One Team, One Purpose

Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Benefit Cost Analyses and Food Safety Regulations on Meat Poultry and Egg Products

Policy Analysis Staff, Office of Policy and Program Development
Food Safety Inspection Service, USDA

Society for Benefit Cost Analysis
9th Annual Conference and Meeting
March 16-17, 2017
Washington, DC
Food Safety and Inspection Service

Presenters
• Richa Ajmera, Team Lead
• Angelica Marrero, Economist
• Flora Tsui, Ph.D. Economist

Discussant
• Sandra Hoffmann, Ph.D. Economist at Economic Research Service, USDA
Topics

• Overview of Food Safety Regulations
• Benefit Cost Analysis for the New Performance Standards for Pathogen Reduction in Certain Poultry Products
• Benefit Cost Analysis on Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products
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Food Safety Regulations Overview

Richa Ajmera
Food Safety and Inspection Service

Background: FSIS

• Public Health Agency in the USDA
• Regulates meat, poultry and egg products for interstate commerce
• Authority:
  • Federal Meat Inspection Act (FMIA), 1906
  • Agricultural Marketing Act (AMA), 1946 (select sections)
  • Poultry Products Inspection Act (PPIA), 1957
  • Egg Products Inspection Act (EPIA), 1970
  • Humane Methods of Slaughter Act (HMSA), 1958
• Inspectors in every establishment collect data and report through the Agency’s Public Health Information System (PHIS)
• OPPD/PAS is in charge of conducting Regulatory Impact Analyses (RIA) for FSIS’ regulations.
• RIAs identify regulatory objectives and ensure transparency and consistency by using Benefit Cost methodology
• Required by Executive Orders 12866 (1993) and 13563 (2011)
  – Required for economically significant rules
    • Economic significance defined as >$100m (1993$)
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Background: Regulatory Impact Analysis Continued..

• Benefit Cost analysis
  – Costs to Industry, Consumers and the Agency imposed by rulemaking
  – Benefits expressed as Public Health Benefits
  – Consideration of alternative policy actions
The current set of regulatory analytical requirements in the United States has been established incrementally during the last 40 to 50 years through a series of Presidential and Congressional initiatives, including statutes, executive orders, circulars, and other documents.
In deciding whether and how to regulate, U.S. Executive Branch Agencies should:

- Assess all quantifiable and qualitative costs and benefits of available regulatory alternatives
- Design its regulations in the most cost-effective manner to achieve the regulatory objective
- Maximize net benefits
- To the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt
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How Economic Analyses Improve Regulations?

Rule: Modernization of Poultry Slaughter Inspection (August 21, 2014)

<table>
<thead>
<tr>
<th>Considered Alternatives</th>
<th>Benefits</th>
<th>Costs</th>
<th>Net Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Taking No Action</td>
<td>No change in the existing inspection systems for poultry.</td>
<td>Establishments would maintain existing practices.</td>
<td>Zero Net Benefits.</td>
</tr>
<tr>
<td>B. The Rule</td>
<td>Public health benefits from reduced illnesses and FSIS savings add to total benefits of $26.0 million to $40.2 million annually. Additional unquantified public health benefits from New Poultry Inspection System and mandatory components of the rule.</td>
<td>Annualized costs equal $25.1 million.</td>
<td>Selected Alternative with annualized net benefits equal to $7.3 million</td>
</tr>
<tr>
<td>C. The Final Rule Without Offline Inspection Activity</td>
<td>Additional FSIS cost savings associated with a reduction in offline inspector positions</td>
<td>Annualized costs equal to Alternative B</td>
<td>Net benefits will be lower than Alternative B due to loss of public health benefits.</td>
</tr>
<tr>
<td>D. Requiring Only the New Poultry Inspection System</td>
<td>Public health benefits from reduced illnesses and FSIS savings add to total benefits of $26.1 million to $40.2 million annually.</td>
<td>Annualized costs greater than $20.5 million. All establishments not included in Alternative B will accrue additional costs.</td>
<td>The net benefits will be lower than Alternative B due to the increased burden on very small establishments.</td>
</tr>
</tbody>
</table>
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Methods for Estimating Benefits and Costs

Academic Research  Internal Databases

Private Contracts  Public Comments

Data Sources
Challenges for Economic Analyses of Regulations

Data
- Availability
- Reliability
- Usefulness

Studies
- Replicable
- Up to date

Timeliness
- Limitations
Benefit Cost Analysis for the New Performance Standards for Pathogen Reduction in certain poultry products

Angélica Marrero-Sánchez
Economist
Food Safety and Inspection Service

Outline

• Healthy People 2020
  – The Goal
  – The Objectives

• FSIS’ role
  – The Pathogens
  – The Products

• Performance Standards
  – The Standards
  – The Categories

• Benefit Cost Analysis

• Questions?
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• Questions?
Illnesses, hospitalizations and deaths caused by the top 5 pathogens, 2015

- **Norovirus**: 58% of total illnesses, 35% hospitalizations, 28% deaths
- **Staphylococcus aureus**: 3% illnesses, 4% hospitalizations, 6% deaths
- **Clostridium perfringens**: 10% illnesses, 15% hospitalizations, 19% deaths
- **Salmonella, nontyphoidal**: 11% illnesses, 26% hospitalizations, 24% deaths
- **Campylobacter spp.**: 9% illnesses, 8% hospitalizations, 11% deaths
Foodborne illnesses caused by Salmonella and Campylobacter per 100,000 cases

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>15</td>
<td>15</td>
<td>17.5</td>
<td>16.4</td>
<td>16.4</td>
<td>15.1</td>
<td>15.3</td>
<td>15.7</td>
<td>11.4</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>12.7</td>
<td>13</td>
<td>13.5</td>
<td>14.3</td>
<td>14.2</td>
<td>13.7</td>
<td>13.3</td>
<td>12.8</td>
<td>8.5</td>
</tr>
</tbody>
</table>
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• Questions?
CDC used outbreaks (1998-2008) to estimate foods responsible for domestic foodborne Salmonellosis
- Poultry was the leading cause among FSIS regulated products
- About 200,000 illnesses are associated with poultry

Painter et al., 2013: http://wwwnc.cdc.gov/eid/article/19/3/11-1866_article
Data from the National Chicken Council and the National Turkey Federation
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• Questions?
### Performance Standards: The Standards

<table>
<thead>
<tr>
<th>Product</th>
<th>Maximum Acceptable % Positive</th>
<th>Performance Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmonella</td>
<td>Campylobacter</td>
</tr>
<tr>
<td>Chicken Parts</td>
<td>15.4</td>
<td>7.7</td>
</tr>
<tr>
<td>Comminuted Chicken</td>
<td>25.0</td>
<td>1.9</td>
</tr>
<tr>
<td>Comminuted Turkey</td>
<td>13.5</td>
<td>1.9</td>
</tr>
</tbody>
</table>
### Categories for Salmonella in all products and Campylobacter in Chicken Parts

<table>
<thead>
<tr>
<th>Category</th>
<th>Process Control</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consistent</td>
<td>Establishments with contamination rates below <strong>50%</strong> of the standard.</td>
</tr>
<tr>
<td>2</td>
<td>Variable</td>
<td>Establishments that <strong>meet</strong> the standard but have contamination rates <strong>higher than 50%</strong> of it.</td>
</tr>
<tr>
<td>3</td>
<td>Highly Variable</td>
<td>Establishments that <strong>do not</strong> meet the standard.</td>
</tr>
</tbody>
</table>
Performance Standards: The Categories (cont’d)

Example: Salmonella in Chicken Parts Performance Standard is 15.4%

<table>
<thead>
<tr>
<th>Category</th>
<th>Process Control</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consistent</td>
<td>Salmonella Contamination Rate less than <strong>7.7%</strong>.</td>
</tr>
<tr>
<td>2</td>
<td>Variable</td>
<td>Salmonella Contamination Rate between <strong>7.7%</strong> and <strong>15.4%</strong>.</td>
</tr>
<tr>
<td>3</td>
<td>Highly Variable</td>
<td>Salmonella Contamination Rate greater than <strong>15.4%</strong>.</td>
</tr>
</tbody>
</table>
Categories for Campylobacter in Comminuted Product

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passing</strong></td>
<td>Establishments that <em>meet</em> the standard.</td>
</tr>
<tr>
<td><strong>Failing</strong></td>
<td>Establishments that <em>do not meet</em> the standard.</td>
</tr>
</tbody>
</table>
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  - The Standards
  - The Categories
- Benefit Cost Analysis
- Questions?
### Benefit Cost Analysis: Costs

<table>
<thead>
<tr>
<th>Level of Establishments Not Meeting the Standard</th>
<th>Cost Component</th>
<th>Primary Estimate ($mil)</th>
<th>Low Estimate ($mil)</th>
<th>High Estimate ($mil)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capital Equipment</td>
<td>2.15</td>
<td>2.15</td>
<td>2.15</td>
</tr>
<tr>
<td>30%</td>
<td>Antimicrobial Solution</td>
<td>6.54</td>
<td>4.61</td>
<td>8.46</td>
</tr>
<tr>
<td></td>
<td>Sampling</td>
<td>9.27</td>
<td>6.18</td>
<td>12.36</td>
</tr>
<tr>
<td></td>
<td>Reassessment &amp; Training</td>
<td>*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total Costs</strong></td>
<td><strong>17.96</strong></td>
<td><strong>12.94</strong></td>
<td><strong>22.97</strong></td>
</tr>
<tr>
<td></td>
<td>Capital Equipment</td>
<td>2.86</td>
<td>2.86</td>
<td>2.86</td>
</tr>
<tr>
<td>40%</td>
<td>Antimicrobial Solution</td>
<td>8.72</td>
<td>6.14</td>
<td>11.28</td>
</tr>
<tr>
<td></td>
<td>Sampling</td>
<td>9.82</td>
<td>6.52</td>
<td>13.05</td>
</tr>
<tr>
<td></td>
<td>Reassessment &amp; Training</td>
<td>*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total Costs</strong></td>
<td><strong>21.4</strong></td>
<td><strong>15.52</strong></td>
<td><strong>27.19</strong></td>
</tr>
<tr>
<td></td>
<td>Capital Equipment</td>
<td>3.58</td>
<td>3.58</td>
<td>3.58</td>
</tr>
<tr>
<td>50%</td>
<td>Antimicrobial Solution</td>
<td>10.89</td>
<td>7.68</td>
<td>14.12</td>
</tr>
<tr>
<td></td>
<td>Sampling</td>
<td>10.40</td>
<td>6.91</td>
<td>13.81</td>
</tr>
<tr>
<td></td>
<td>Reassessment &amp; Training</td>
<td>*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total Costs</strong></td>
<td><strong>24.87</strong></td>
<td><strong>18.17</strong></td>
<td><strong>31.51</strong></td>
</tr>
</tbody>
</table>

*$3,800 at 30%, $5,100 at 40%, $6,400 at 50% – values too small to display in table.
## Annualized Public Health Benefits

<table>
<thead>
<tr>
<th>Level of Establishments Not Meeting the Standard</th>
<th>Illnesses Averted</th>
<th>Primary Estimate ($mil)</th>
<th>Low Estimate ($mil)</th>
<th>High Estimate ($mil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>23,900 (14,900 – 37,600)</td>
<td>50.87</td>
<td>31.84</td>
<td>79.89</td>
</tr>
<tr>
<td>40%</td>
<td>37,100 (23,400 – 58,700)</td>
<td>79.66</td>
<td>50.43</td>
<td>125.89</td>
</tr>
<tr>
<td>50%</td>
<td>50,600 (31,800 – 79,500)</td>
<td>109.10</td>
<td>68.80</td>
<td>171.24</td>
</tr>
</tbody>
</table>
**Benefit Cost Analysis : Net Benefits**

### Summary of Estimated Net Benefits

<table>
<thead>
<tr>
<th>Level of Establishments Not Meeting the Standard</th>
<th>Cost/Benefit Component</th>
<th>Primary Estimate ($mil)</th>
<th>Low Estimate ($mil)</th>
<th>High Estimate ($mil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>Industry Costs</td>
<td>18.0</td>
<td>12.9</td>
<td>23.0</td>
</tr>
<tr>
<td></td>
<td>Public Health Benefits</td>
<td>50.9</td>
<td>31.8</td>
<td>79.9</td>
</tr>
<tr>
<td></td>
<td><strong>Net Benefits</strong></td>
<td><strong>32.9</strong></td>
<td><strong>18.9</strong></td>
<td><strong>56.9</strong></td>
</tr>
<tr>
<td>40%</td>
<td>Industry Costs</td>
<td>21.4</td>
<td>15.5</td>
<td>27.2</td>
</tr>
<tr>
<td></td>
<td>Public Health Benefits</td>
<td>79.7</td>
<td>50.4</td>
<td>125.9</td>
</tr>
<tr>
<td></td>
<td><strong>Net Benefits</strong></td>
<td><strong>58.3</strong></td>
<td><strong>34.9</strong></td>
<td><strong>98.7</strong></td>
</tr>
<tr>
<td>50%</td>
<td>Industry Costs</td>
<td>24.9</td>
<td>18.2</td>
<td>31.5</td>
</tr>
<tr>
<td></td>
<td>Public Health Benefits</td>
<td>109.1</td>
<td>68.8</td>
<td>171.2</td>
</tr>
<tr>
<td></td>
<td><strong>Net Benefits</strong></td>
<td><strong>84.2</strong></td>
<td><strong>50.6</strong></td>
<td><strong>139.7</strong></td>
</tr>
</tbody>
</table>
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Benefit Cost Analysis on Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products

Flora H. Tsui, Ph.D.
Economist
Background on Control of Listeria monocytogenes (Lm)

- Lm is a leading cause of food-related hospitalization, fetal loss, and death
  - Estimated 1,500 hospitalizations and 260 deaths annually*
    - Hospitalization rate 90%
    - Mortality rate over 20% vs. 0.5% for E. Coli or Salmonella
  - Most from consuming Ready To Eat (RTE) products

*Source: Food Safety and Inspection Service
Food Safety and Inspection Service: Background (cont.)

- FSIS efforts to control Lm
  - 1987 begun to sample and test
  - 1989 adopted of 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 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 anti-microbial agents or processes
    • Alternative 2: post-lethality treatment (2a) or anti-microbial agents or processes (2b)
    • Alternative 3: only sanitation program
To encourage industry adoption of more effective interventions, FSIS sample establishments based on the Lm-control alternatives.

- For example, FSIS conducts more testing at establishments that choose Alternative 2 than Alternative 1.
Based on movement table of how industry changed Lm-control alternatives

Estimated changes in Alternative Groups (AG)

<table>
<thead>
<tr>
<th>AG</th>
<th>Large</th>
<th>Small</th>
<th>VS (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>
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Benefit (cont.)

• Reduced listeriosis illnesses and deaths
  – Risk assessment model simulation
    • How inplant-contamination transfers to retail contamination
  • Using dose-response relationship

<table>
<thead>
<tr>
<th>Intervention Alternative</th>
<th>Median</th>
<th>5%</th>
<th>95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/4</td>
<td>3.1</td>
<td>1.0</td>
<td>3.2</td>
</tr>
<tr>
<td>2b</td>
<td>12.0</td>
<td>4.0</td>
<td>14.0</td>
</tr>
<tr>
<td>1</td>
<td>12.2</td>
<td>3.9</td>
<td>14.0</td>
</tr>
<tr>
<td>Total</td>
<td>27.3</td>
<td>8.9</td>
<td>31.2</td>
</tr>
</tbody>
</table>
• Monetizing health benefit
  – Fatality rate: 20%
  – COI (cost of illness)
    • Moderate (5%): $10,300
    • Severe (95%): $28,300
  – VSL (value of statistical life) $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
Cost - Industry Wide

- 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 7% discount rate over 10 years: $16.6 m.
• In 2015, FSIS affirmed 2003 interim final rule with minor changes
  – Percent positive in FSIS testing for Lm in RTE products decreased from 0.76% in CY2003 to 0.34% in 2013