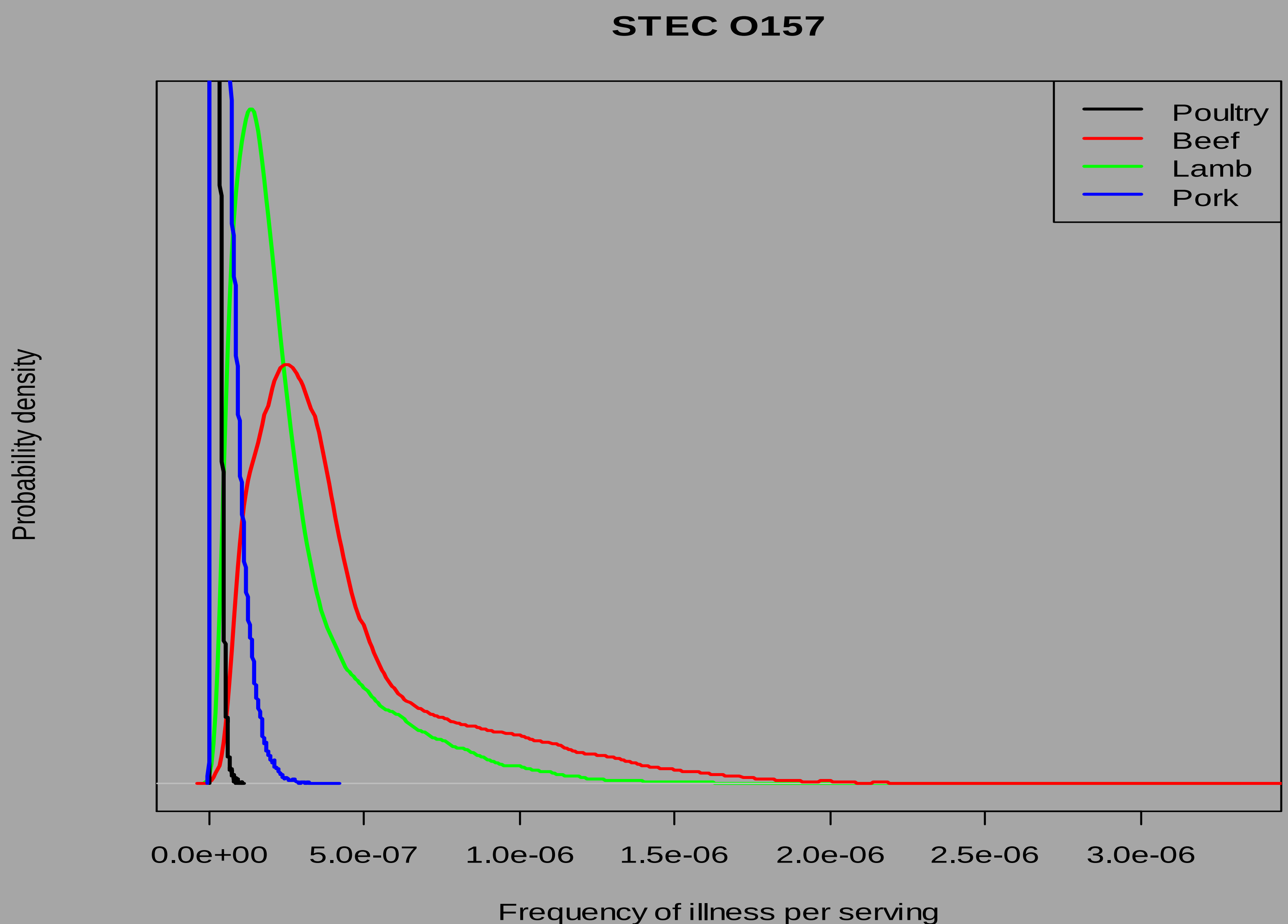
Uncertainty distributions describing risk of salmonellosis per serving



Uncertainty distributions describing risk of *E. coli* O157:H7per serving



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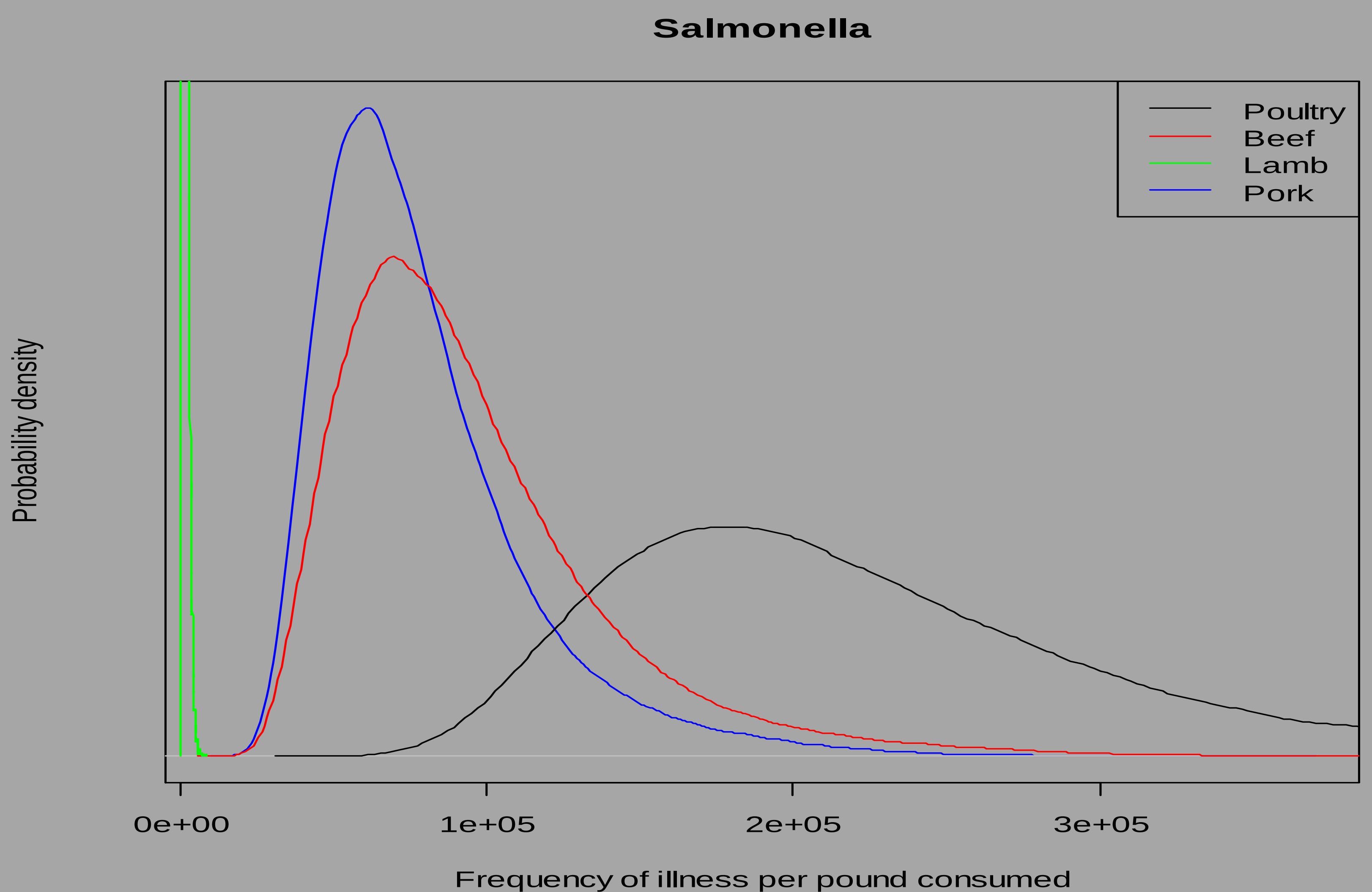
Uncertainty distributions describing total illnesses from *Salmonella*



Summary of results

- Lamb *similar* risk to beef for both *Salmonella* and *E. coli* O157:H7, respectively. Low consumption leads to few illnesses
- Simplified framework allows estimation of $P_{lamb}(ill)$ even when FSIS lacks sufficient data to build traditional model.
- Conundrum:
  - Improving food safety -> reducing risk -> regulate lamb and bee similarly.
  - Reducing societal cost of illness -> reduce total illness burden -> continue to focus on chicken-*Salmonella* and beef-*E.coli* O157:H7

Example 3: How effective was the PR/HACCP rule for reducing *Salmonella* illnesses in chicken?

- FSIS implemented the Pathogen Reduction / Hazard Analysis and Critical Control Point (PR/HACCP) program
  - Staged introduction between 1996-2000
  - Set performance standards for meat and poultry products
  - FSIS observed significant drop in *Salmonella, particularly* in chicken between 1995 (pre-PR/HACCP) and 2000
- CDC implemented new FoodNet human surveillance program
  - Staged introduction between 1996-2000
  - Program expanded to cover larger population
- Risk assessors asked "How many illnesses were prevented by PR/HACCP?" (retrospective assessment of policy effectiveness)

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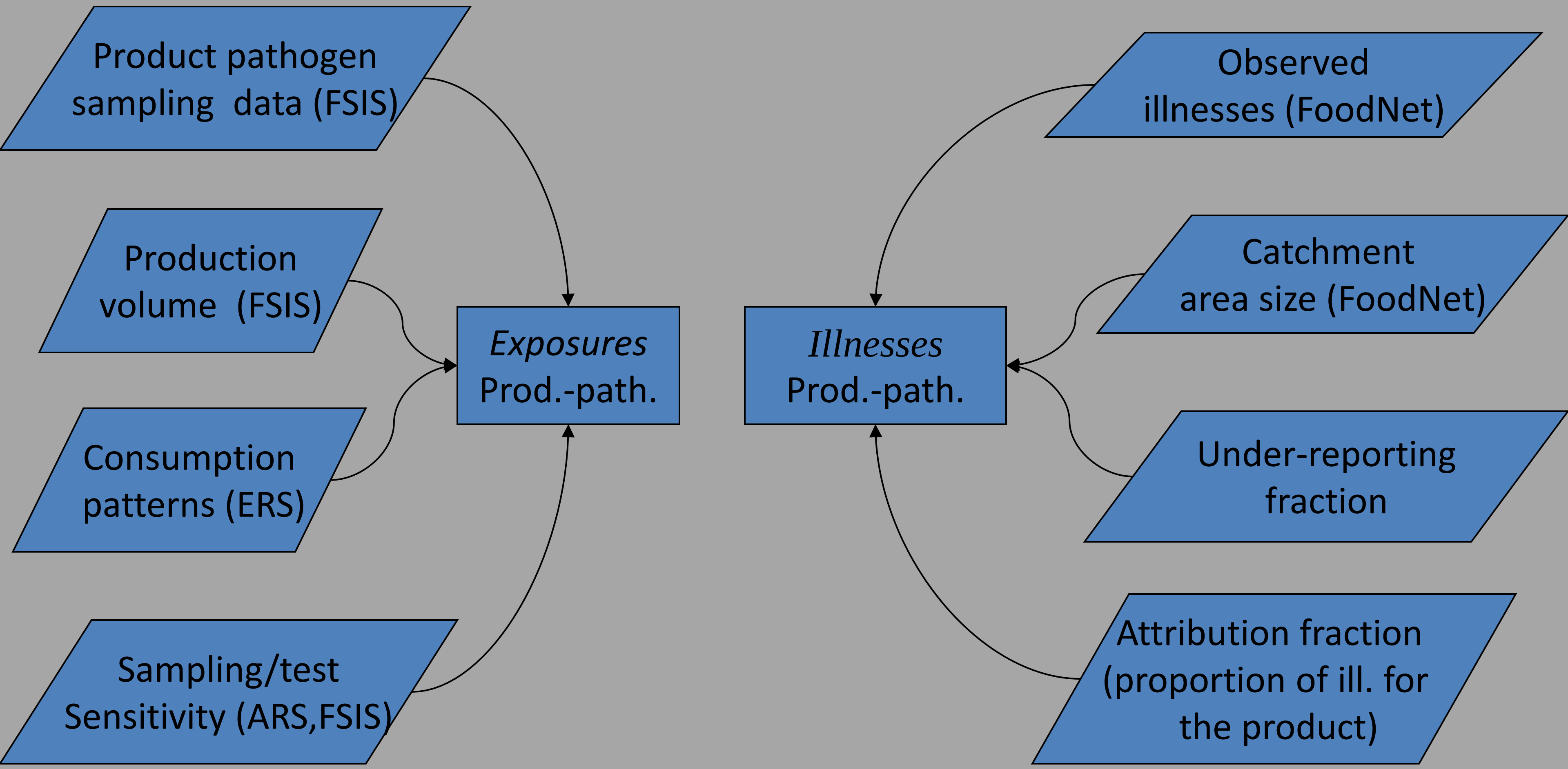
Risk assessment objectives

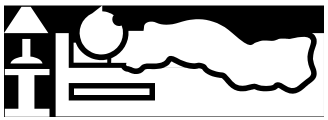
- Estimate the total annual *Salmonella* illnesses and illnesses associated with chicken consumption in 1995 (i.e., prior to PR/HACCP and FoodNet)
- Estimate number of cases in subsequent time periods (2000 and 2007).
- Estimate magnitude of the reduction
- Assess power of the public health surveillance system (FoodNet) to detect changes in illness rates

Data Requirements



Data source and modeling

Estimation of human illness with uncertainty



FoodNet Illness(2000)=

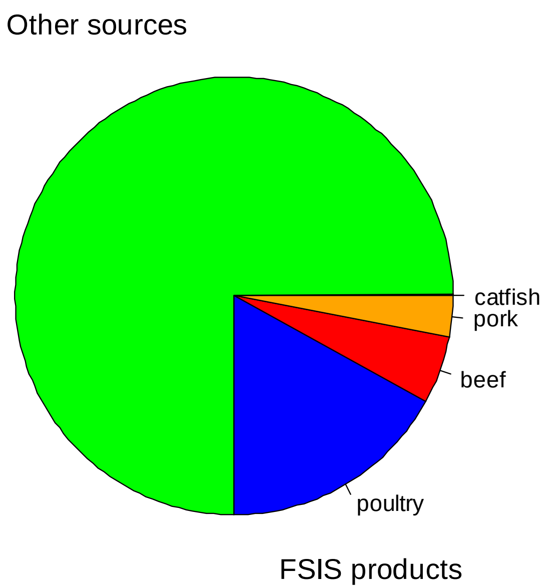
4,237

{ 600,000?
1,125,000?
2,000,000?

The 4237 confirmed illnesses scale up to somewhere between 600,000-2 million salmonellosis cases (Scallan 2011).

Data Sources: FoodNet & Scallan et al. (2011) Foodborne Illness Acquired in the United States—Major pathogens. *Emerging Infect. Disease*

What fraction of salmonellosis cases are due to chicken (attribution)?



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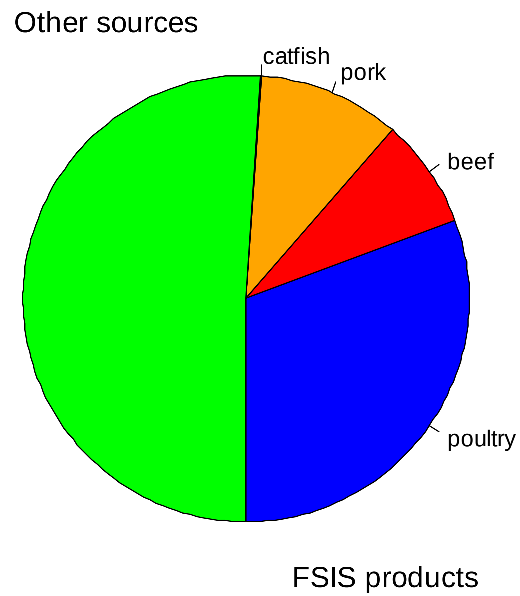

Data Sources: FSIS analysis of CDC outbreak data suggest between 10 and 40% of illnesses in 2000. Painter et al. (2013) Attribution of Foodborne Illnesses… *Emerging Infect. Disease*

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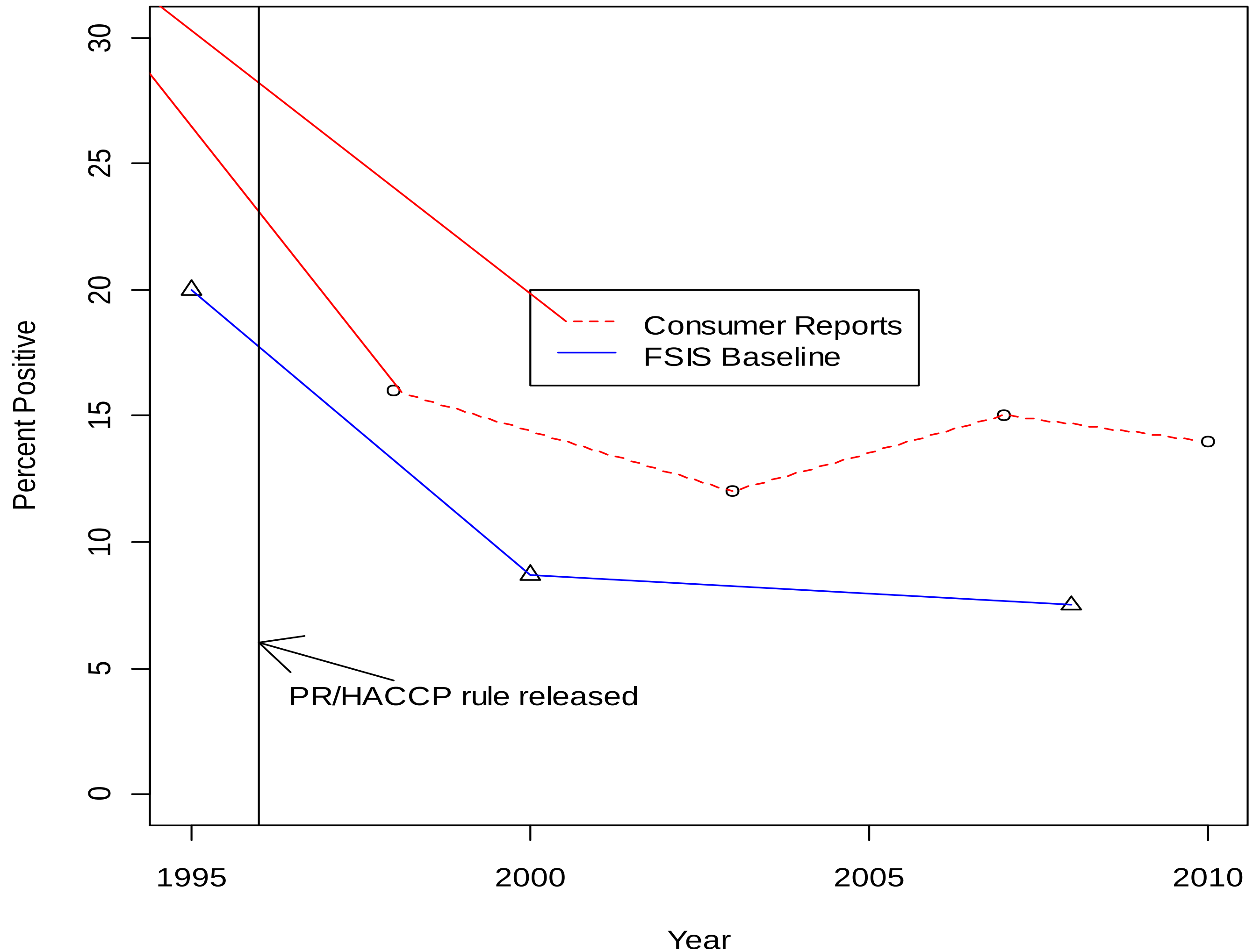
Changes (reductions) in *Salmonella* contamination of chicken



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Other data:

- **FoodNet observed illnesses in 2000 and 2007(CDC)**
  - 4837 in 2000
  - 6828 in 2007
- **Change in US population over time (US Census Bureau)**
- **Number of chicken servings (ERS/FSIS, 2008)**
- **Change in chicken consumption over time (AMI 2009)**
- **FSIS testing data finds no change significant change in the number of *Salmonellae* per chicken across the three surveys (1995,2000,2007).** $P(illness|exposure)$ =constant across time.

Modeling: Bayesian sampling importance resampling (SIR)

- Construct parametric distributions to describe the uncertainty in each model parameter
- Draw a large number (*N*) of samples from each distribution (3 million)
- Combine the samples to generate an estimate the observed number of illnesses in FoodNet for the year 2000.
- Compared estimated FoodNet illnesses with observed illnesses in the year 2000. The degree of similarity defines a weight ω_i
- Resample (*n*) with replacement from the *N* with weights ω_i
- The *n* samples represent posterior distribution

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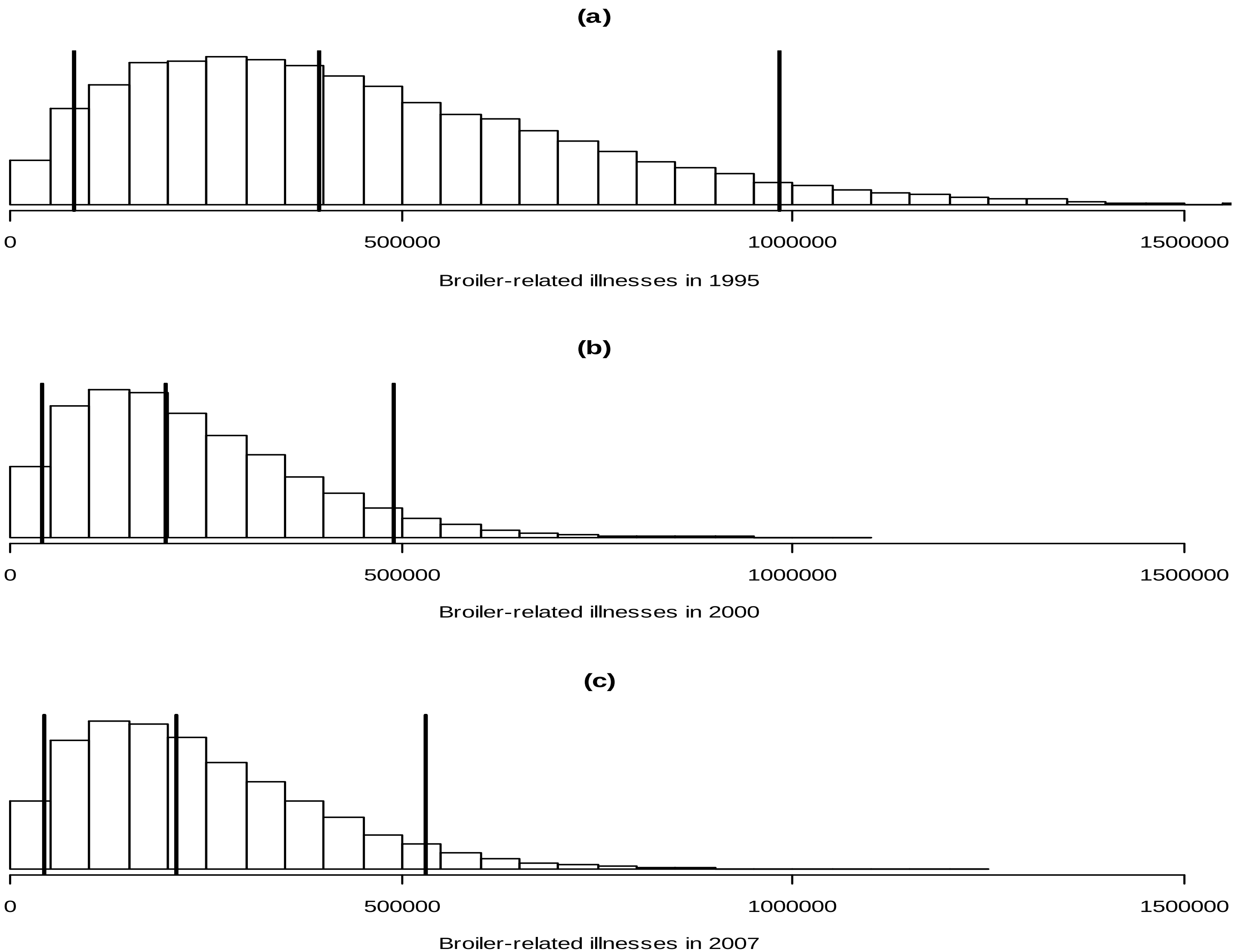
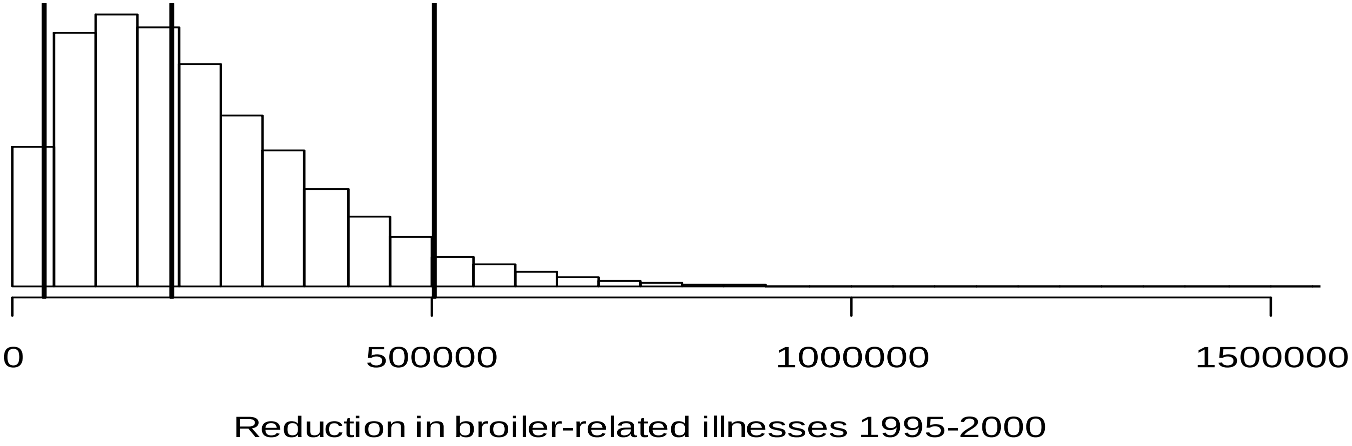
Results:

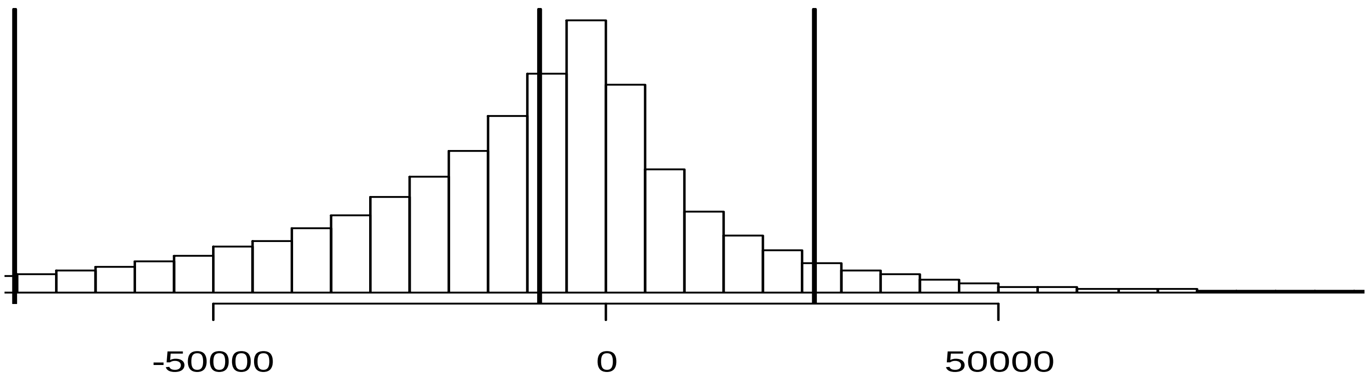


Change in chicken-related salmonellosis cases

(a)



(b)



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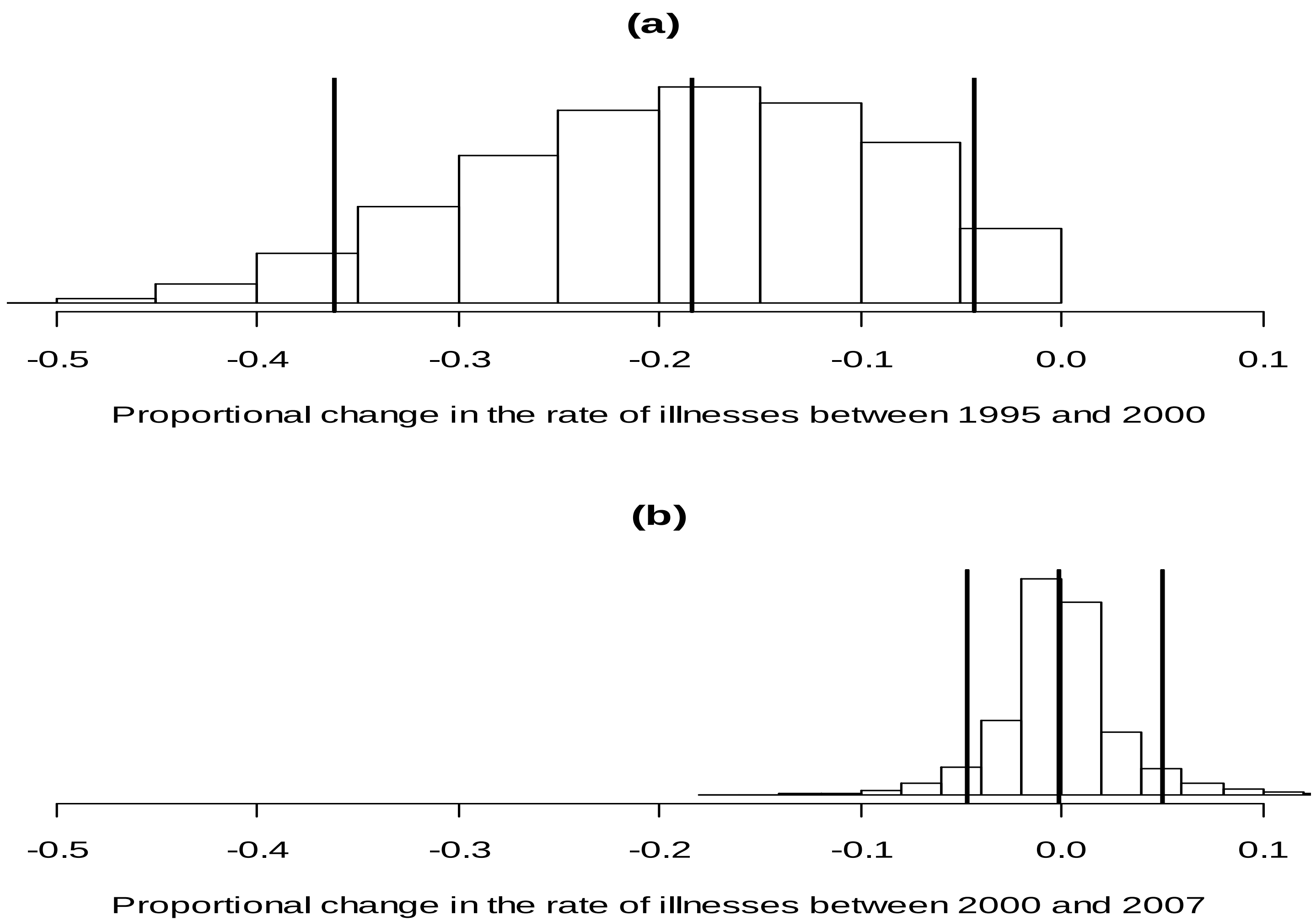
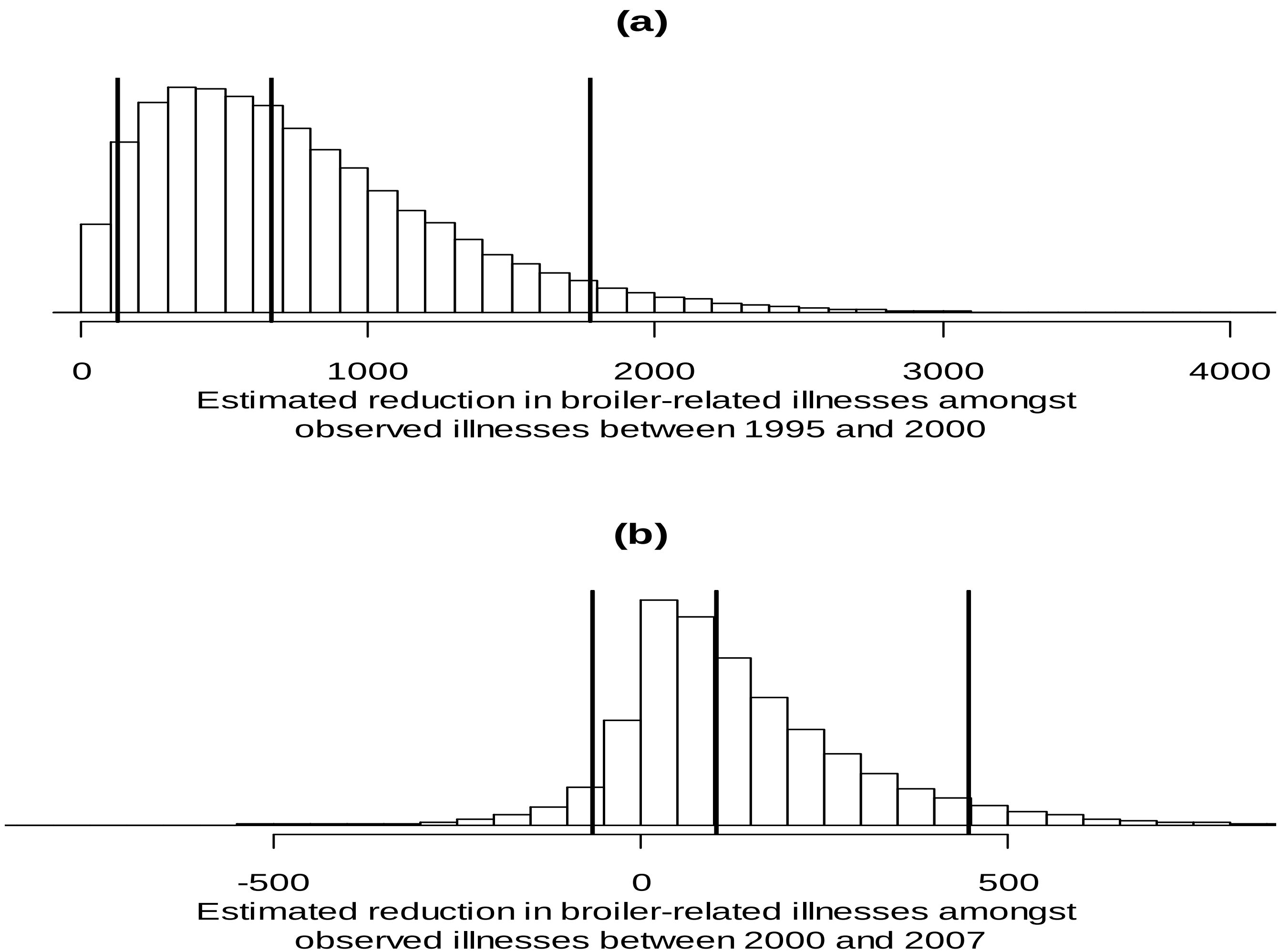
Proportional change in chicken-related salmonellosis cases



Estimated change in chicken-related salmonellosis cases in FoodNet



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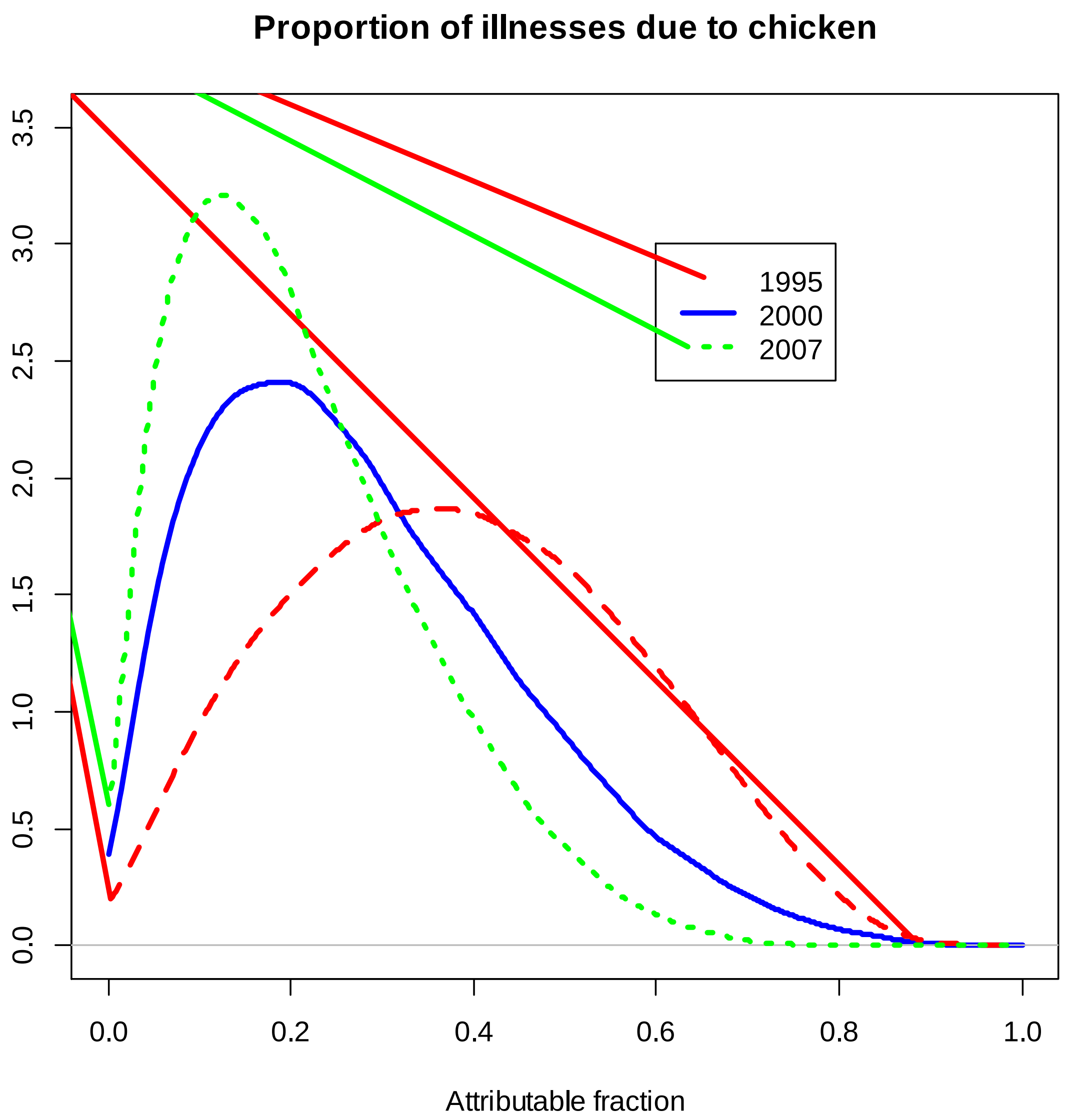
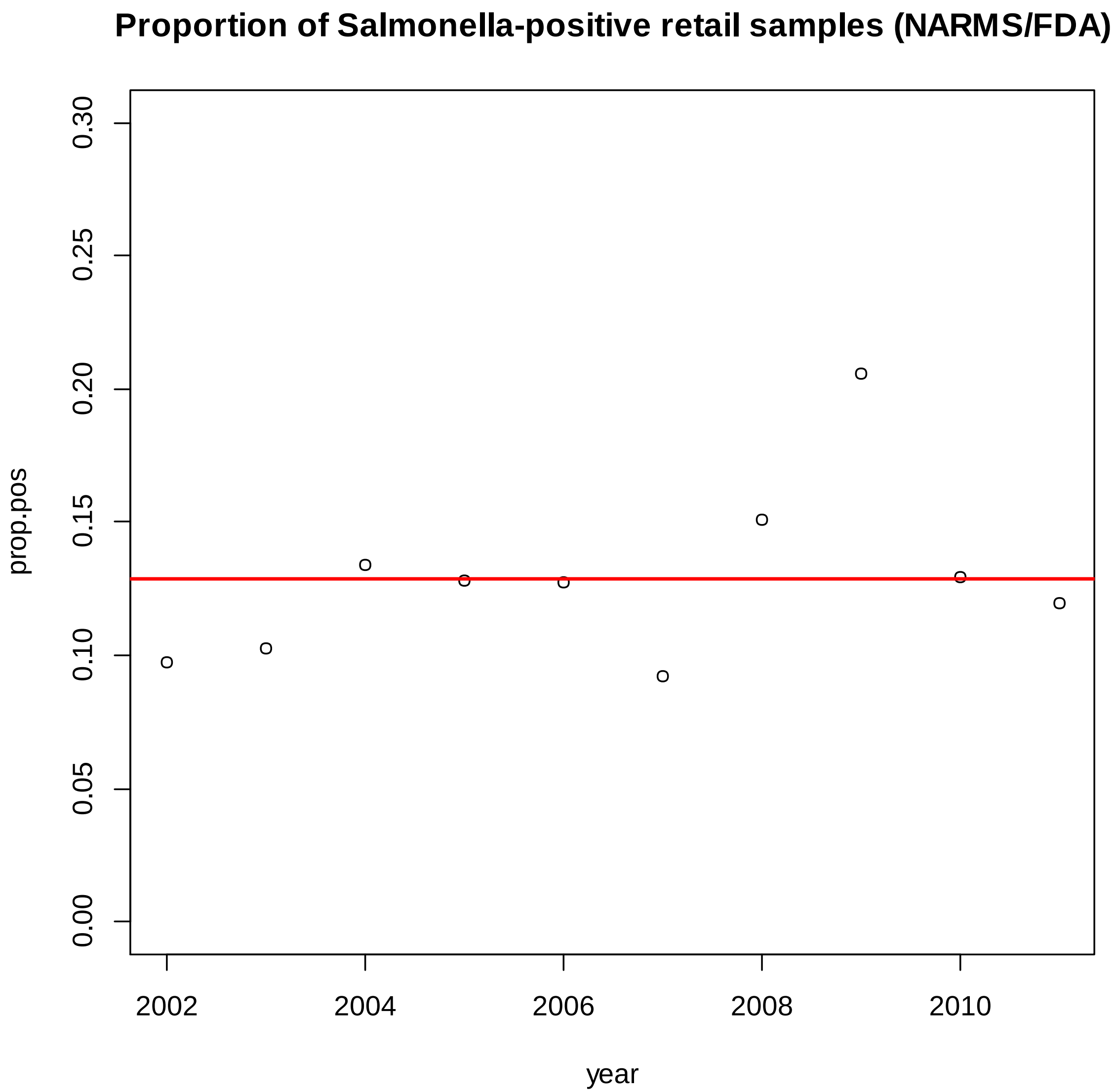
Proportion of illnesses attributed to chicken



Model *validation*

- The model estimates a 19% reduction in total salmonellosis cases between 1995 and 2000. CDC provides estimates an 8% (range 2 to15%) and 25%
- The model estimates that about 18% of salmonellosis cases are attributed to chicken – CDC (2013) estimates that 19% are attributed to poultry
- The model estimates little or no change between 2000 and 2007. Retail survey data (NARMS/FDA) finds that proportion of contaminated chicken breasts is basically unchanged between 2002 and 2011.

NARMS (FDA) exposure data



Conclusions

- **PR/HACCP program lead to a reduction of approximately 200,000 illnesses from *Salmonella*-contamination chicken**
- **Number of illnesses was relatively stable 2000 and 2007**
- **Reduction in illnesses would have been observed if FoodNet were operational in 1995**
- **Changes in contamination were too small for FoodNet to detect between 2000 and 2007**
- **FSIS institutes stricter performance standards in 2011 to further reduce salmonellosis cases**

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Final thoughts

- Model are constructed to be no more complex than necessary
- The models depend heavily on public health/epidmiology
- Simplified framework ensures predicted illnesses are consistent with observed numbers.
- Provide a framework for ongoing annual estimates of illness with appropriate uncertainty

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Questions?

Except where noted, the views presented in
this presentation are solely those of the presenter.