Role of Economics in Pathogen Control Regulations

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FSIS Activity

In FY06

- ~ 7,600 full-time inspectors
- ~ 5,921 processing establishments inspected daily
- ~ 1,100 slaughter establishments in which every animal inspected
- ~ 140 million head of livestock; **9.3 billion poultry carcasses**; 4.4 billion pounds of liquid egg product
- ~ 8 million inspection procedures annually
- ~ 3.9 billion pounds of meat and poultry and ~ 5.9 million pounds of liquid egg products presented for import inspection
United States Department of Agriculture
Food Safety and Inspection Service

FSIS Inspection Systems

Traditional system (beginning - 1906)
- Regulatory enforcement
  - Animal disease
  - In-plant focus of sanitary operations

HACCP system (beginning - 1996)
- Food safety hazard control
  - Prevent, eliminate, reduce biological, chemical, and physical hazards reasonably likely to occur

Risk-based system (evolving beyond HACCP - 2006)
- Focus on risk of product and the degree of control of risk
- Conducting inspection in a manner designed to measurably impact public health and effectively use inspection resources
Inspection System Design

• Microbiological data, in the form of verification testing results for each establishment, supplement on-site observations and give a perspective on compliance with regulatory requirements over time.

• Changes in the % positive rate serve as an early warning of systemic problems arising, tracked quarterly and annually.

• Public health assumption is that a reduction in the % positive rate of product containing pathogens of public health concern should result in a reduction on disease incidence in humans.
<table>
<thead>
<tr>
<th></th>
<th>1997 Baseline</th>
<th>2010 Target</th>
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</thead>
<tbody>
<tr>
<td><em>Campylobacter</em></td>
<td>24.6</td>
<td>12.3</td>
</tr>
<tr>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2.1</td>
<td>1.0</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>0.5</td>
<td>0.25</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>13.7</td>
<td>6.8</td>
</tr>
</tbody>
</table>

*Laboratory confirmed cases/100,000 humans (FoodNet)

** Changed to year 2005 by E.O. (President Clinton)
Food Safety concerns – *Salmonella*

- CDC estimates **1.4 million** cases of foodborne illness annually.
- For 2006, CDC estimated the *Salmonella* incidence at **14.81 cases per 100,000 population** (2010 goal of **6.8 cases per 100,000**).
  - *S. Typhimurium* decreased significantly from baseline (MMWR 56(14): 337)
FSIS Public Health Driven Program

- *Salmonella* verification sampling program for raw product \( \geq 90\% \) Category 1 target by 2010 – i.e., at half the current standard
### Salmonella Categories

#### Set History

<table>
<thead>
<tr>
<th>Previous</th>
<th>Current</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 50% of standard</td>
<td>≤ 50% of standard</td>
<td>1</td>
</tr>
<tr>
<td>• No prior set</td>
<td>• &gt;50%</td>
<td></td>
</tr>
<tr>
<td>• Above standard</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Any result</td>
<td>&gt; 50% of standard without failing</td>
<td></td>
</tr>
<tr>
<td>Any result</td>
<td>Exceeded standard</td>
<td>3</td>
</tr>
</tbody>
</table>

71 FR 9772; February 27, 2006
Predicted Public Health Benefits – *Salmonella* on Broiler Carcasses

As the proportion of establishments in Category 1 increases (blue line), the relative risk of illness from *Salmonella* on broiler carcasses decreases (pink line)
Program effectiveness:
Categorization of broiler establishments

<table>
<thead>
<tr>
<th>% of Plants</th>
<th>July 2007</th>
<th>Sep 2010 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>Actual</td>
<td>Projected</td>
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<tr>
<td></td>
<td>35</td>
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<td></td>
<td>87</td>
<td>90</td>
</tr>
</tbody>
</table>

Category II  
Category III
Category 1 Update – November 2007

• Broilers

• 73.5% (up from ~35% in 1st Qtr CY2006 when first tracked)
## FSIS % Positive Rate

<table>
<thead>
<tr>
<th>Source</th>
<th>Raw Product Salmonella Baseline</th>
<th>Raw Product Salmonella 3rd Quarter CY2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broilers</td>
<td>20.0%</td>
<td>10.6%</td>
</tr>
<tr>
<td>Cow/Bulls</td>
<td>2.7%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Ground Beef</td>
<td>7.5%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Ground Chicken</td>
<td>44.6%</td>
<td>28.3%</td>
</tr>
<tr>
<td>Ground Turkey</td>
<td>49.9%</td>
<td>16.3%</td>
</tr>
<tr>
<td>Market Hogs</td>
<td>8.7%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Steers/Heifers</td>
<td>1.0%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Turkeys</td>
<td>19.6%</td>
<td>9.4%</td>
</tr>
</tbody>
</table>
Long Term Focus on *Salmonella* and *Campylobacter*

1. Looking at primal/sub-primal and other parts of raw products in Federal establishments regarding new performance standards based on current baseline studies

2. Looking at carcasses and parts at *retail*, particularly poultry, and association between the type and enumerative level of these pathogens at slaughter, further processing, and *retail*
How Economics Impact Risk Management

- Risk assessment for *Salmonella* and *Campylobacter* bacteria
  - Prevalence and serotype informs FSIS’ selection of alternative risk management actions listed in an index for successive analysis of each alternative action
  - Establishments select interventions, based on a risk assessment
  - Interventions would effect supply chain; shift the supply curves of affected establishments because of net changes in costs and quantities of young chickens produced
  - Public health benefits of the reduction of the targeted microbes and the net dollar cost of the interventions for the targeted reduction of bacteria would be used for the computation of the benefit-cost and cost effectiveness analysis of each of the proposed risk management actions
  - The results would be a ranking of the cost-effectiveness ratios and the benefit-cost ratios of the risk management actions
Impact Considerations

- **Producer**
  - Large, small, very small establishments
  - Establishments that also slaughter other poultry
  - Effect on new hires and training
  - Facility and equipment modifications/purchase
  - Adding inspection stations
  - Evisceration linespeed
  - Dressing performance standards
  - HACCP plan/Sanitation SOP modifications

- **Consumer – food safety vs other (e.g., bruises)**

- **FSIS inspection – training**
Economic Impact Report
Cost-Effectiveness Analysis (to produce the least burdensome plan)
The comparison of benefits among other alternatives

- Cost: Government, Industry and Indirect Cost

+ Benefit: Lower Incidences of food-borne Illness and All associated costs

Net Benefit
Against Baseline as the absence of the alternative

Benefit-Risk Analysis (Select a suitable risk level vs. expected benefits)
Cost-Effectiveness Analysis (to produce the least burdensome plan)
Making Decision to maximize benefit or minimize the cost

Repeat the process as Risk Mgmt Alternative (A)
Economic Analysis for RTE Listeria monocytogenes

- Benefit-cost Analysis compares:
  - Cost of the rule to industry, and
  - Monetized health benefit
- Cost-effectiveness estimates:
  - Cost per QALY saved
  - Cost per death averted
  - Cost per life-year saved
  - Net cost per QALY
- Risk assessment model estimates averted death and illnesses
- FSIS analyses policy alternatives by changing parameters in risk assessment model and the cost items
Dynamic Simulation Model

Lm Risk Assessment

In plant component
- Contamination event
- Intervention
- Contamination at retail

Risk of illness component
- Retail to table exposure assessment (Contamination at retail + Lm growth)
- Dose-response relationship
- # of illnesses and death
Thank you