S.T.O.P. – Safe Tables Our Priority

Working Together To Make Safe Food A Reality

FSIS-2005-0031-5 and 04-026N-5
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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 04-026N
Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection

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, volunteer health organization dedicated to preventing suffering, illness and death due to foodborne illness by advocating sound public policy, increasing awareness and education, and providing victim assistance. 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 California and the Pacific Northwest.

The Impact of Foodborne Illness

Foodborne disease is a serious public health issue and the cost to American society is very high. 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 individuals with a compromised immune system.

Each year in the United States, there are approximately 1.4 million cases of Salmonellosis that cause an estimated 400 deaths. According to USDA's Economic Research Service (ERS), each of those cases costs an average of $2,126 in lost wages and medical costs[1]. According to another ERS report[2], "Foodborne illnesses account for about 1 of every 100 U.S. hospitalizations and 1 of every 500 U.S. deaths." In fact, the ERS estimates that, each year in the United States, five foodborne illnesses – *Camploybacter, Salmonella, E. coli* O157:H7, *Listeria monocytogenes* and *Toxoplasma gondii* - cause $6.9 billion in medical costs, lost productivity and premature deaths[3]. These estimates do not include many other foodborne illnesses, such as, Norwalk virus -

[1] Economic Research Service, USDA. *Foodborne Illness Cost Calculator*, www.ers.usda.gov
[2] Buzby, Frezen, and Rasco. Food and Rural Economics Division, Economic Research Service, USDA. Agricultural Economic Report No. 799: *Product Liability and Microbial Foodborne Illness.*
[3] Buzby. Food and Rural Economics Division, Economic Research Service, USDA. *Children and Microbial Foodborne Illness.* Food Review, Vol 24, Issue 2.

the leading cause of foodborne disease in the United States - botulism, shigella, foodborne staph, and parasites. Nor does it reflect any of the hidden costs that victims and their families suffer: the cost of traveling to receive medical care, time lost from work caring for sick children, lost leisure time, and pain and suffering.

Further, the acute stage of foodborne disease can be only the start of the problem. The Food and Drug Administration (FDA) estimates 2 to 3 percent of foodborne illness victims develop secondary long-term medical problems[4] – that is an estimated 1.5 million lingering health problems per year. *Salmonella* is one of the leading predictors for reactive arthritis, a painful, chronic and potentially debilitating condition that causes joint inflammation. *Camplyobacter* is believed to be a leading cause of Guillian-Barre Syndrome, an autoimmune reaction that causes paralysis and kills between five and ten percent of its victims. *E. coli* O157:H7 and other foodborne diseases are almost the exclusive cause of HUS, the relentless condition characterized by cascading organ failure. HUS can cause its victims, most of them young children, to have seizures, strokes and heart attacks and many HUS patients require spleenectomies, chemotherapy, repeated blood transfusions, and even intestinal reconstruction. One-third of HUS survivors will suffer life-long medical problems such as high blood pressure, diabetes, kidney failure and brain damage. In fact, HUS caused by *E. coli* O157:H7 is the leading cause of acute kidney failure in children in the United States.

Clearly, besides the ethical/moral responsibility to provide consumers with food free from disease-causing pathogens, there is a fiscal argument for reducing foodborne illness and its resulting consequences. The United States has a responsibility to its citizens to provide strong regulatory requirements, coupled with strict inspection enforcement, for all food products, but especially for those foods – like eggs, meat and poultry – that carry heavy loads of microbiological pathogens.

Background

1. 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.[5] 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 new action must not weaken what S.T.O.P.

[4] Frezen. Economic Research Service, USDA. *The Economics of Food, Farming, National Resources and Rural America,* www.ers.usda.gov

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

already perceives as an insufficient regulation to protect the public from unsafe meat and poultry.

2. *Salmonella* Performance Standards

The PR/HACCP system, which is rooted in sound science and statistical quality control, relies on continuous control and monitoring of Critical Control Points along the production process. Performance standards are an objective measure for determining whether a plant's HACCP plan is effective in pathogen reduction.

FSIS performance standards are based on the Microbiological Baseline Surveys conducted in the 1990's. These surveys were designed to provide national prevalences and levels of selected microorganisms in broiler chickens, market hogs, turkeys, cows/bull, steers/heifers, ground beef, ground chicken, and ground turkey. The microorganisms targeted were: *Clostridium perfringens*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Camplyobacter jejuni*, *E. coli* O157:H7 and *Salmonella*. Based on the results of these studies, the performance standards were selected so that there is 80% probability that plants operating at an acceptable level will have test results showing that they have complied with the standard.

In the final PR/HACCP rule, pathogen-specific performance standards were identified as an essential component and were intended to be revised as the Microbiological Baseline Surveys were repeated to determine the progress being made in pathogen reduction[6]. Further, *Salmonella* was identified as the first of many pathogen-specific performance standards that would be used to determine whether a plant's HACCP plan is effective. As stated in the directive, *Salmonella* was chosen as the first target organism since it is a common cause of foodborne illness and interventions/controls designed to reduce *Salmonella* levels are believed to reduce other pathogen levels.

3. FSIS *Salmonella* Verification Testing Program

In order to verify that establishments were achieving the *Salmonella* performance standard, FSIS implemented the *Salmonella* Verification Testing Program. Based on the performance standard for a product category, FSIS personnel collect a designated number of samples that constitutes a sample set. These samples are analyzed by FSIS laboratories and the number of positive samples is compared to the maximum number of positive samples allowed by the performance standard. If the maximum number of positive samples is exceeded, a second and, possibly, a third sample set are taken. According to the directive, FSIS generally tests establishments once annually, unless the establishment fails to meet the performance standard.

The *Salmonella* Verification Testing program is a strictly regulatory program that was designed to determine if a particular establishment was meeting the HACCP *Salmonella* performance standard at a particular point in time. This regulatory program was not statistically designed to measure the effectiveness of HACCP or estimate the level of *Salmonella* in the food supply. The Verfication Testing Progam is flawed because it is not

[6] The Pathogen Reduction/HACCP Final Rule, Federal Register, Vol. 61, No. 144 (Jul 25, 1996)

statistically designed, samples different establishments from year to year and samples are not randomly taken. Further compounding the interpretability of the data is the fact that the program presents unweighted percentages rather than weighted percentages. As a result, any inferences drawn about the effectiveness of HACCP and/or the prevalence of *Salmonella* in the food supply are inappropriate.

Agency Decisions

1. **FSIS will add results from individual *Salmonella* verification sample tests to reports the Agency regularly makes to meat and poultry establishments.**

Allowing plants to know sooner that their process is out of control certainly has a public health advantage. Posting this information will provide an incentive to establishments to bring their process into control quickly to avoid failing the sample set and the subsequent further testing. However, the impact of this decision on the results of the Verification Testing Program should not be overlooked.

As stated earlier, the Verification Testing Program is purely regulatory in nature and few inferences can be drawn from the data. However, the Agency has, from time to time and sometimes inappropriately, used data from the Verification Testing Program to make year-to-year comparisons and to draw inferences about the prevalence of specific pathogens. By informing establishments of results after each individual sample in a sample set, establishments will be made aware that they are in danger of failing a sample set and will be likely to take corrective action. It should, therefore, be expected that the number of failed sample sets will decrease. As a result, the Verification Testing Program will have an inherent bias, and it will become even more important that the data collected is not used to draw inferences about the prevalence of a pathogen or trends over time.

In the past, FSIS has not informed an establishment until the sample set is complete that they failed to meet the performance standard. This policy allowed an establishment whose processes are out-of-control to continue producing and distributing product to unsuspecting consumers. In the interest of public health, an establishment should be informed as soon as the maximum number of allowed positives for a sample set is exceeded so that corrective action can be taken and a new sample set can begin.

S.T.O.P. is pleased with this proposed change in policy as it represents a shift in focus to that of public health. However, the impact of this change on the interpretability and generalizability of data collected from the Verification Testing Program is significant. As a result of this change, the Verification Testing Program will, in essence, become simply a tool for establishments to know when their process is not meeting the *Salmonella* performance standard.

S.T.O.P. believes that this change will better protect public health as long as the Verification Testing Program data is not used to make and/or imply larger statements about the nationwide prevalence of *Salmonella.*

2. **FSIS will post quarterly, nationwide data for *Salmonella,* presented by product class.**

Posting quarterly, nationwide data for Salmonella, by product class, is not problematic as long as FSIS does not use the data to draw inferences about trends over time (see discussion for Decision #1) or change its sampling scheme based on interim results. The purpose of the Verification Testing Program is to determine whether a particular establishment is meeting the performance standard at a particular point in time. It is very important that FSIS take extreme care in interpreting and generalizing data collected from this program.

3. **FSIS will classify *Salmonella* verification sample sets into one of three categories: consistent, variable, and highly variable process control.**

According to the proposed directive, Salmonella verification sample sets will be categorized into one of three categories, defined as:

Category 1: Consistent Process Control for Salmonella Reduction. 50% or less of the performance standard or baseline guidance.

Category 2: Variable Process Control for Salmonella Reduction. From 51% of the performance standard or regulatory guideline to the performance standard or baseline guideline.

Category 3: Highly Variable Process Control for Salmonella Reduction. Greater than the performance standard or baseline guidance.

As stated in the proposed directive, the percentage of positive samples in broiler chickens has been increasing since 2002. Due to proposed change #1, classifying sample sets based on the degree to which the performance standard is achieved may provide a more useful measure than examining the percentage of sample sets that met/failed the performance standard.

Also, given the number of products selected for testing – along with the large number of plants involved nationwide - the Agency may want to consider expanding the number of categories so that it can more easily oversee and report its findings.

4. **FSIS will classify establishments into one of three categories that will dictate the frequency of *Salmonella* verification testing.**

According to the proposed directive, establishments will be classified into one of three categories based on their past two consecutive *Salmonella* verification sample set test results. Category 1 establishments are classified as having sustained good control by achieving 50% or less of the performance standard on their past two consecutive sample sets. In an effort to maximize limited resources, these establishments would be tested at most once a year and at least once every two years unless they are reclassified in the meantime as a Category 2 or 3 establishment. Category 2 and 3 establishments will be tested at least annually and more frequently, if needed.

There are several problems with the proposed classification of establishments and the corresponding schedule for testing:

- Since, in general, establishments are currently being tested annually, two consecutive sample sets that meet 50% or less of the performance standard is not sufficient to conclude that the plant has sustained good control.
- Since Category 1 establishments may only be tested once every two years, there is no incentive for maintaining good and consistent control.
- It is unclear under what circumstances an establishment would be reclassified. After an outbreak? After one case of serious disease or death? After a specified number of hospitalizations? After a specified number of NR's during regular inspection?
- Other factors, such as production level, plant size and facility activity, are not considered when classifying establishments. Using only two consecutive *Salmonella* verification sample sets to classify establishments is a rather simplistic approach and ignores several other very important risk factors.

It is essential that FSIS take a proactive, not reactive, role in preventing pathogenic contamination of meat and poultry products. It is important to provide establishments with an incentive to achieve sustained control of their processes, but it is equally important to provide an incentive to maintain that control. While decreasing testing to once every two years provides an incentive to establishments to initially achieve sustained control, the Agency is not providing incentive for establishments to maintain that control in the one to two years of no testing. This is analogous to knowing that, once you see a traffic officer, you will not see another one for 100 miles. This type of enforcement effort by police does not create an incentive to obey the speed limit after you have seen a police officer. Smart law enforcement offices know this and have adjusted by sometimes placing a second or even third police officer a little further down the road. Similarly, there is no incentive to maintain good control over the entire two year period. Minimally, there should be random testing, even if in smaller numbers. In conjunction with the random testing, establishments should be encouraged to demonstrate continued control by contracting with the Agency to voluntarily report all internal test results to FSIS on a regular, scheduled basis.

Establishments that have higher risk of experiencing pathogenic contamination ought to be tested more frequently than those with less risk of pathogenic contamination. Careful consideration must be given in determining the number of categories needed to create effective control, as well as clearly defining how the Agency will classify establishments. Incentives must be provided for both achieving and maintaining good control. Clearly, this proposed change is a step towards risk-based inspection, and as such, this policy change could be viewed as a model for future efforts. As a result, any decisions regarding the implementation of this policy change should be made in conjunction with the ongoing risk-based inspection discussions.

5. **FSIS will provide a new compliance guideline particularly related to the broiler chicken industry containing information that FSIS has found to be relevant to the control of *Salmonella*.**

Given the limited amount of information provided on the contents of the new compliance guideline, S.T.O.P. cannot comment on its appropriateness at this time.

6. **FSIS will obtain more timely *Salmonella* serotype information for each positive test result from its verification program, pursue sub-typing of the *Salmonella* found, and publish annual aggregate results for serotypes.**

On February 24, 2006, the CDC reported on a 2004 multi-state outbreak of *Salmonella* Typhimurium that was associated with eating ground beef, caused 31 illnesses and resulted in 9 hospitalizations. The illnesses occurred in nine states and the District of Columbia between August 11, 2004 and October 2, 2004. The outbreak was identified after a review of PFGE patterns submitted to the National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet) database. Upon investigation by the state health departments, CDC and FSIS, it appeared that the outbreak was associated with ground beef purchased at a national retail chain that originated from three processing plants and, ultimately, their common supplier. Since *Salmonella* is not considered an adulterant in food and the plants involved seemed to be in accordance with current FSIS production guidelines, no recall or public warning was issued, even though there were documented cases of illness associated with a specific food product. Millions of American consumers were put at risk for serious foodborne illness due to consuming this tainted product, yet the overseeing agencies did little to protect the American public.

Despite the fact that no recall or public warning was issued, this case demonstrates the importance of obtaining timely *Salmonella* serotype information. State health departments, CDC, FDA and FSIS need to work together, using sub-typing, such as pulsed-field gel electrophoresis (PFGE), to identify potential outbreaks and focus their combined resources in a thorough epidemiologic and product tracing investigation. As a result of this type of collaboration, FSIS will be better able to identify the mechanisms and possible sources of *Salmonella* contamination; in addition, FSIS will be better able to determine if its regulatory requirements are adequate and appropriate, and identify potential new interventions for reducing *Salmonella* in meat and poultry.

7. **FSIS will conduct baseline studies for *Salmonella* and other pathogens and indicator organisms among specific product classes.**

S.T.O.P. is pleased that FSIS has undertaken and will continue to undertake new Microbiological Baseline Surveys for *Salmonella* and other pathogens and indicator organisms.

The Microbiological Baseline Studies, which were conducted in the 1990's to estimate national prevalences for selected foodborne pathogens and used to establish performance standards for HACCP in 1996, were flawed in their design and scope, especially in regard to ground meat products. Some of the problems include grossly inadequate sample sizes and lack of testing during summer months when levels of pathogens are known to be higher.

In any study, a statistically-designed sampling scheme is critical to ensuring the validity, interpretability and generalizability of the study results. The first step is clearly identifying the study objective(s) and population of interest. The sampling and data collection methods should then be clearly defined, taking into account potential factors, such as seasonal variation, and consistent throughout the study. In addition, it is crucial that the resulting samples are randomly selected and representative of the population of

interest. Further, the sample size matrix selected for each study should be statistically justified using power calculations.

In 2003, the National Academies of Science report, Scientific Criteria to Ensure Safe Food, recommended that new Microbiological Baseline Surveys be conducted on a regular basis. The report also recommended that the new surveys be designed to 1) allow comparisons of the new baseline and previous baseline results and 2) correct the sampling deficiencies of the original baseline studies. In order to further reduce foodborne suffering, illness and death, it is crucial that FSIS follow these recommendations, repeat the baseline surveys in a timely manner and use this new data to establish tighter performance standards that will result in increased process control.

Further Agency Considerations

1. **FSIS will post *Salmonella* verification sample set results on the Agency website, identified by establishment name and number.**

USDA's Economic Research Service's report on *Product Liability and Microbial Foodborne Illness* identifies three economic incentives most likely to result in the production of safe food: market forces, food safety laws and regulations, and product liability. Posting *Salmonella* verification sample set results on the Agency website along with the establishment name and number is one mechanism to provide one of these economic incentives: market forces. As cited in the proposed directive, providing information about the process control performance of establishments related to Salmonella will enable further processors to make informed purchasing decisions. This, in turn, provides an incentive, through market forces, for the meat and poultry slaughter industry to invest in food safety innovation and seek to attain consistent control for *Salmonella*.

2. **FSIS will consider inspection modification based on industry-wide performance and demonstration of process control.**

The goal of HACCP is to achieve, sustain and improve quality control of meat and poultry products in terms of pathogenic contamination. Critical to the success of HACCP is statistical quality control. In other words, the collection, analysis, and interpretation of data is critical to assessing the adequacy and effectiveness of process controls.

Central to statistical quality control is the reduction of variation in the process to achieve consistent control. Every process has some degree of variation, some of which is random. Eliminating all non-random variation will help achieve statistical quality control. This requires the following: 1) identifying a method of process measurement, 2) establishing acceptable levels of variation that are indicative of process control and 3) monitoring the process over time to identify unexpected process variation. When control limits – or performance standards – are exceeded, the process is considered to be not in control and process adjustments must be made. As processes achieve sustained control over time, process improvements can be made that will further reduce variation and, in terms of HACCP, reduce pathogenic contamination. As this happens, the control limits – or performance standards – are tightened.

According to the PR/HACCP final rule, FSIS would repeat the Microbiological Baseline Surveys periodically and, over time, adjust the performance standards downward. According to the proposed directive, FSIS will consider allowing inspection modification based on industry-wide performance and demonstration of process control. FSIS further gave the example of allowing broiler and hog industries to study the effect of increasing linespeeds if there were an industry-wide demonstration of good, consistent control of *Salmonella*. Clearly, this type of incentive will encourage industry to work together to achieve good, consistent process control and invest in food safety innovation. However, inspection modification cannot happen in the absence of improving statistical quality control. Once an industry achieves consistent process control, the performance standards must be re-adjusted to reflect the new norm. If industry can demonstrate that process changes, such as increasing linespeeds, will not impact their ability to maintain process control and meet the adjusted performance standards, then it may be appropriate to consider such changes.

In recent years, several interventions – including reduction of linespeeds – have resulted in better process control and the reduction of pathogenic contamination of foods. Modifications of these interventions should only be considered in conjunction with adjustment of performance standards and evidence of improved process control and pathogen reduction. In order to meet the public health objective of reducing foodborne illness, the Agency and industry must strive for improvement, not just maintaining status quo.

Conclusion

To date, *Salmonella* remains behind schedule for meeting the Healthy People 2010 targets for pathogen reduction. While there has been some level of decrease, *Salmonella* has stubbornly held its ground as a "problem pathogen," and the really bad news is that many *Salmonella* strains have developed multi-drug resistant capabilities.

Some of these strains, like *Salmonella Newport MDR-AmpC*, spiked alarmingly from 1999-2003. Fortunately, according to the 2004 and 2005 FoodNet data, *Salmonella Super 9* has leveled and slightly decreased over the past two years, and while that is good, this gain has been offset by the five-fold increase in *Salmonella enteriditis* in broilers for the 2005 FoodNet data. Not only is *Salmonella enteriditis*—which has been heavily associated with eggs, not broilers—increasing, it is also showing resistance to clinically important drugs for treating human disease.

In addition, when you look at the overall trends in *Salmonella's* multi-drug resistant development, there is a significant increase in the number of strains that are becoming drug resistant—currently the CDC is reporting that 14+ strains of *Salmonella* are showing drug resistance to one or more clinically important drugs. For example, some *Salmonella* strains have gone from 0% resistant to 7% resistant to quinalones, which is the class of drugs most commonly used in treating adults with *Salmonella* infections. (Quinolones are not used to treat children because the drug may damage cartilage formation.) Clearly, the challenges that *Salmonella* is presenting to food safety goals is formidable. Further research, as well as increased oversight—including testing at all poultry and meat production establishments—are essential if this dangerous pathogen is going to be contained to the limits set out in Healthy People 2010.

Over the years, S.T.O.P. has steadily maintained that using the best science available to reduce pathogens in food is a paramount public health objective. Thousands of Americans suffer and die each year due to serious foodborne disease. FSIS must, as mandated, seek to protect public health by providing strong regulatory requirements, coupled with strict inspection enforcement.

Respectfully submitted,

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