Use of Microbiological Testing and Microbiological Criteria in Regulatory Programs for Meat, Poultry, and Processed Egg Products

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Responsibility

- FSIS is the public health regulatory agency within USDA

- FSIS ensures that the nation’s commercial supply of meat, poultry and processed egg food products is not adulterated or misbranded

- FSIS authorizing authorities (FMIA, PPIA, EPIA) do not bind the Agency to in-plant activity
Approximately 7,600 full-time inspectors (meat, poultry, eggs)

Approximately 6,000 establishments
- 52.8 billion pounds of poultry in FY04
- 43.6 billion pounds of meat in FY04
- 4 billion pounds of egg products

Approximately 75 import inspectors
- 135 establishments; 4.2 billion pounds of meat and poultry and 12.1 billion pounds of egg products

FSIS Structure

Microbiological Testing

- **FSIS regulatory testing**
  - Verification of PR/HACCP systems to ascertain compliance (routine and intensified) and to encourage industry action
  - Baseline studies to ascertain prevalence
  - Threat agents (separate from food safety scheme)

- **Industry testing**
  - Validation to support HACCP system
  - Verification of HACCP system to ascertain compliance
**Level of Testing**

### 2003 FSIS Regulatory Testing

<table>
<thead>
<tr>
<th></th>
<th># annually</th>
<th># Est.</th>
<th>Average #/Est/Yr</th>
<th>Shifts*</th>
<th>Rate/Shift</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Raw Ground Beef for E. Coli O157:H7</strong></td>
<td>5,000</td>
<td>1,800</td>
<td>2.8</td>
<td>500,000</td>
<td>1/100</td>
</tr>
<tr>
<td><strong>RTE for Listeria monocytogenes and Salmonella</strong></td>
<td>6,600</td>
<td>2,400</td>
<td>2.8</td>
<td>600,000</td>
<td>1/90</td>
</tr>
<tr>
<td><strong>Salmonella in Raw Products</strong></td>
<td>50,000</td>
<td>1,100**</td>
<td>1/Yr</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Salmonella in Egg products</strong></td>
<td>1,600</td>
<td>80</td>
<td>20/Yr</td>
<td>20,000</td>
<td>1/12</td>
</tr>
</tbody>
</table>

* Production shifts assumed as an average of 250 per plant (range - >600 to < 100 per year)
** Sampling only substantial producers (ground beef - 26 per year; cattle and hog slaughter - 500 per year)

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**Policy Considerations**

### Salmonella trends in Raw Products

<table>
<thead>
<tr>
<th>National</th>
<th>Baseline</th>
<th>CY2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broilers</td>
<td>20.0</td>
<td>12.8</td>
</tr>
<tr>
<td>Market hogs</td>
<td>8.7</td>
<td>2.5</td>
</tr>
<tr>
<td>Cows/Bulls</td>
<td>2.7</td>
<td>1.5</td>
</tr>
<tr>
<td>Steers/Heifers</td>
<td>1.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Ground beef</td>
<td>7.5</td>
<td>1.7</td>
</tr>
<tr>
<td>Ground chicken</td>
<td>44.6</td>
<td>35.5</td>
</tr>
<tr>
<td>Ground turkey</td>
<td>49.9</td>
<td>25.4</td>
</tr>
</tbody>
</table>

Overall FSIS regulatory testing (Set “A”):
### Escherichia coli O157:H7 -- % positives in raw ground beef (CY 2003-2004)

<table>
<thead>
<tr>
<th>Source</th>
<th>CY 2003</th>
<th></th>
<th>CY 2004</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Analyzed</td>
<td>%Positive</td>
<td>Analyzed</td>
<td>%Positive</td>
</tr>
<tr>
<td>Federal Plants</td>
<td>5,735</td>
<td>0.349</td>
<td>7,683</td>
<td>0.182</td>
</tr>
<tr>
<td>Retail Stores</td>
<td>779</td>
<td>0</td>
<td>311</td>
<td>0</td>
</tr>
<tr>
<td>State Plants</td>
<td>39</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Imports</td>
<td>31</td>
<td>0</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>Totals</td>
<td>6,584</td>
<td>0.304</td>
<td>8,010</td>
<td>0.175</td>
</tr>
</tbody>
</table>

### Policy Considerations

#### Salmonella -- % positives in RTE

<table>
<thead>
<tr>
<th>Summary by HACCP process type for meat and poultry*</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
<td>0.34</td>
<td>0.15</td>
<td>0.15</td>
<td>0.28</td>
<td>0.16</td>
</tr>
<tr>
<td>Summary for processed eggs*</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>Overall</td>
</tr>
<tr>
<td></td>
<td>0.73</td>
<td>0.33</td>
<td>0.34</td>
<td>0.95</td>
<td>0.54</td>
</tr>
</tbody>
</table>

* CY 2001-2002 combined for meat and poultry; CY 1995-2003 combined for egg

A = Not Heat Treated Shelf Stable
B = Heat Treated Shelf Stable
C = Fully Cooked Not Shelf Stable
D = Product with Secondary Inhibitors, Not Shelf Stable
E = Egg Whites
F = Whole Eggs or Yolks
G = Whole Eggs with Added Yolks or Whole Egg Blends
H = Dried Yellow Egg Products
Policy Considerations

*L. monocytogenes* -- % positives in RTE (CY 2001-2002)

<table>
<thead>
<tr>
<th>Process Type</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Not Heat Treated Shelf Stable</td>
<td>2.03</td>
<td>.023</td>
<td>1.33</td>
<td>1.68</td>
<td>1.16 **</td>
</tr>
<tr>
<td>B: Heat Treated Shelf Stable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C: Fully Cooked Not Shelf Stable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D: Product with Secondary Inhibitors, Not Shelf Stable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Healthy People 2010 goal for human infections from Lm expected to be halved by 2010 adjusted in order to be met 2005 by President Clinton

Informing Risk

Conducting baseline studies for risk assessment use:

- On-going
- Of sufficient duration to address regional and seasonal effects
- Looking at more than one point in the process
- Looking at use of indicator organisms for process control as well as pathogen impact
Historically, sampling was randomly scheduled

Now, drive for more effective use of resources; impact on public health
- Targeted to those products most likely to result in illness; amplifies impact; focuses follow-up verification activity
- Data-driven mechanistic model (risk factors are weighted)

FSIS Risk-Based Testing

Risk Management

For *L. monocytogenes* in RTE:
- Interim final rule for post-lethality exposed RTE (October 2003)
  - Effective control measures through HACCP plan, Sanitation SOP, or other prerequisite program:
    - Alternative 1 – post-lethality treatment and antimicrobial growth inhibitor
    - Alternative 2 – post-lethality treatment or antimicrobial growth inhibitor
    - Alternative 3 – Sanitation
Establishments within each Alternative have characteristics:
- Growth potential of product, compliance history, volume of production, product, food-contact surface, and environmental testing; results of FSA report; etc.

Risk-Based categories defined by RA model, Interim Final Rule

Nearly 16,000 tests in CY 2005 vs. 6,600 tests in CY 2003

Secondary Stratification

For Salmonella in Raw Product:
- Addressing sustained, upward trend in classes of raw poultry, especially broilers
  - Targeting poorer performers
  - Targeting serotypes of epidemiological importance
  - Getting results back to establishments immediately
Risk Management

For *E. coli* O157:H7 in Raw Product:

- Addressing all producers; no exemption
- Targeting high volume
- Targeting high prevalence season
- Sampling ground beef and manufacturing trimmings

* CY2000-2004 - % positives decreased by >80% with 43.3% decline in 2004 – CDC reported decline in human infections by 42% from baseline years of 1996-1998

Industry Testing

Performance standards/criteria:

- RTE
  - 5.0-log₁₀ reduction for *E. coli* O157:H7 in beef
  - 6.5-log₁₀ reduction for *Salmonella* in meat
  - 7-log₁₀ reduction for *Salmonella* in poultry
  - 8.75-log₁₀ reduction for *Salmonella* for processed eggs
  - No multiplication of *C. botulinum*
  - No more than 1-log₁₀ growth for *C. perfringens*
  - Non-detectible *L. monocytogenes* in all product and food-contact surfaces

- Raw
  - Generic *E. coli* at slaughter specific to fecal contamination control
  - *E coli* O157:H7 – Notably, testing conducted to provide high confidence of absence of low level contamination (e.g., “N-60”)