

October 11, 2005

Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
300 12<sup>th</sup> Street, SW  
Room 102 Cotton Annex  
Washington, DC 20250

**Re: Docket Number 05-024N**

**Notice of a Section 610 Regulatory Flexibility Act Review of the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule**

S.T.O.P.—Safe Tables Our Priority appreciates this opportunity to comment on the above notice. S.T.O.P. is a national, not-for-profit, grassroots organization consisting of victims of foodborne illness and their families, friends and concerned parties who recognize the threat pathogens pose in the U.S. food supply. S.T.O.P. was founded in 1993 in the aftermath of the Jack-In-The-Box *E. coli* O157:H7 epidemic from ground beef in the west and Pacific Northwest. Our mission is to prevent suffering, illness and death from foodborne disease by providing information and education, advocating sound public policy and supporting victims of foodborne disease.

**1. The Importance of Strong Food Safety Regulations**

Foodborne disease exacts a heavy toll. The Centers for Disease Control and Prevention (CDC) estimate that annually, 76 million people in the United States suffer a foodborne illness; 350,000 are hospitalized; and 5,000 die. Children, the elderly, pregnant and postpartum women and anyone with a compromised immune system are at highest risk of developing serious complications due to foodborne illness. Estimates of the annual costs to taxpayers range from approximately \$7 billion to \$34 billion.<sup>1</sup> Both an ethical/moral and a fiscal argument can be made for the need to reduce foodborne illness and death through strong regulatory requirements of the meat and poultry industry coupled with strict inspection enforcement.

Pathogens do not discriminate based on plant size. Nor do victims and their families suffer any less if the source of the contaminated food is a small or very small “family” plant versus a “mega” company.

It is therefore critical that all plants, regardless of size, be required to perform and meet all the same requirements and standards under a single program. This includes sanitation standards, microbial testing regimes, paperwork requirements, etc.

**2. The PR/HACCP Regulation**

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<sup>1</sup> (Need to footnote/endnote ERS stats)

The final PR/HACCP rule published on July 25, 1996, was the result of an 18-month process which included: seven information briefings; three scientific and technical conferences; a two-day public hearing; six issue-focused public meetings; a Federal-State conference; and a Food Safety Forum chaired by (then) Secretary of Agriculture, Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.<sup>2</sup> The process was transparent and the participation of all interested stakeholders was welcomed.

Members of S.T.O.P. committed prodigious amounts of personal time and resources to participate in these meetings. We also submitted public comments (attached). We were disappointed that not all of our suggestions and concerns were addressed and/or implemented in the final rule. Hence, any action taken on behalf of this regulatory review must not weaken what S.T.O.P. already perceives as an insufficient regulation to protect the public from unsafe meat and poultry.

### **3. Additional Outreach to Small and Very Small Plants**

The actual implementation of the HACCP rule did not begin until approximately 16 months after the rule was published. It was then phased in over a three year period beginning with large plants (500+ employees) on January 26, 1998; small plants (10-499 employees and sales under \$2.5 million) on January 25, 1999; and very small plants (fewer than 10 employees and sales under \$2.5 million) on January 24, 2000.

During the period before the small and very small plants had to implement HACCP, FSIS offered abundant guidance and assistance to help facilitate these plants ability to implement HACCP on the required date. Outreach included:

- Establishment of the Office of the HACCP National Small and Very Small Plant Coordinator in June 1998.
- Establishment of HACCP contacts/coordinators in all 50 states, Puerto Rico, Washington D.C. and the Virgin Islands. This network was composed of representatives from industry, academia, state-inspected programs and university extension offices.
- 190+ Demonstration Workshops from 1997-1999 to provide small and very small plants technical guidance and assistance on HACCP principles and FSIS requirements. Language assistance workshops were provided in selected locations in Spanish and Asian Pacific dialects.
- Materials including: HACCP videotapes, software, HACCP workbooks, process control charting information, and a video and workbook on recordkeeping.

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<sup>2</sup> "Improving the Safety of Meat and Poultry: Background on a Science-based Strategy for Protecting Public Health", page 3. (July 25, 1996)

- Development of a Sponsor/Mentor program between large plants and small and very small plants.
- 20 implementation meetings were conducted across the country (and Puerto Rico) prior to small plant HACCP implementation in 1999. A video of one meeting was made available in English, Spanish and Chinese for those unable to attend and for further reference.
- 13 Generic HACCP Models and Guidebooks.
- Model HACCP plants. Five land grant universities worked with FSIS to utilize their meat and poultry inspected laboratories as model plants. These sites were open to the industry to view a very small plant in action under HACCP. These schools also offered one-on-one assistance.
- Bi-monthly correspondence from the Administrator was sent to plants reminding them of their implementation date and referring them to available resources.
- Self-study packages, available in English and Spanish, were distributed in 1999 to very small plants.
- Establishment of a toll-free HACCP Hotline.<sup>3</sup>

Clearly, information and resources to help small and very small plants perform under the requirements of the PR/HACCP rule have been provided since implementation of the rule. Lack of information and/or resources is not a justifiable claim for any small or very small plant to make as a reason for why they could not meet the requirements of HACCP. All plants must be required to play on a level playing field.

#### 4. The Economic Impact on Small and Very Small Plants

Quoting the background information from the notice:

Section 610 of the Regulatory Flexibility Act (RFA) as amended (5 U.S.C. 601-612), requires that all Federal Agencies review any regulations that have been identified (emphasis ours) as having a significant economic impact upon a substantial number of small entities as a means to determine whether the associated impact can be minimized.

FSIS has failed to provide any information whatsoever that any small and very small businesses, let alone substantial numbers of them, have in fact, been economically impacted at all, let alone significantly impacted economically by the PR/HACCP regulation's requirements.

Even if there was information available demonstrating that a significant number of small and very small businesses were being significantly impacted economically, S.T.O.P. would take issue with any loosening of requirements and standards for such entities

<sup>3</sup> "Food Safety and Inspection Service HACCP Small and Very Small Plant Outreach Initiatives". FSIS website.

Foodborne illness victims and their families have suffered enormous financial and health losses due to contaminated food. Some have paid the ultimate price: their life. Therefore, it would be unconscionable for government to put the convenience and financial success of business ahead of the health and safety of consumers.

## 5. Conclusion

S.T.O.P. strongly opposes granting any concessions of requirements under the PR/HACCP regulation to small and very small plants. They must be required to perform under the same law as larger establishments. Consumers want and expect that the meat and poultry they serve their families has been produced in an environment, regardless of size, that is governed by a single set of standards.

S.T.O.P. has steadily maintained that using the best science to produce the food free of pathogens is a paramount public health objective. Therefore, any claim that small and very small plants have in regard to cost is secondary and any allowances for small and very small plants should only be considered if there is solid scientific evidence that those allowances will not affect the HACCP standards that were specified in the 1996 Final Rule.

If after the comment period is over and FSIS is considering any allowances for small and very small plants, public hearings need to be held so that the issues can be discussed and debated.

The health and safety of the public must take precedence over the financial health of business entities. Thousands of Americans are suffering and dying each year due to serious foodborne disease. FSIS must keep their public health mandate front and center at all times.

Respectfully submitted,

Barbara Kowalcyk  
President

Nancy Donley  
President (1997-2002)  
Policy Committee Chair