Lessons from USDA’s Mandatory HACCP Rule for Meat and Poultry

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Presentation Overview

- What is the relationship between HACCP regulations and the FSMA preventive controls rule?

- What were the economic effects of the HACCP regulation on the meat & poultry industry?
  - Original regulatory impact analysis estimates versus post-regulation studies
  - Analysis of closure of meat and poultry plants in response to the regulation

- What are the implications of the meat and poultry HACCP experience for the FSMA preventive controls rule?
History of Mandatory HACCP Regulations for Food Manufacturers and Processors

- **Seafood**: 3,500 domestic processors, began in 1998 (FDA)
- **Meat & poultry**: 7,300 domestic processors (state and federal inspection) and 950 foreign, began in 1999 (USDA)
- **Juice**: 2,300 domestic processors, began in 2001 (FDA)
- **Dairy**: voluntary starting in 2002 with Pasteurized Milk Ordinance already in place (FDA)
- **Egg products**: 80 domestic processors, regulation still in development (USDA)
- All other processors (97,600 domestic and 109,200 foreign) fall under FSMA but refers to “preventive controls” rather than “HACCP”
Meat & Poultry HACCP vs Preventive Controls for Food Manufacturers

- Basic idea of HACCP rules versus the Preventive Controls rule is the same
  - Plants are required to understand the hazards reasonably likely to occur in the plant and put in place a plan to minimize or prevent the hazards.

- HACCP = hazard analysis and critical control points
  - Conduct a hazard analysis
  - Determine CCPs
  - Establish critical limits for CCPs
  - Establish system to monitor CCPs
  - Establish corrective actions if CCP is not under control
  - Establish verification procedures
  - Establish recordkeeping procedures
Meat & Poultry HACCP versus Preventive Controls for Food Manufacturers

- **1996 Meat and poultry HACCP regulation**
  - Required all plants develop and implement Sanitation Standard Operating Procedures (SSOPs) and HACCP plans
  - Established performance standards for pathogenic microorganisms (specifically *Salmonella*)
  - Required at least one antimicrobial treatment in slaughter plants
  - Set standards for cooling red meat carcasses

- **Preventive controls rule**
  - Requires plants to develop and implement a “written food safety plan” including all of the same 7 components of HACCP
    - Exempts some plants based on limited risk and modifies requirements for smallest plants
  - Clarifies that Good Manufacturing Practices must address cross-contamination of food by allergens
Meat & Poultry HACCP Implementation

- Final rule was published on July 25, 1996.

<table>
<thead>
<tr>
<th>Date</th>
<th>Affected Plants</th>
<th>Requirements</th>
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<tbody>
<tr>
<td>January 1997</td>
<td>All Plants</td>
<td>• Sanitation standard operating procedures (SOPs)</td>
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<td></td>
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<td>• Generic <em>E. coli</em> carcass testing</td>
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<tr>
<td>January 1998</td>
<td>Large Plants (&gt;500 employees)</td>
<td>• HACCP</td>
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<td>• <em>Salmonella</em> testing of some raw products</td>
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<tr>
<td>January 1999</td>
<td>Small Plants (10-500 employees)</td>
<td>• HACCP</td>
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<tr>
<td></td>
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<td>• Salmonella testing of some raw products</td>
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<tr>
<td>January 2000</td>
<td>Very Small Plants (&lt;10 employees or &lt;$2.5 million in annual sales)</td>
<td>• HACCP</td>
</tr>
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<td></td>
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<td>• Salmonella testing of some raw products</td>
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Estimates of the Costs of Meat & Poultry HACCP

- **Ex-ante** estimates from the Regulatory Impact Analysis (1996)
  - **Per-plant costs**
    - Development & implementation: $10K-$13K
    - Annual: $8K-$9K
  - Included HACCP plan development, training, recordkeeping, and pathogen testing

- **Ex-post** estimates from Ollinger, Moore, Chandran (2004) based on survey data
  - **Per-plant costs**
    - Development & implementation: $259K--$639K
    - Annual: $119K-503K
  - Also included costs of new capital equipment and hiring more workers
Evaluation of Meat & Poultry HACCP

- Final rule required FSIS to conduct an ex-post evaluation of the regulation
- Areas covered by the evaluation study:
  - Foodborne illness reduction
  - Inspection effectiveness and efficiency
  - Consumer confidence in product safety
  - Animal and egg food safety production practices
  - Domestic and international economic effects
    - Productivity of U.S. meat and poultry plants
    - Entry and exit of meat and poultry plants (rates and factors affecting)
    - Imports and exports of meat and poultry
Did the HACCP regulation cause meat and poultry plants to close?

- Plants might close because
  - Lack the technical knowledge to implement HACCP
  - Lack the financial resources to develop a HACCP plan, make changes to plant operations, and train workers
  - Increased costs of production decrease profitability

- Used FSIS’s meat and poultry inspection database to estimate rates of plant exit and factors affecting exit
  - Pre-HACCP: 1993-1996
  - Post-implementation: 2000-2002
Annualized Rates of Exit: Meat Slaughter Plants

- Pre-HACCP
- Implementation
- Post-Implementation

Very Small
Small
Large
Annualized Rates of Exit: Poultry Slaughter Plants

Very Small
Pre-HACCP
Implementation
Post-Implementation

Small

Large

0%
2%
4%
6%
8%
10%
12%
14%
16%
18%
20%
Annualized Rates of Exit: Meat and Poultry Processing-Only Plants

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-HACCP</th>
<th>Implementation</th>
<th>Post-Implementation</th>
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<tbody>
<tr>
<td>Very small</td>
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<td></td>
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<tr>
<td>Small</td>
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<td></td>
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<tr>
<td>Large</td>
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- Very small: 4%, 6%, 7%
- Small: 5%, 5%, 6%
- Large: 6%, 6%, 7%
Results of Probit Analyses Controlling for Other Factors

- **Effects of HACCP Regulation:**
  - **Meat Slaughter**—statistically significant increased exit pre-HACCP to implementation for very small and small plants
  - **Poultry Slaughter**—statistically significant increased exit pre-HACCP to post-implementation for very small and small plants (and also pre-HACCP to implementation for small plants)

- **Other Factors Affecting Exit:**
  - **Age of plant**—reduced exit rates for older plants up to a point, then exit rate begins to increase
  - **Volume**—reduced exit rate for plants with greater slaughter volumes
  - **Regional competitiveness**—higher exit rate for smaller plants in regions with higher market concentration
  - **Input prices**—higher exit rate for plants in regions with higher livestock prices
What are the implications for the FSMA preventive controls rule?

- Substantially different situation for meat and poultry versus foods under FSMA preventive controls
  - **Number of affected plants and range of products produced**—greater implementation challenges for FSMA preventive controls
  - **Frequency of inspectors in the plants**—plays a key role in communicating requirements of the regulation and providing technical assistance and education
  - **Extent of plant level data for monitoring and analysis**—due to inspection procedures, more extensive and up-to-date data on meat and poultry plants
  - **Pathogen testing results for monitoring**—FSIS has access to *Salmonella, Campylobacter, E. coli O157:H7* (raw ground beef), and *Listeria monocytogenes* (RTE products) test results
References on Plant Exit


More Information

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