United States Department of Agriculture
Food Safety and Inspection Service

Iowa State University

5th Annual BIGMAP Symposium

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United States Department of Agriculture
Food Safety and Inspection Service

The Food Safety and Inspection Service's mission is to ensure that meat, poultry, and processed egg products distributed in commerce for use as human food are safe, wholesome and accurately labeled.

Statutory Authority

FSIS performs its food safety, public health and food defense activities under these main acts:

- The Federal Meat Inspection Act of 1906
- The Poultry Products Inspection Act of 1957
- The Egg Products Inspection Act of 1970

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Who Handles What?

- Food Safety and Inspection Service

- Food and Drug Administration

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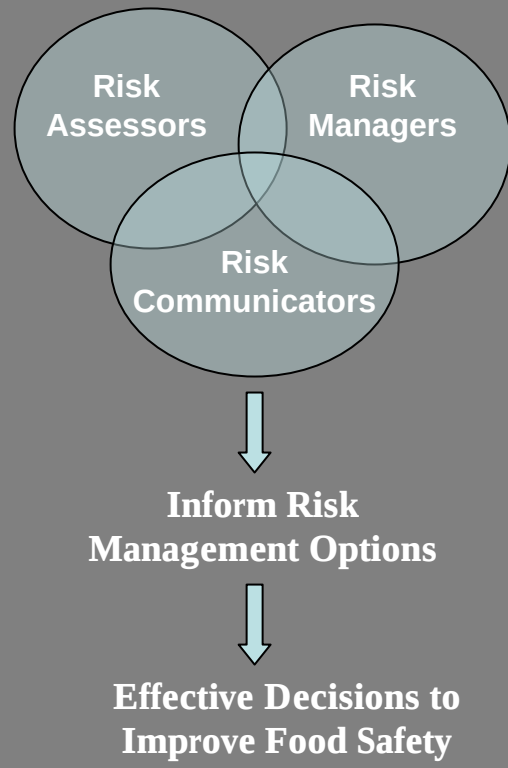
Risk Analysis at USDA/FSIS

- USDA/FSIS food safety program
  - Scientific basis for food safety policies and allocation of inspection resources
  - FSIS corporate strategic plan/SOPs
- Powerful public health tool
  - Allows for transparency and stakeholder involvement to ensure credibility and scientific accountability



Overview of QMRA Applications

Risk assessments required when regulation is expected to have significant impact on industry.

- SPS Agreement
- WTO guidelines
- OMB Executive Order 12866
- Information Quality Act
  - Peer review

Agency also actively seeks stakeholder input to continually refine risk assessment process.

Overview of QMRA Applications

- **Inform various agency decisions**
  - Industry regulations (standards)
  - Allocation of agency inspection resources
  - Food safety research priorities
  - Equivalence criteria (trade)
  - Recalls
- **Scientific basis for food safety decisions**
  - Explicitly link policies to public health outcomes

$$p(H \mid D, I) = p(H \mid I)\frac{p(D \mid H, I)}{p(D \mid I)}$$

Microbial risk assessment integrates a wide variety of science and data to provide a comprehensive understanding of the food safety system.

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Microbial Risk Assessment Activities 1998-2003

- USDA/FDA risk assessment for *Salmonella* Enteritidis in eggs and egg products (1998)
- Harvard BSE risk assessment (2001, updated 2003/2005/2006)
- *E. coli* O157:H7 in ground beef (2001)
- *E. coli* O157:H7 in non-intact beef (2002)
- USDA/FSIS risk assessment for *Listeria* in deli meats (2003)
- FDA/FSIS risk ranking of ready-to-eat foods for Lm (2001/updated September 2003)

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Microbial Risk Assessment Activities 2004-2006

- Risk-based *Listeria monocytogenes* verification sampling algorithm (2005)
- *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products (2005)
- *Salmonella* spp. in ready-to-eat meat and poultry products (2005)
- USDA/FSIS risk assessment for *Salmonella* in beef and poultry (2006)
- Poultry Slaughter Risk Assessment (draft 2006, updated 2008)

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Microbial Risk Assessment Activities 2007-2008

- Risk-based *E. coli* O157:H7 verification sampling algorithm (2007)
- Comparative risk assessment for *L. monocytogenes* in ready-to-eat meat and poultry products (draft 2004/updated 2008)
- FoodNet Interagency *Salmonella* Attribution Model (2008)
- Risk Assessment to Guide Performance Standards for *Salmonella* and *Campylobacter* in Poultry (2008)
- Pre-harvest Intervention *E. coli* risk assessment (draft 2008)

Listeria Risk Assessments

- FDA-FSIS Quantitative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Foods
- FSIS *Listeria* Risk Assessment
- Risk-based *Listeria monocytogenes* Verification

Lm: Public Health Context

- Causes septicemia, abortion and encephalitis in humans and in animals
- Incubation period 7 - 60 days
- Human listeriosis occurs in both epidemic and sporadic cases
- Affects predominantly elderly and immuno-compromised people, pregnant women and newborns
- Approx. 2,500 human cases/year in the U.S., resulting in 350 - 450 deaths/year
- Responsible for majority of microbial food recalls

General Risk Management Questions

- **Which ready-to-eat foods pose the greatest risk of listeriosis?**
  - 2003 FDA-FSIS Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat (RTE) Foods

- **Which interventions effectively control *Lm*?**
  - 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat

- **How can FSIS target its inspection resources to effectively address *Lm*?**
  - 2005 FSIS Risk-based Verification Sampling for *Lm* in ready-to-eat meat and poultry products

Which Interventions Effectively Control *Lm*?

- 2003 FSIS *Listeria* Risk Assessment
- Evaluated the effectiveness of industry controls in mitigating the risk of listeriosis associated with deli meats
  - Industry regulations (standards)
  - Post-lethality intervention
  - Growth inhibitors
  - Sanitation
- Built from FDA/FSIS *Listeria* risk assessment
- **Processor-to-table** risk assessment

Specific Risk Management Questions

- What is the effectiveness of testing and sanitation of food contact surfaces on mitigating product contamination and reducing the subsequent risk of illness?
- How effective are other pre- and post-packaging interventions in mitigating product contamination and reducing the subsequent risk of illness?
- What guidance can be provided on testing and sanitation of food contact surfaces for *Listeria* species?

In-Plant Model

- Incorporates food contact surface testing, product testing, sanitation, pre-and post-packaging interventions, and the effect of growth inhibitors

- Output combined with the FDA/FSIS exposure retail-to-table exposure pathway for deli meats and Listeria dose-response relationship to estimate the risk of illness or death on a per serving and per annum basis

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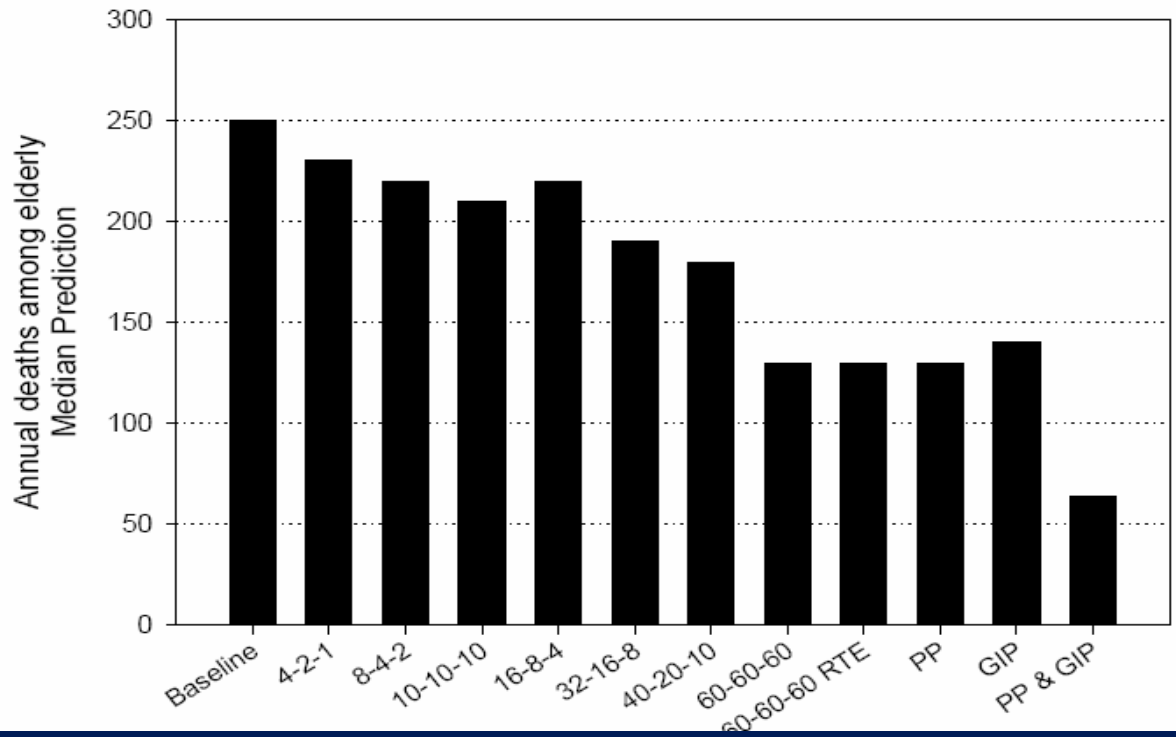
2003 FSIS *Listeria* Risk Assessment Output

Figure 21 depicts estimated numbers of deaths among the elderly for the scenarios tested. For the proposed minimal amount of food contact surface testing (i.e., the 4-2-1 scenario ; FSIS, 66 FR 12589, February 27, 2001), the estimated median number of deaths among the elderly is reduced by about 20 per year.



USDA/FSIS Risk Management Strategy

Interim Final Rule (issued June 2003, effective October 6, 2003; 9 CFR 430 RTE)

- Based on the 2003 FSIS *Listeria* risk assessment and the 2003 FDA-FSIS Risk-Ranking for *Lm* in ready-to-eat foods
- Established three alternative control measures

FSIS Directive 10,240.4 (10/2/03)

- Established a risk-based sampling program to verify compliance with *Lm* Rule

Lm Risk-Based Verification: Purpose

- To prevent adulteration of product by *Lm*.
- To focus USDA/FSIS verification sampling efforts on establishments producing product predicted to pose the greatest risk of listeriosis based on two previously developed *Listeria* risk assessments and real time laboratory data.
- To evaluate an establishment's food safety system so that FSIS can focus on establishments with less effective *Lm* control measures.
- To provide an appropriate incentive for establishments to adopt more effective *Lm* control measures.
- To protect public health.

Lm Risk-Based Verification: Implementation

FSIS implemented a risk-based verification testing program in January 2005

- Previously, establishments were tested randomly; now, using the risk ranking algorithm, frequency of sampling is dependent on relative risk for *Lm* contamination
  - Approximately 10,000 product samples annually
  - Expanded to collect product, environmental and food contact samples in April 2006
  - Risk is defined quantitatively for each facility

Enhances FSIS' focus on verification and provides increased confidence in public health protection.

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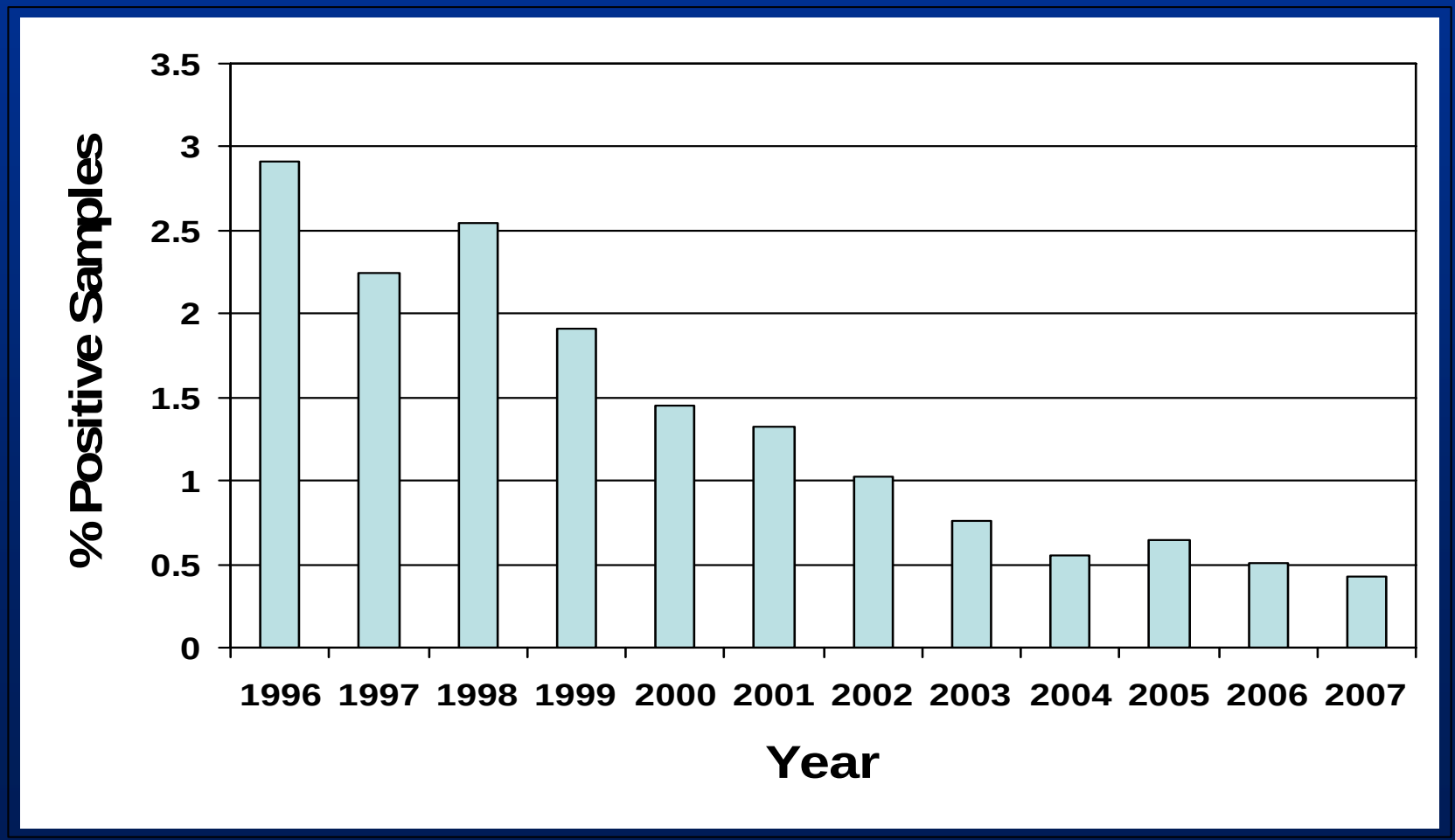
Listeria monocytogenes



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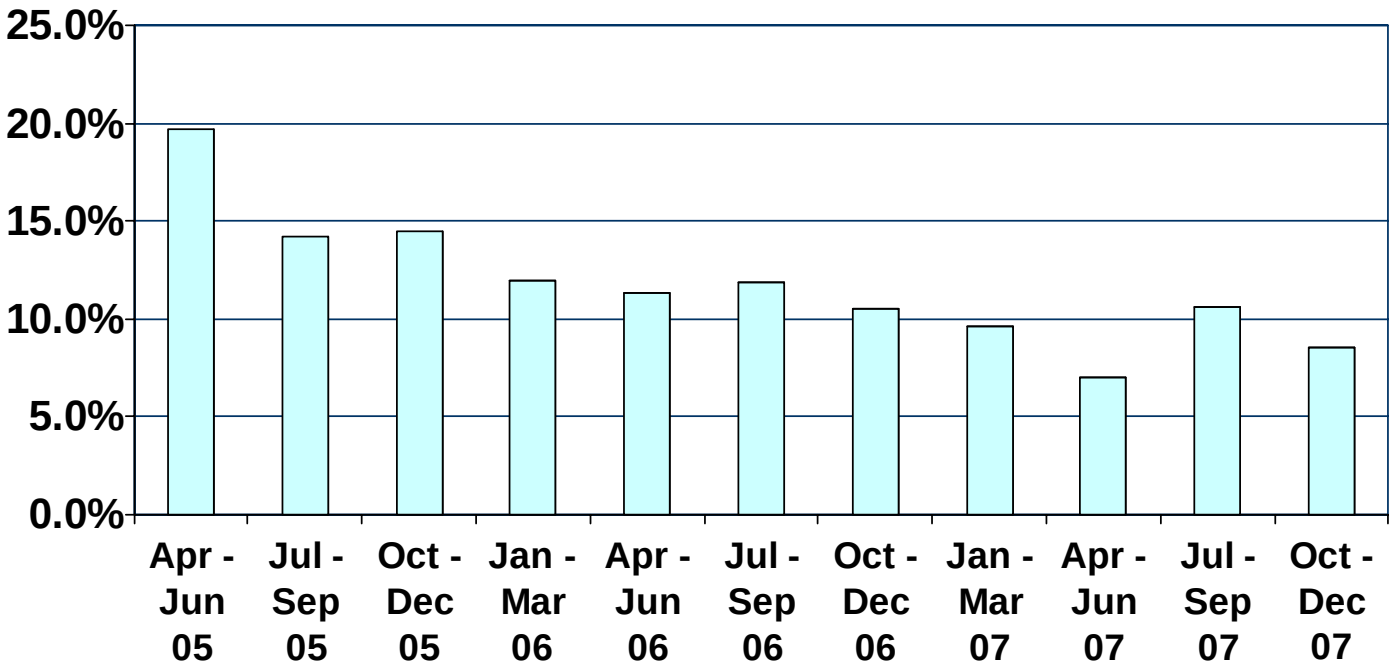
Results of Broiler Carcasses Analyzed by Quarter for *Salmonella* from April 2005 to December 2007



Percentage of Positive Regulatory Samples

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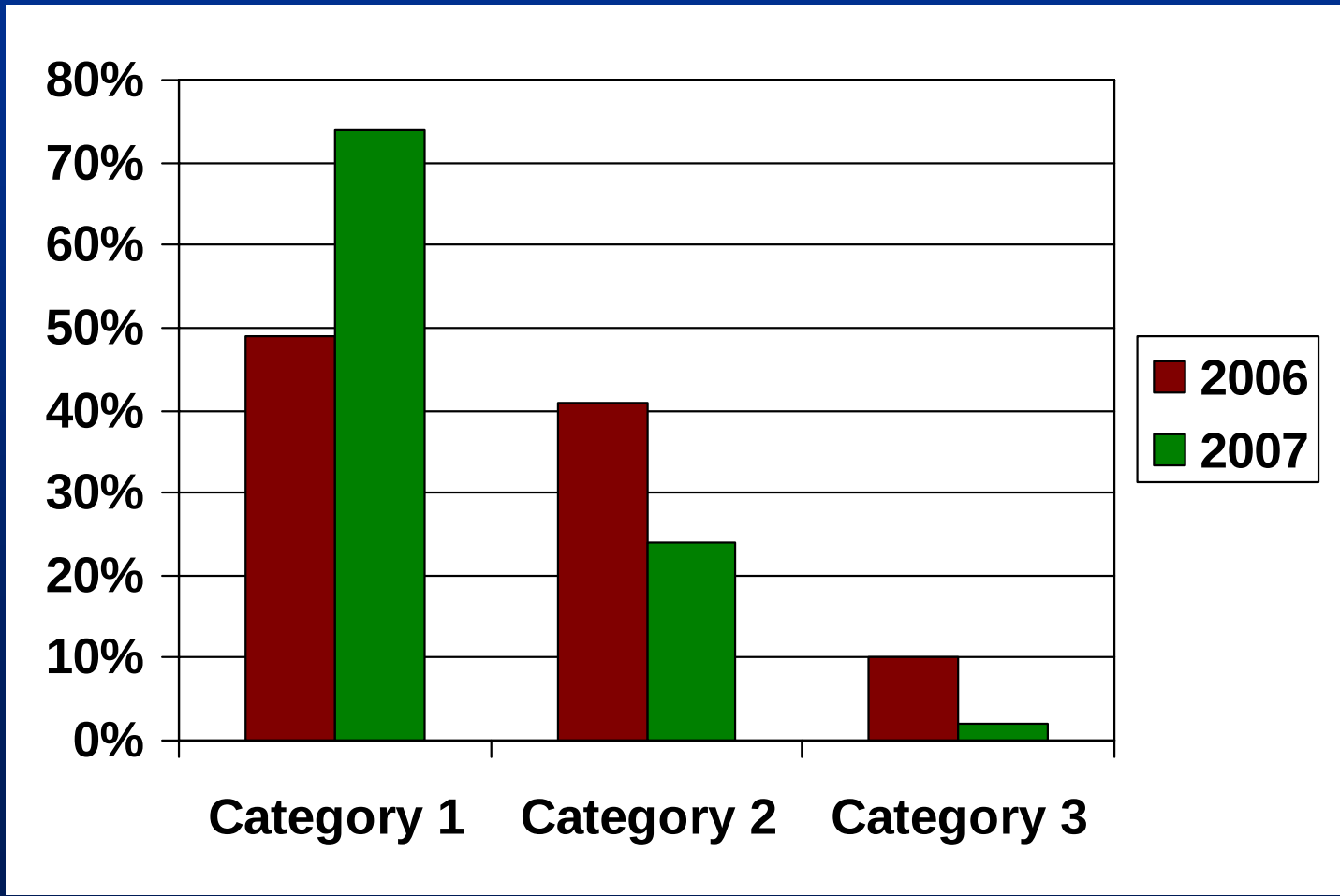
Plant Categories based on Broiler Carcasses Analyzed for *Salmonella*



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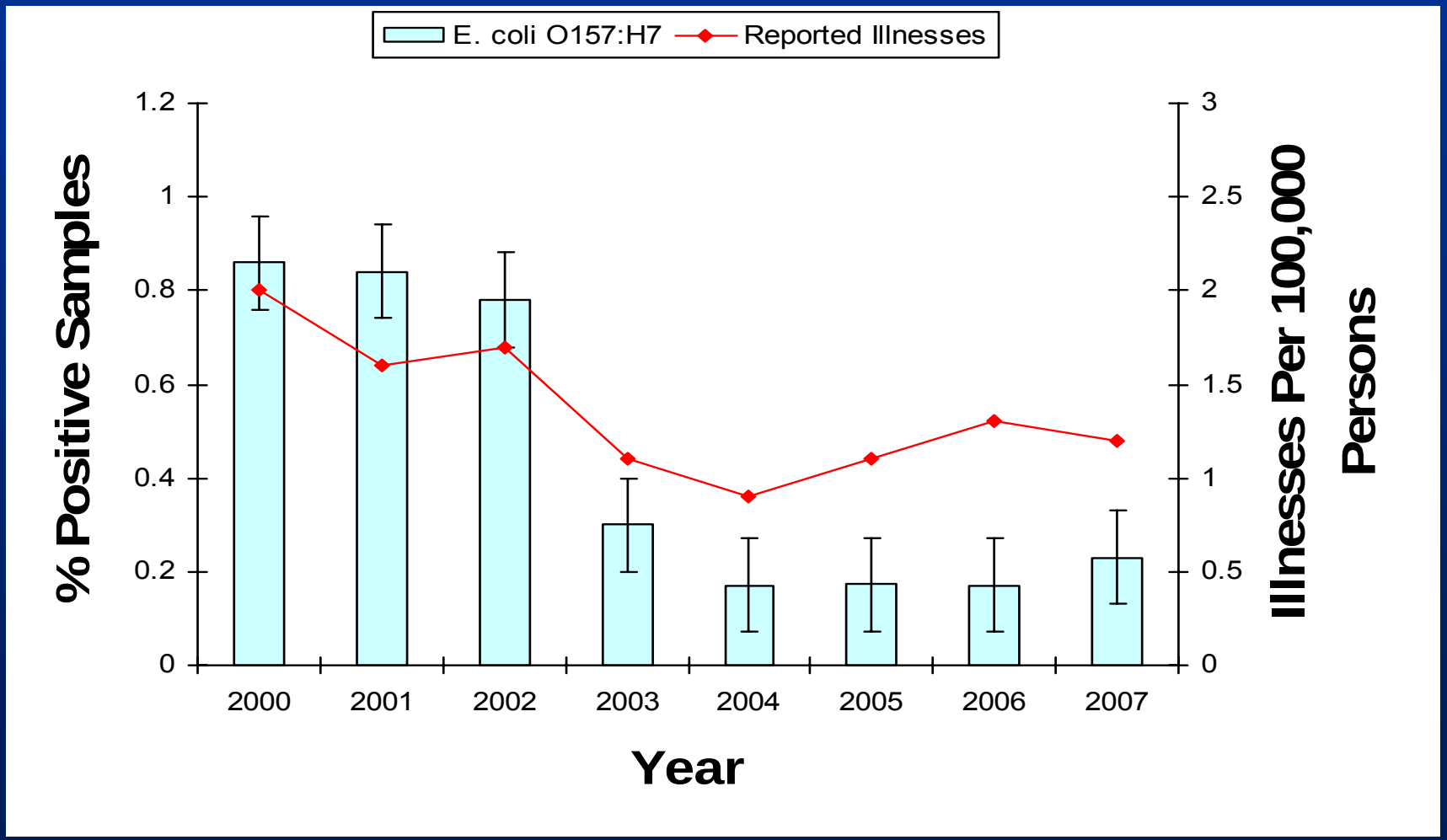
E. coli O157:H7 in Raw Ground Beef



FSIS and the Future

- Working to strengthen our system and our data collection and analysis,
- Developing new initiatives based on science, and
- Conducting Food Safety Assessments in all plants to obtain an in-depth analysis of an establishment's risk control measures.

Continued Evolution of Inspection

- Based on public health and risk
- Enhanced data infrastructure