Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
An Assessment of Prevalence-based Models for Predicting Reductions in Illnesses Attributed to Microbial Food-Safety Policies

Michael Williams, Eric Ebel
Risk Assessment and Analytics Staff
Food Safety and Inspection Service
Outline specific risk management question (estimate illness reductions)
• Brief review of risk assessment models (process models) previously used by FSIS
• Describe available data (limitations/advantages)
• Introduce a simpler process model and an approximation based on apparent prevalence (prevalence model)
• Compare illnesses reduction estimates from process- and prevalence models for Campylobacter, Salmonella and E. coli O157:H7
Do cost savings from illnesses avoided outweigh industry costs for implementing a new regulation?

\[
Cost \ savings = \Delta N_{ill} \times (cost/illness) \geq Industry \ cost
\]

Illnesses reductions are proportional to the current number of illnesses

\[
\Delta N_{ill} = KN_{illnesses}, \ 0 \leq K \leq 1
\]
Total illness burden:
\[ N_{ill} = N_{servings} \cdot P(ill), \text{ where } P(ill) = \text{illness per serving} \]

Probability of illness depends on level of contamination:
\[ P(ill) = \int P(ill \mid D) \cdot f(D) \, dD, \text{ where } D = \text{dose}, \]
\[ f(D) \text{ is dose distribution,} \]
\[ P(ill \mid D) \text{ is dose-response model} \]

The effect of a change (reduction) in contamination (risk) is:
\[ \Delta N_{ill} = N_{servings} \left[ P_{baseline}(ill) - P_{new}(ill) \right] \]
\[ \Delta N_{ill} = N_{ill} \left[ 1 - \frac{P_{new}(ill)}{P_{baseline}(ill)} \right] \]

Desired risk assessment output
\[ KN_{ill} \]
Food Safety and Inspection Service: Typical Food Safety Risk Assessment

- Growth or attenuation
- Cross-contamination, partitioning, attenuation

Data collection by FSIS at slaughter or processing

Partitioning, Cross-contamination

Growth

Difficult to fill data gaps

Is there a sufficient dose to be a cause of illness?

Log(CFU) per carcass

Frequency

Growth or attenuation

Cross-contamination, partitioning, attenuation

Log(CFU) per carcass

Frequency

$f(\lambda)$

$f(D)$
Food Safety and Inspection Service:
Motivation for alternative models

• Can we do something different?
• What data are available in a timely and consistent manner?
• Are there simpler ways to estimate $K$?
• Can we approximate $K$?
Food Safety and Inspection Service: Available Data

• FSIS product sampling data
  – Measures how contaminated is the existing product

• CDC surveillance (FoodNet, FDOSS)
  – FoodNet provided estimates of the total number of illness
  – FDOSS provides estimates of what proportion of all illnesses can be attributed (assigned) to an FSIS product (e.g., chicken, beef...)

Sample Collection

Screening test for pathogen presence $P(\cdot)$

Screening test is dependent on the LOD

Enumeration to determine levels $\lambda$
Food Safety and Inspection Service: Summarizing FSIS testing data

log10 transformed *Campylobacter* concentration (cfu/ml)

Limit of Detection ($L_\lambda$)

$P(-) = 0.54$  $P(+) = 0.46$

$f(\lambda)$
The confirmed illnesses scale up to somewhere between 600,000-2 million salmonellosis cases (Scallan 2011). About 84% of these are from domestic food sources.

Data Sources: FoodNet & Scallan et al. (2011) Foodborne Illness Acquired in the United States—Major pathogens. Emerging Infect. Disease
Food Safety and Inspection Service:
Attribution to Chicken

FDOSS data are used to estimate the proportion of salmonellosis cases due to chicken consumption.

Painter et al. (2013) Attribution of Foodborne Illnesses... *Emerging Infect. Disease*
Bayesian calibration determines which combinations of inputs and outputs “make sense” and updates parameters.

Prior distributions for intermediate processes are specified and final distribution applied to dose-response:

\[
\Delta N_{\text{ill}} = N_{\text{ill}} \left[ 1 - \frac{P_{\text{new}}(\text{ill})}{P_{\text{baseline}}(\text{ill})} \right]
\]

Production / Processing

\[f_{\text{baseline}}(\lambda), f_{\text{new}}(\lambda), N_{\text{servings}}\]

Illness

\[N_{\text{ill}}\]
Food Safety and Inspection Service:
A prevalence-based model

- Illness reductions can be estimated by the process models, but....
- Can we do something less complicated?
- What if we only considered $P(+) \text{and } N_{ill}$?
- A simple prevalence-based model is:

$$\Delta N_{ill} = N_{ill} \left[ 1 - \frac{P_{\text{new}}(\text{ill})}{P_{\text{baseline}}(\text{ill})} \right] \approx N_{ill} \left[ 1 - \frac{P_{\text{new}}(+)}{P_{\text{baseline}}(+)} \right]$$

$LOD$ can change relationship
• Simpler model is more transparent to reviewers and stakeholders
• For the given risk management question, any approximation should be conservative
  – predict fewer illnesses avoided
  – “Better to under-promise and over-deliver”
Food Safety and Inspection Service: Comparisons

• Use Bayesian process model as a baseline
• Compare illness reductions estimates from Bayesian process- and prevalence-based model over a range of datasets
Food Safety and Inspection Service: Datasets

• Product-Pathogens pairs considered:
  – *Campylobacter*-chicken
  – *Salmonella*-chicken
  – *E.coli O157:H7*- ground beef

• Data sources
  – HACCP ground beef sampling (2007-2009, N=30,995)
• Effect of a new policy (i.e., how does contamination change during production)
  – Case I: Reduction in log-transformed mean (models a reduction in contamination for all servings)
    $$\lambda_{\text{baseline}} \sim \text{lognormal}(\mu, \sigma)$$
    $$\lambda_{\text{new}} \sim \text{lognormal}(\mu - \Delta, \sigma)$$
  – Case II: Reduction in $P(+)$, but average concentration on test-positive samples is unchanged.
    $$\lambda_{\text{baseline}} \sim \text{lognormal}(\mu, \sigma)$$
    $$\lambda_{\text{new}} \sim \text{lognormal}(\mu - \delta, \sigma + \gamma) \quad \delta, \gamma > 0$$
Results
Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

Campylobacter

Desired result (conservative)
Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

![Graph showing the proportional reduction in illnesses compared to the proportional reduction in the log10-transformed mean for Salmonella. The graph includes lines for different LOD values and model types, indicating the effectiveness of reduction strategies.]
Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

![Graph showing proportional reduction in illnesses vs. proportional reduction in the log10-transformed mean for E.coli O157:H7. The graph includes three curves: full process model, prevalence-based LOD=0.003, and prevalence-based LOD=0.015.](image)
Food Safety and Inspection Service:
Case II: Reduction in P(\(+\)). Maintain concentration in failing establishments

Campylobacter

- full process model with LOD=0.03
- full process model with LOD=1
- prevalence-based

Estimated proportional reduction in illnesses
Proportional reduction in observed prevalence

Desired region
Food Safety and Inspection Service:
Case II: Reduction in $P(+)$. Maintain concentration in failing establishments

Salmonella

- process model, LOD=0.003
- process model, LOD=0.04
- process model, LOD=1
- prevalence-based

estimated proportional reduction in illnesses

proportional reduction in observed prevalence
Food Safety and Inspection Service:
Case II: Reduction in P(+), maintain average concentration in failing establishments (Note only 0.4 log reduction for *E.coli*).
Conclusions

- Prevalence-based model is conservative for reasonable LOD values.
- Agreement is highest for “rare” pathogens.
- Prevalence-based model can be used in situations where enumeration data are not available.
  - Substantial cost savings.
  - Works in situations where contamination levels are too low to fit $f(\lambda)$. 
Food Safety and Inspection Service:

Questions?