



S.T.O.P. – Safe Tables Our Priority

Working Together To Make Safe Food A Reality

October 11, 2005

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th 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 through the advocacy of sound public policy, providing information and education to all sectors throughout the farm-to-fork continuum and by offering support to victims of foodborne illness.

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. While everyone is at risk, the most vulnerable populations to develop serious complications due to foodborne illness are children, seniors, pregnant and postpartum women and anyone with a compromised immune system. In 2000, the USDA's Economic Research Service (ERS) estimated the cost from five bacterial foodborne pathogens as \$6.9 billion.¹ Both an ethical/moral and a fiscal argument can be made for the need to reduce foodborne illness and death through strong regulatory requirements applied to 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.

¹ The five pathogens are *Campylobacter* (all serotypes); *Salmonella* (nontyphoidal); *E. coli* O157; *E. coli* non O157 STEC; and *Listeria monocytogenes*.

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. These include sanitation standards, microbial testing regimes and paperwork requirements.

2. The PR/HACCP Regulation

The final PR/HACCP rule published on July 25, 1996, was the result of an 18-month process that 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.² 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. 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 PR/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.

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

- Materials including: HACCP videotapes; software; HACCP workbooks; process control charting information; and a video and workbook on recordkeeping.
- Facilitation 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.³

Clearly, information and resources to help small and very small plants perform under the requirements of the PR/HACCP rule have been provided since the enactment of the rule. Lack of information and/or resources does not justify a claim by any small or very small plant that it cannot meet the requirements of HACCP. Public health demands that all plants be required to play on a level playing field.

4. The Economic Impact on Small and Very Small Plants

Quoting the background information from this 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 to support its initial determination 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. As noted above, the agency has provided substantial assistance to small and very small plants throughout the PR/HACCP rule development process. We believe that this assistance has lessened any economic burden caused by the PR/HACCP regulation.

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

However, if comments reveal some additional economic impact on these plants, S.T.O.P. cautions FSIS not to make any changes to the PR/HACCP rules as applied to small and very small plants without substantial evidence on the record that demonstrates significant economic hardship.⁴ S.T.O.P. would take issue with any substantive or wide-scale relaxation of the PR/HACCP rule as applied to small and very small plants.

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 convenience and profit for industry ahead of the health and safety of consumers.

5. Conclusion

S.T.O.P. strongly opposes granting any concessions regarding 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 available to reduce pathogens in food is a paramount public health objective. Therefore, any claim that small and very small plants regarding 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 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 meetings need to be held so that the issues can be discussed and debated by all interested stakeholders.

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

Respectfully submitted,

Barbara Kowalczyk
President

Nancy Donley
President (1997-2005)
Policy Committee Chair

⁴ If FSIS were to change the PR/HACCP rule applicable to small and very small plants without adequate supporting evidence, then we believe that the action could be challenged as “arbitrary and capricious” under the Administrative Procedures Act, 5 U.S.C. §706(2)(A). See, e.g., Associated Industries of New York State, Inc. v. U.S. Dept. of Labor, (487 F.2d 342, 349-50 (2d Cir. 1973) (a decision must be considered “arbitrary and capricious” if the facts on which it is purportedly based are not supported by the record).