Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Retrospective Analysis on Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products

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Content

• Background
• Benefit-cost analysis (BCA) in 2003
• Final regulatory impact analysis (FRIA)
• Retrospective BCA
• Conclusion
• Acknowledgment
Background

- *Listeria monocytogenes* (*Lm*) is a leading cause of food-related hospitalization, fetal loss, and death
  - Estimated 1,600 cases and 260 deaths per year
    - CDC Dec. 2017
  - Before 2003, most of the illnesses were from consuming Ready-to-Eat (RTE) meat and poultry products
    - 2013 study of 1998-2008 data found RTE-MPP-caused outbreaks decreased after 2003
    - 2017 study of 1998-2013 outbreak data suggested over 75% from fruit and dairy products
Food Safety and Inspection Service:
Background (cont.)

• FSIS efforts to control *Lm*
  – 1987 began to sample and test
  – 1989 adopted ε/zero tolerance standard

Incidence of listeriosis reduced but large outbreaks continued

• Further FSIS action
  – 2001 proposed rule
  – 2003 risk assessment
  – 2003 interim final rule (more on the next slide)
  – 2015 affirmation of interim final rule
• Key provisions of the 2003 interim final rule
  – Must control *Lm* in processing environment through Hazard Analysis and Critical Control Point (HACCP) system or prevent contamination through Sanitation Standard Operating Procedures (SSOP)
  – Instead of specifying a single *Lm*-control method, FSIS identified three alternatives
    • Alternative 1: both post-lethality treatment and antimicrobial agents or processes
    • Alternative 2: post-lethality treatment (2a) or antimicrobial agents or processes (2b)
    • Alternative 3: only sanitation program
To encourage industry adoption of more effective interventions, FSIS samples establishments based on the $Lm$-control alternatives

- For example, FSIS conducts more testing at establishments that choose Alternative 2 than Alternative 1
In response to the interim final rule, many establishments changed their *Lm*-control alternative.

The table shows the estimated changes in Alternative Groups (AG) from the 2003 FRIA:

<table>
<thead>
<tr>
<th>AG</th>
<th>Large</th>
<th>Small</th>
<th>Very Small</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+16</td>
<td>+31</td>
<td>0</td>
<td>+47</td>
</tr>
<tr>
<td>2a</td>
<td>-7</td>
<td>0</td>
<td>0</td>
<td>-7</td>
</tr>
<tr>
<td>2b</td>
<td>-4</td>
<td>+77</td>
<td>0</td>
<td>+74</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>-5</td>
<td>-108</td>
<td>0</td>
<td>-113</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
• Reduced listeriosis illnesses and deaths
  – Risk assessment model simulation
    • How in-plant-contamination transfers to retail contamination
    • Using dose-response relationship

<table>
<thead>
<tr>
<th>Intervention Alternative</th>
<th>Deaths Reduced</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>3/4</td>
<td>3.1</td>
</tr>
<tr>
<td>2b</td>
<td>12.0</td>
</tr>
<tr>
<td>1</td>
<td>12.2</td>
</tr>
<tr>
<td>Total</td>
<td>27.3</td>
</tr>
</tbody>
</table>
Food Safety and Inspection Service: Benefits in 2003 FRIA (cont.)

• Monetizing health benefits
  – Fatality rate: 20%
  – Cost of illness (COI)
    • Moderate (5%): $10,300
    • Severe (95%): $28,300
  – Value of statistical life (VSL): $4.8 million
  – Discounted benefit by 50% to adjust for fact that risk assessment model only dealt with deli meat

• Total: $67.5 m. at median, $22 m. at 5th percentile, and $77 m. at 95th percentile
Costs in the 2003 FRIA

• Validating post-lethality treatment in HACCP plans: $2.6 m.
• Food-contact-surface (FCS) testing: $0.18 m.
• Production adjustment: $1.15 m.

• Installing post-lethality treatment, initial and annual operating
  – Initial cost: $51.6 m.
  – Annual operating cost: $5.2 m.
• Adding antimicrobial agent to products
  – Initial: $10.1 m.
  – Annual operating: $1.0 m.
• Test and hold: $0.97 m.
• Total industry cost after annualizing initial equipment costs with a 7% discount rate over 10 years: $16.6 m.
Updated the movement table using 2016 PHIS data

<table>
<thead>
<tr>
<th>AG</th>
<th>Large</th>
<th>Small</th>
<th>Very Small</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+1</td>
<td>+14</td>
<td>12</td>
<td>+26</td>
</tr>
<tr>
<td>2a</td>
<td>-21</td>
<td>-12</td>
<td>-9</td>
<td>-42</td>
</tr>
<tr>
<td>2b</td>
<td>-10</td>
<td>+206</td>
<td>178</td>
<td>+374</td>
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<tr>
<td>3</td>
<td>-7</td>
<td>-477</td>
<td>-627</td>
<td>-1111</td>
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<tr>
<td>Total</td>
<td>-37</td>
<td>-269</td>
<td>-446</td>
<td>-752</td>
</tr>
</tbody>
</table>
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### Movement – compared with FRIA

<table>
<thead>
<tr>
<th>AG</th>
<th>L</th>
<th>S</th>
<th>VS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FRIA</td>
<td>Retro</td>
<td>FRIA</td>
<td>Retro</td>
</tr>
<tr>
<td>1</td>
<td>16</td>
<td>1</td>
<td>31</td>
<td>14</td>
</tr>
<tr>
<td>2a</td>
<td>-7</td>
<td>-21</td>
<td>0</td>
<td>-12</td>
</tr>
<tr>
<td>2b</td>
<td>-4</td>
<td>-10</td>
<td>77</td>
<td>206</td>
</tr>
<tr>
<td>3*</td>
<td>-5</td>
<td>-7</td>
<td>-108</td>
<td>-477</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>-37</td>
<td>0</td>
<td>-269</td>
</tr>
</tbody>
</table>
The Retrospective Analysis kept some of the same assumptions used in the 2003 FRIA (e.g. pre-rule average cost per FCS test)

- Updated many others
  - Updated data, if available
  - Industry experts’ opinion: RTE Workgroup members, internal and external industry experts
• Cost to validate post-lethality (PL) treatment
  – No. of establishments affected
  – Average no. of HACCP plans

• Cost of additional PL treatment
  – Cost of installing equipment: accounted for different technology in addition to establishment size
  – Annual operating cost: more comprehensive than “10% of the installation cost”
• Cost of antimicrobial agent/process
  – Cost of installing equipment: accounted for different technology, in addition to establishment size
  – Annual operating cost: more comprehensive than “10% of the installation cost”

• Cost of FCS testing
  – Average no. of lines
  – Average cost per test
• Cost of production adjustment

• Cost of test-and-hold
  – % of establishments had test-and-hold and average number of such event
  – Cold storage cost
  – Decreasing stream instead of constant every year
    • Calculated annualized cost for the stream
<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Retro</th>
<th>FRIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validating PL</td>
<td>2,517</td>
<td>2,645</td>
</tr>
<tr>
<td>Install PL equipment</td>
<td>680</td>
<td>51,584</td>
</tr>
<tr>
<td>Install anti-microbial equipment</td>
<td>7,213</td>
<td>10,109</td>
</tr>
<tr>
<td>Production adjustment</td>
<td>678</td>
<td>1,151</td>
</tr>
<tr>
<td><strong>One time cost total</strong></td>
<td>11,087</td>
<td>65,488</td>
</tr>
<tr>
<td>Annualized one-time cost</td>
<td>1,579</td>
<td>9,324</td>
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<tr>
<td>PL annual operating cost</td>
<td>477</td>
<td>5,158</td>
</tr>
<tr>
<td>Antimicrobial annual cost</td>
<td>6,810</td>
<td>1,011</td>
</tr>
<tr>
<td>FCS tests</td>
<td>700</td>
<td>175 (2,100)</td>
</tr>
<tr>
<td>Test and hold</td>
<td>348</td>
<td>966</td>
</tr>
<tr>
<td><strong>Recurring cost total</strong></td>
<td>8,335</td>
<td>7,310 (9,235)</td>
</tr>
<tr>
<td><strong>Annual total cost (annualized + recurring)</strong></td>
<td>9,913</td>
<td>16,600 (18,500)</td>
</tr>
</tbody>
</table>
FSIS’s Office of Public Health Science ran the risk assessment model using updated industry practices (movement table) to estimate illnesses prevented.

- Results: annual benefit of $102.5 million from prevented illnesses and deaths.
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Comparison & Net Benefit

$ million

Cost  Benefit  Net Benefit

Retro BCA  FRIA  FRIA*

0  20  40  60  80  100  120

$ million
Conclusions

• The rule is cost-beneficial
• No disproportionate cost on small and very small establishments
  – 95% of the industry, 92.7% of the cost
• Data limitations of the analysis
  – Baseline scenario
  – Establishments movement
  – Production volume
Acknowledgement

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Questions