United States Department of Agriculture

One Team, One Purpose

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

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Food Safety and Inspection Service:

Outline

- 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?

$$Cost\ savings = \Delta N_{ill} \times \left(cost/illness \right) \geq Industry\ cost$$

- Illnesses reductions are proportional to the current number of illnesses

$$\Delta N_{ill} = KN_{illnesses},\ 0 \leq K \leq 1$$

Food Safety and Inspection Service:
Mathematics of food-safety risk assessment

- Total illness burden:

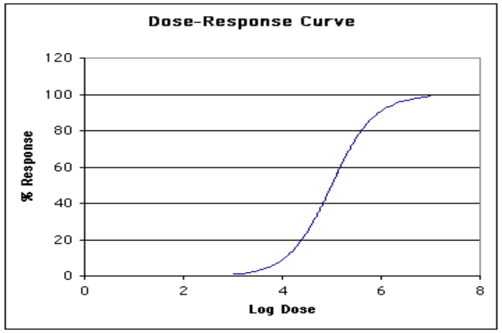
$$N_{ill} = N_{servings} P(ill), \text{ where } P(ill) = \text{illness per serving}$$

- Probability of illness depends on level of contamination:

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

$$f(D) \text{ is dose distribution,}$$

$$P(ill \mid D) \text{ is dose-response model}$$



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

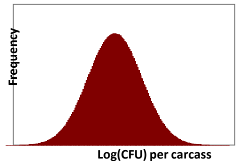
$$\Delta N_{ill} = N_{servings} \left[P_{baseline}(ill) - P_{new}(ill) \right]$$

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

Desired risk assessment output

$$KN_{ill}$$

Food Safety and Inspection Service:
Typical Food Safety Risk Assessment

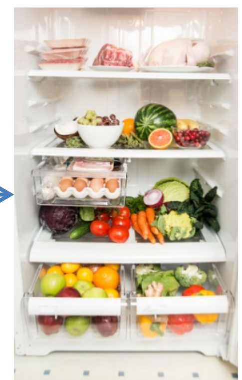


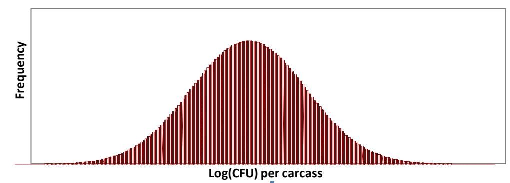
$f(\lambda)$

Data collection by FSIS at slaughter or processing

Partitioning, Cross-contamination

Growth





Is there a sufficient dose to be a cause illness?

$f(D)$

Difficult to fill data gaps

Growth or attenuation

Cross-contamination, partitioning, attenuation

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

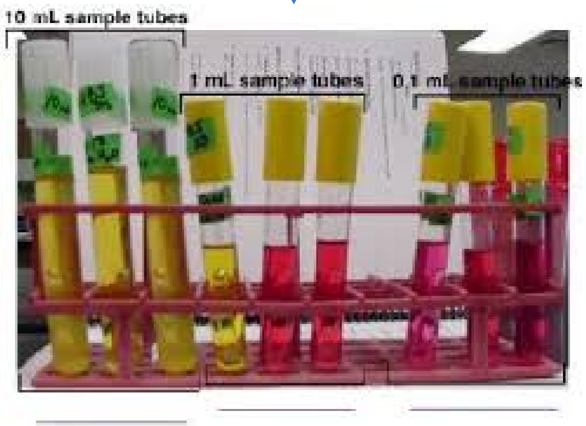
- FSIS product sampling data
  - Measures how contaminated is the existing product
- CDC surveillance (FoodNet, FDOSS)
  - FoodNet provided estimates of the total number of illness
  - FDOSS provides estimates of what proportion of all illnesses can be attributed (assigned) to an FSIS product (e.g., chicken, beef…)

Food Safety and Inspection Service:
FSIS Sample Collection and Testing

Sample Collection

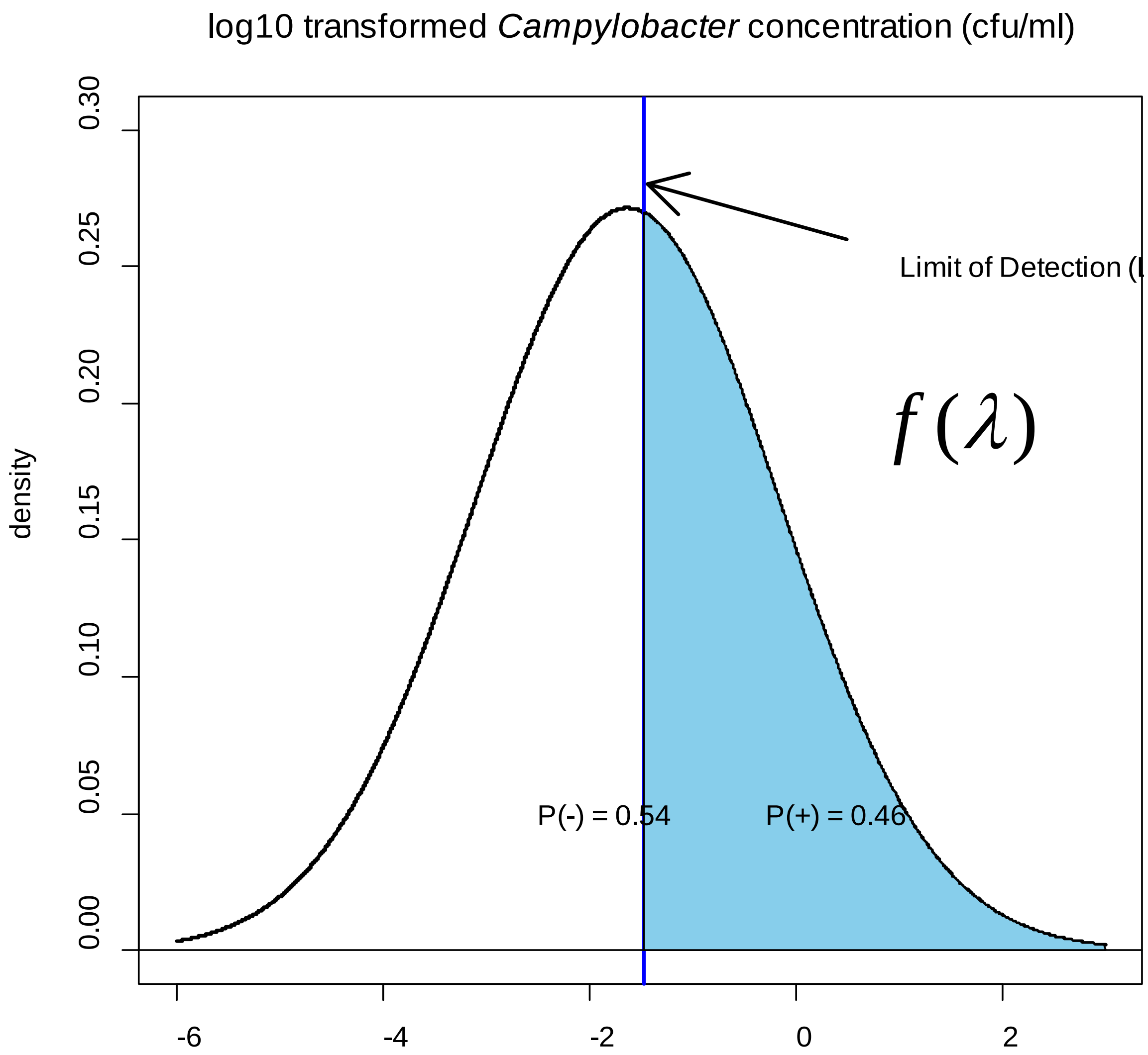
Screening test for pathogen presence $P(+)$

Screening test is dependent on the LOD

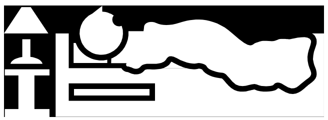


Enumeration to determine levels λ

Food Safety and Inspection Service:
Summarizing FSIS testing data



Food Safety and Inspection Service:
Estimation of human illnesses (with uncertainty)



FoodNet Illness (2013)=

7,277

600,000?

1,125,000?

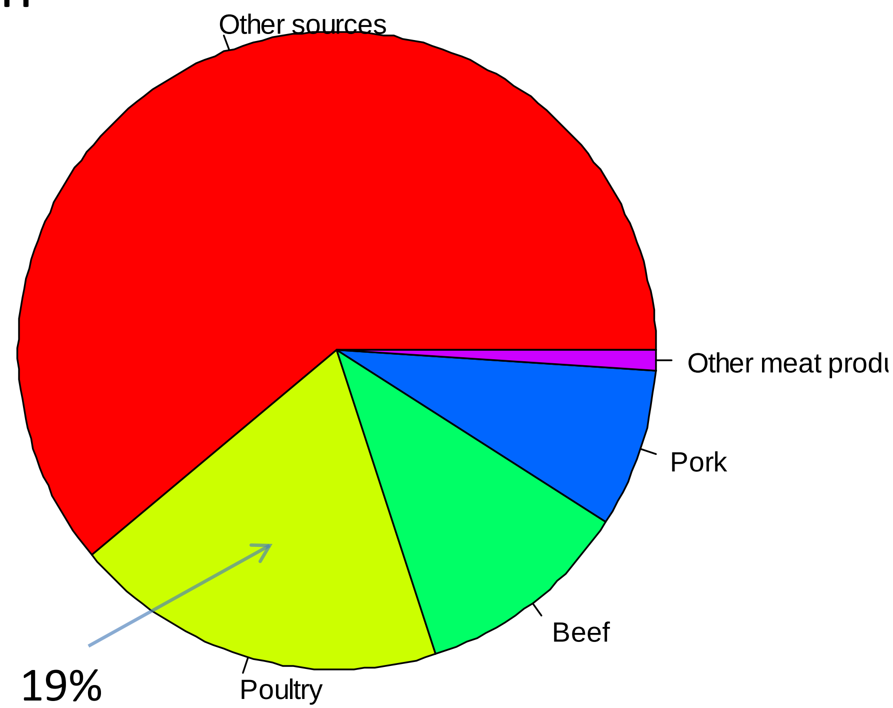
2,000,000?

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*

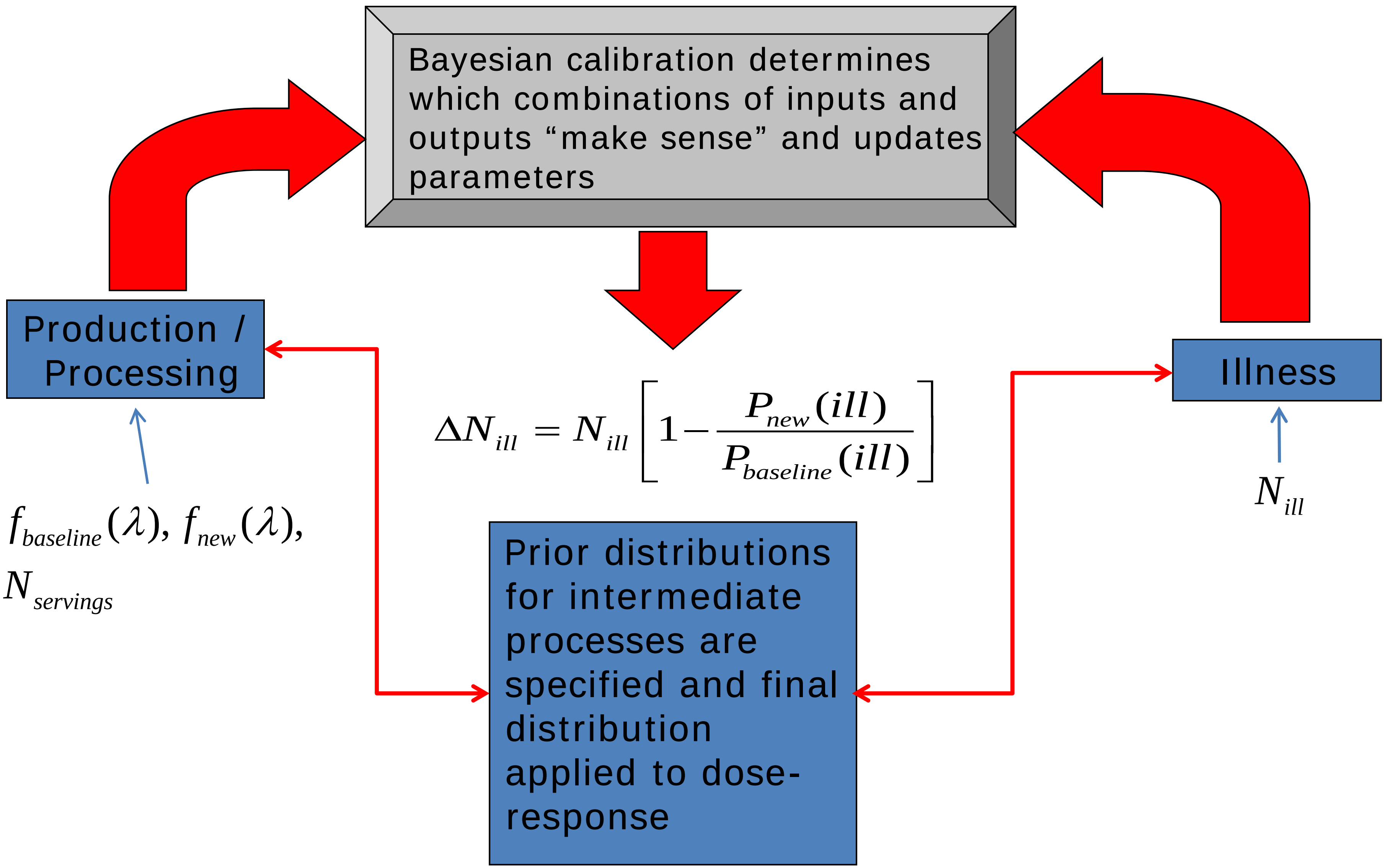
Food Safety and Inspection Service:
Attribution to Chicken

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*

Food Safety and Inspection Service:
Schematic of simplified process model



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 $P(+)$ and N_{ill}?
- A simple prevalence-based model is:

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

LOD can change relationship

Food Safety and Inspection Service:
Desired properties of prevalence-based model

- 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
  - FSIS broiler chicken baseline (2007-2008, N=3,275)
  - HACCP ground beef sampling (2007-2009, N=30,995)

Food Safety and Inspection Service: Examples/Scenarios

- 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)

$$\lambda_{baseline} \sim lognormal(\mu, \sigma)$$
$$\lambda_{new} \sim lognormal(\mu - \Delta, \sigma)$$

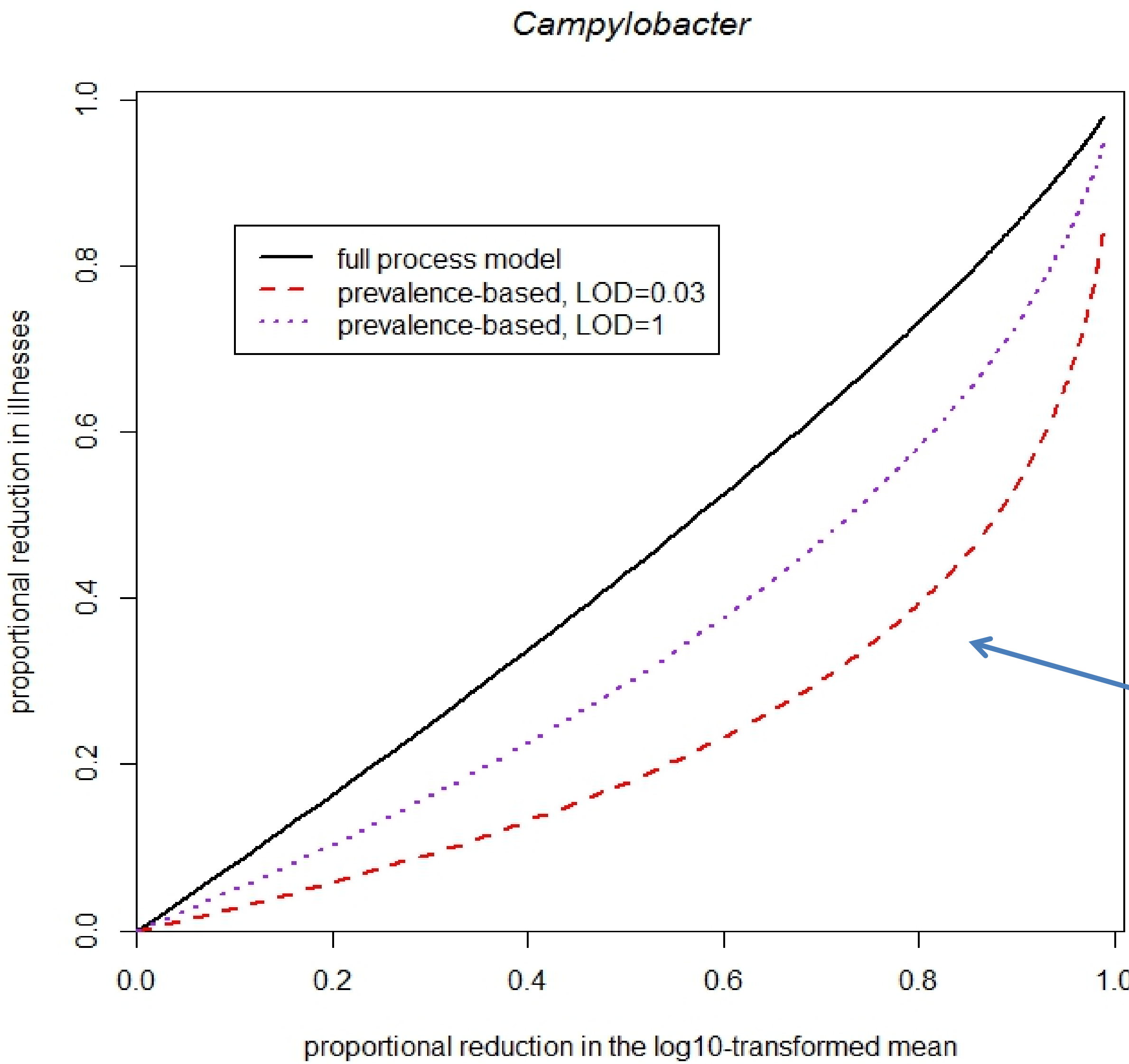
  - Case II: Reduction in $P(+)$, but average concentration on test-positive samples is unchanged.

$$\lambda_{baseline} \sim lognormal(\mu, \sigma)$$
$$\lambda_{new} \sim lognormal(\mu - \delta, \sigma + \gamma) \quad \delta, \gamma > 0$$

Food Safety and Inspection Service:

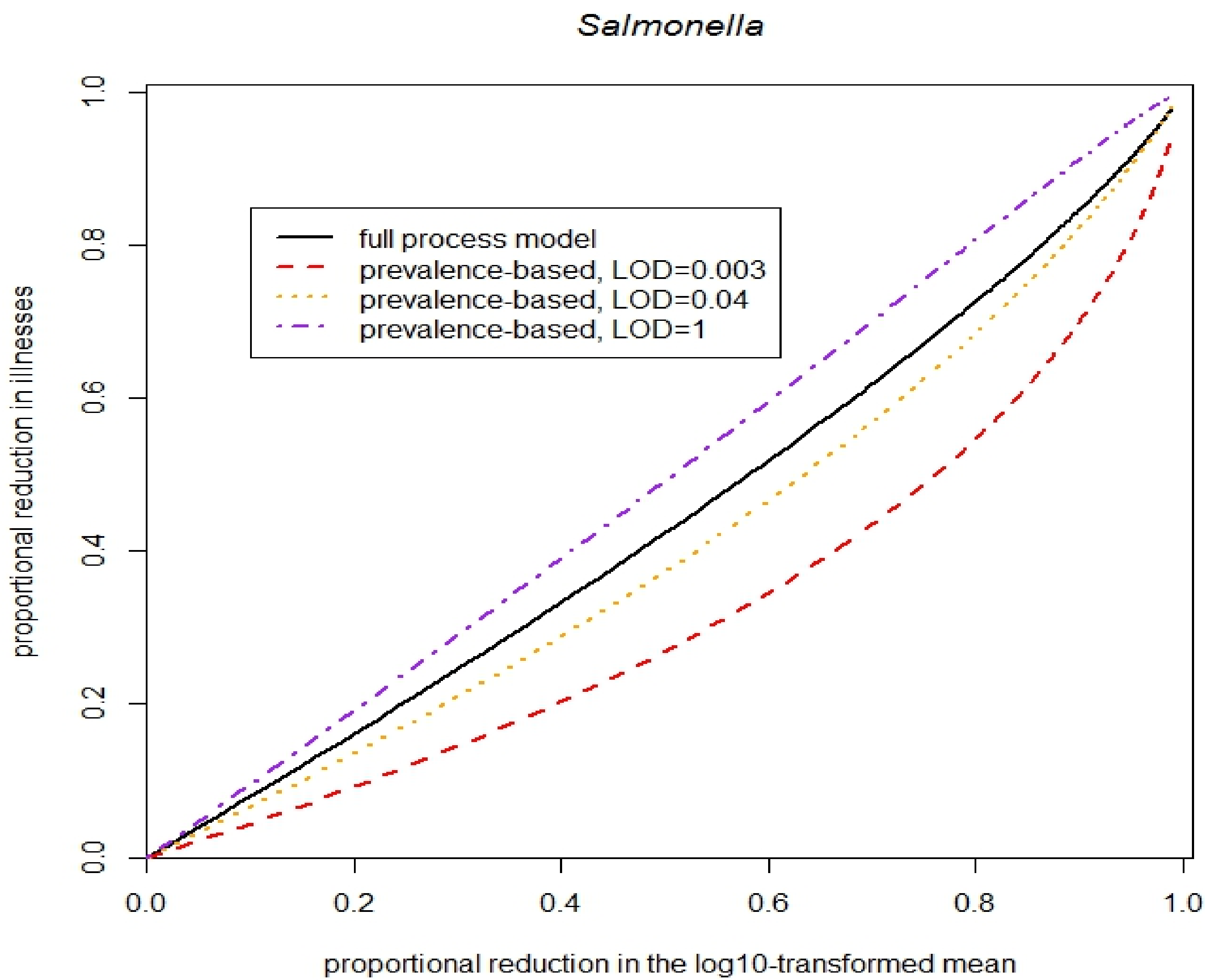
Results

Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

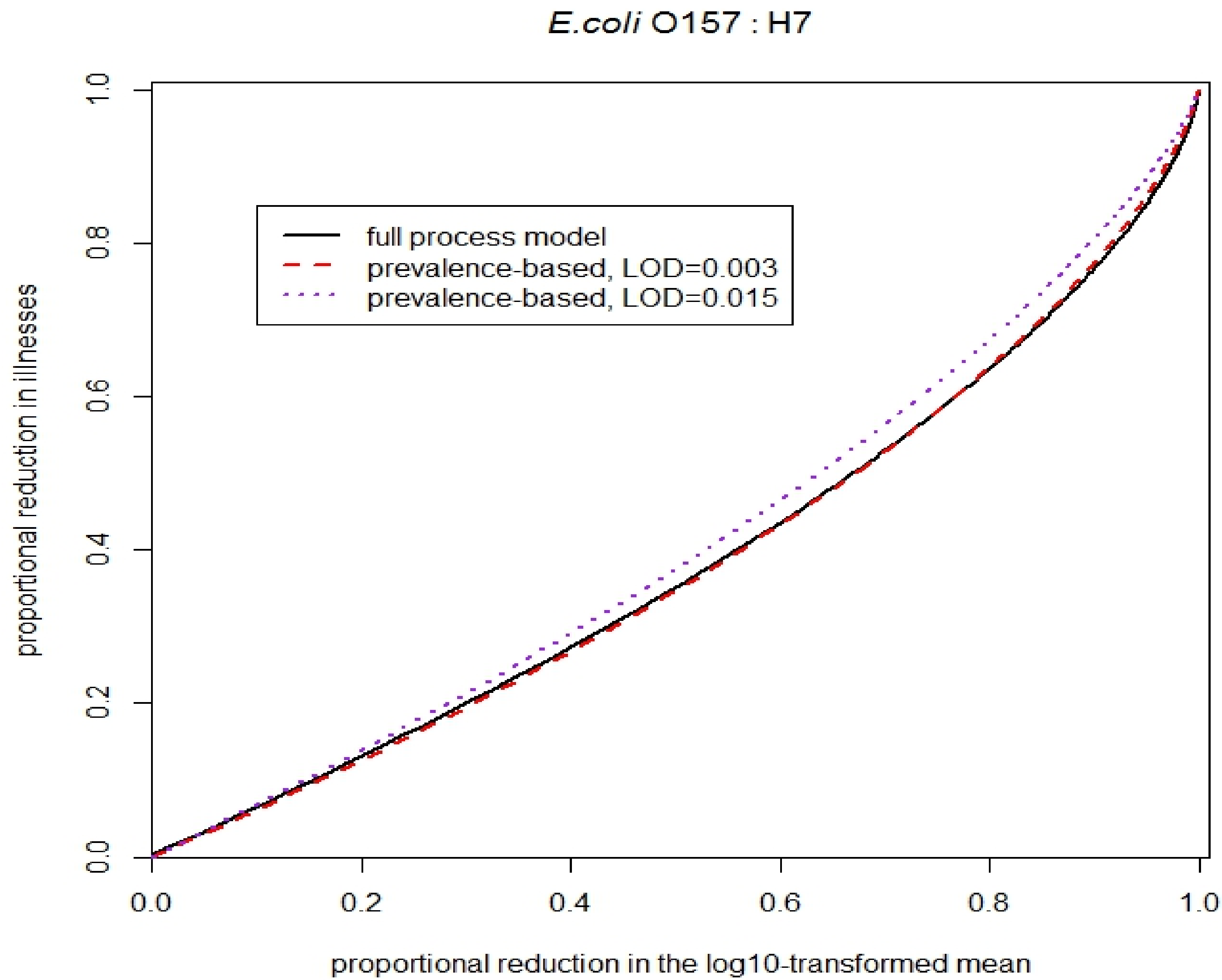


Desired result (conservative)

Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

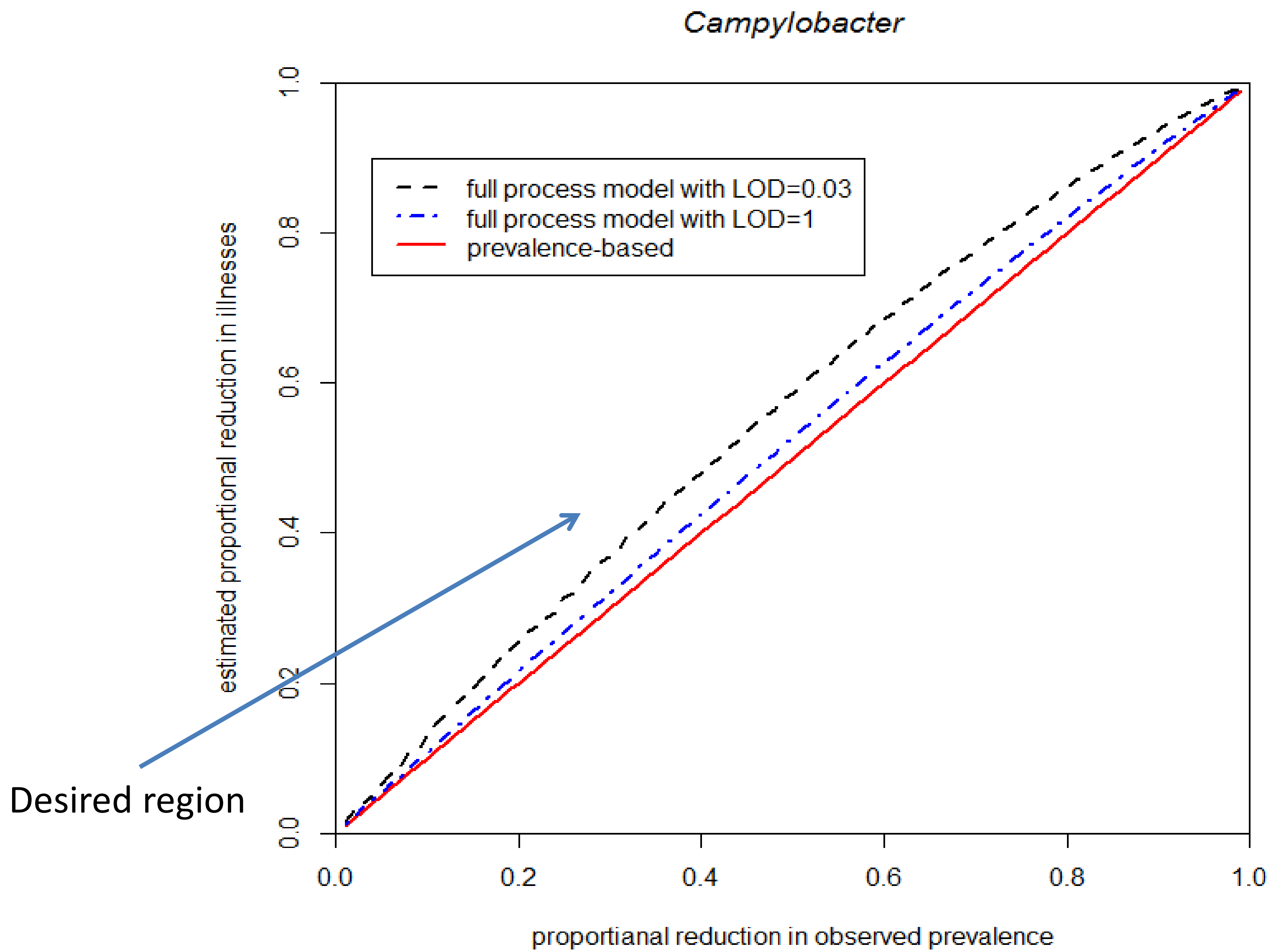


Food Safety and Inspection Service:
Case I: Reduction in average log-transformed mean

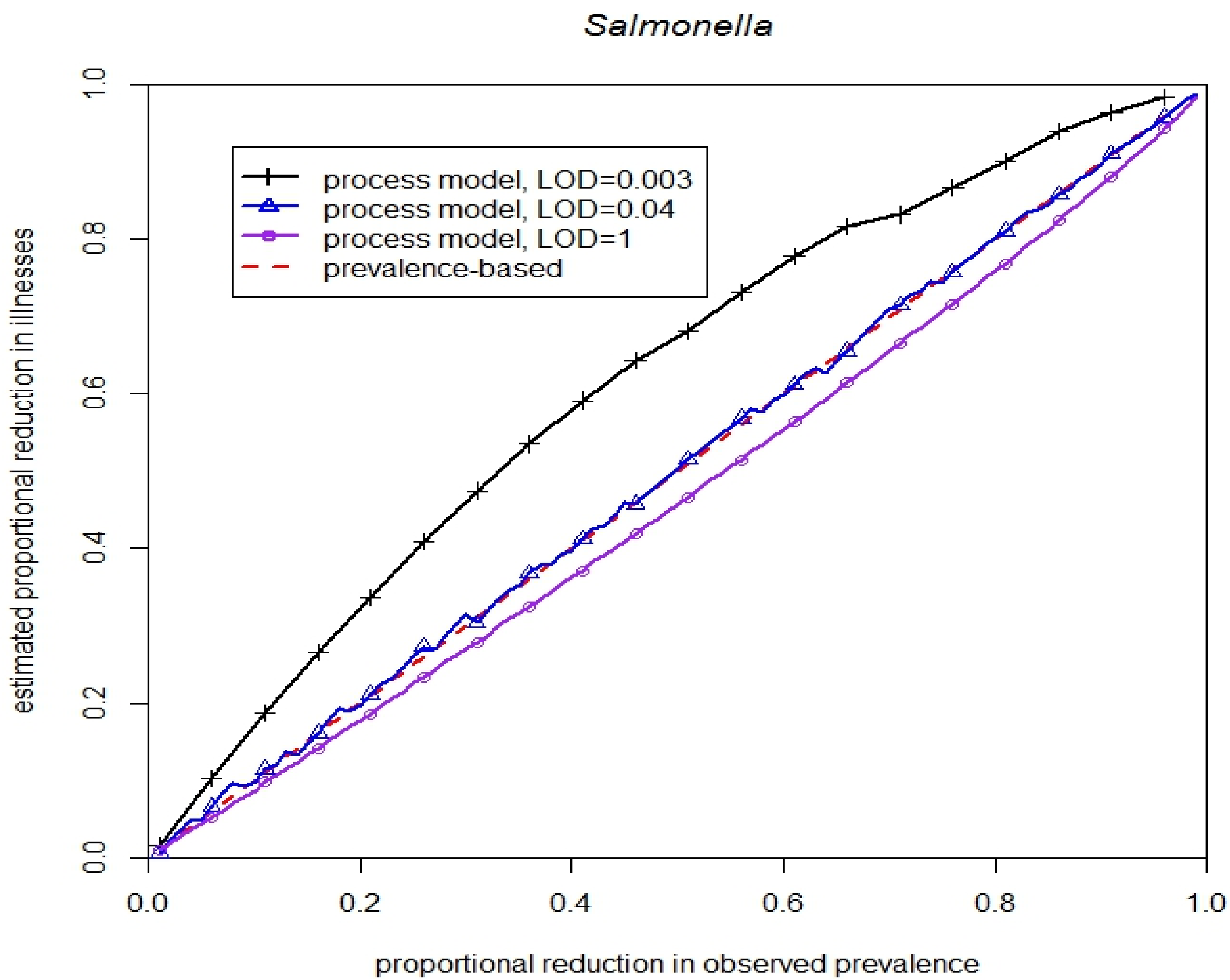


Food Safety and Inspection Service:

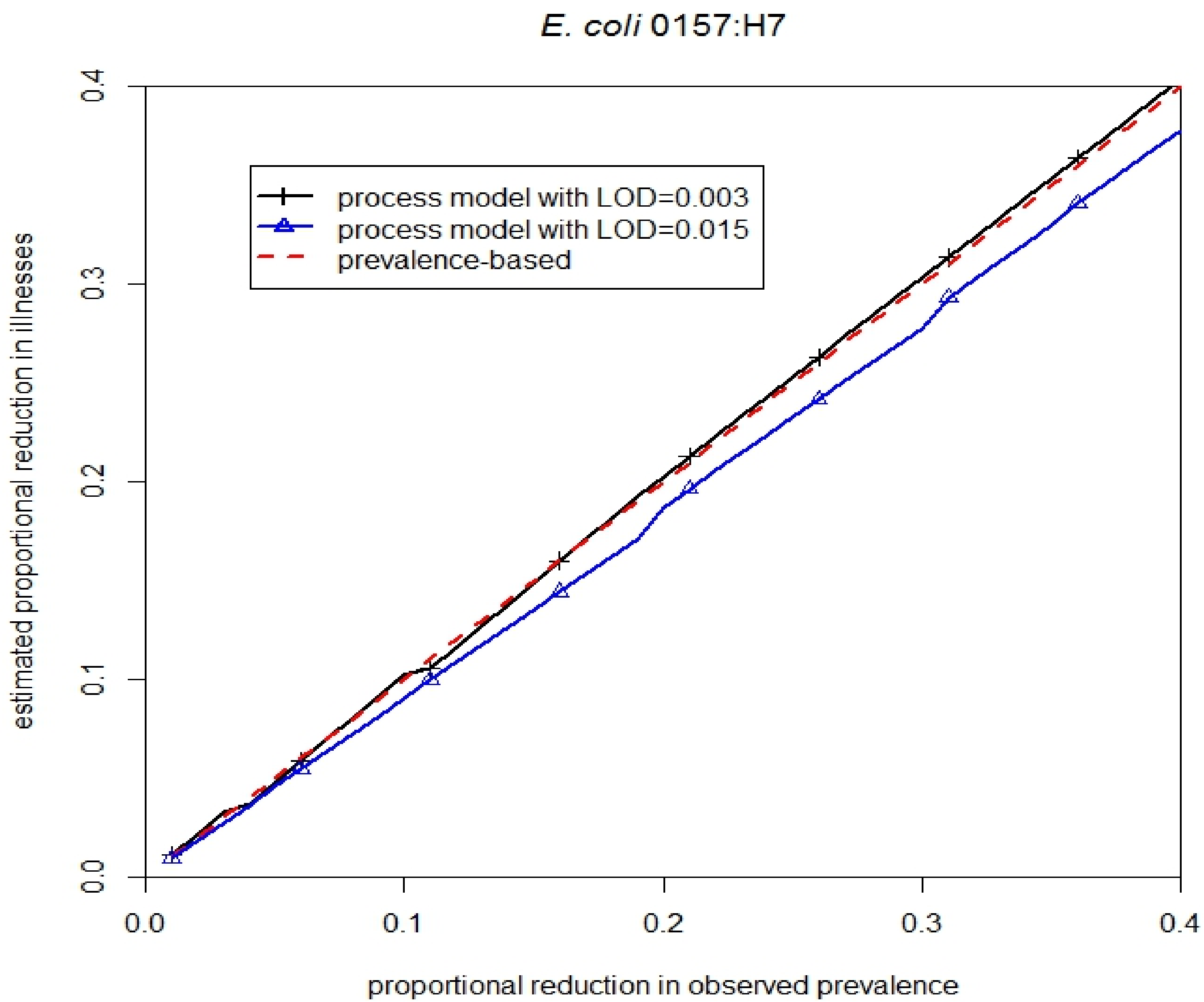
Case II: Reduction in P(+). Maintain concentration in failing establishments



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



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*).



Food Safety and Inspection Service: 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 $f(\lambda)$

Questions?