Consumer Federation of America

December 17, 2008

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 2534
Washington, DC 20250

RE: Docket No. FSIS-2008-0035

The Consumer Federation of America (CFA) is pleased to provide comments on the Food Safety and Inspection Service's (FSIS) public meeting on Sampling and Testing Procedures for *Escherichia coli* O157:H7 in Beef Manufacturing Trimmings, held October 14-15, 2008 (Docket No. FSIS-2008-0035). CFA is a nonprofit association of some 300 consumer groups, representing more than 50 million Americans nationwide, that was established in 1968 to advance the consumer interest through research, education and advocacy.

CFA appreciates FSIS' willingness to examine its sampling and testing procedures for *E. coli* O157:H7 in beef trimmings. In 2007, FSIS recalls due to *E. coli* O157:H7 were at their highest level in five years: 21 recalls with 10 of them associated with illness. In 2008, FSIS announced 16 recalls due to *E. coli* O157:H7. More importantly, the Centers for Disease Control and Prevention reported that illnesses from *E. coli* O157:H7 in 2007 did not change significantly since 2004-2006[1]. The federal government reached the Healthy People 2010 goal of 1.0 *E. coli* O157:H7 illnesses per 100,000 population in 2004. However, that level has not been sustained and in fact, illnesses have increased. Clearly, the federal government needs to do more to assure that the risk to consumers from *E. coli* and other pathogens is reduced.

Sampling is Only One Part of a Microbiological Testing Program

The primary goal of meat and poultry inspection is to protect the public health by reducing the incidence of foodborne pathogens in these products. To achieve this goal, the government must require companies to adopt preventative process controls that identify and limit foodborne pathogens such as *E. coli* O157:H7 and *Salmonella*. The government must also set public health standards and assure that the results of the process

[1] Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Commonly Transmitted Through Food – 10 States, 2007." *MMWR,* 57(14), April 11, 2008, p. 366-370.

controls implemented by meat and poultry processors meet those standards. A strong microbiological testing program is essential to determine whether those standards are being met. As part of such a program, both the government and individual companies must perform regular sampling of meat and poultry products to verify the company's process controls are working as intended. Plants should utilize the results of their sampling to identify possible problems with their process controls. FSIS should use the results of its sampling to assure that plants are maintaining adequate process controls and to review the effectiveness of their regulatory measures.

A microbiological testing program is not simply about utilizing a particular testing method. Rather, developing a program requires a careful process that also includes implementation of policies to enhance the effectiveness of the sampling that is being conducted. Specifically, elements of an adequate microbiological testing program should include: clearly identified public health objectives and a robust sampling plan designed to meet those objectives; a plan to increase sampling frequency over time; requirements to provide inspectors with sampling results; proper implementation of the testing program; and a clear regulatory response when a positive is identified. In addition, FSIS should periodically review its overall sampling program to determine whether the program is meeting its identified objectives and after seeking public input, change the program as necessary. These elements must all work together for a microbiological testing program to be effective.

Clearly Identify Microbiological Testing Objectives

Consumers expect FSIS to be transparent and involve the public in adopting its approach for microbiological testing programs. The first step in developing a microbiological testing program is to identify the public health goals and objectives the agency wishes to achieve. Those goals and objectives will drive the testing objectives which in turn will drive the agency's sampling plan. Thus identifying the public health goals and objectives is an essential first step. Without it, FSIS could develop a testing program that does not meet its needs or, more importantly, the needs of the public.

As part of a transparent process, FSIS must identify the particular sampling plan or plans it is considering and the potential public health benefits for each option. The agency should also identify techniques to improve the effectiveness of sampling which could be used by FSIS or the industry. The following criteria are important elements to consider when the agency, or industry, is developing a sampling program.

- The actual capabilities of the program compared to the program goals;
- The acceptable parameters of a sample lot vs. a production lot;
- The power of the sampling program;
- The sensitivity and specificity of the microbiological tests;
- The rationale for the program;
- The limitations of the program; and
- The trade-offs of choosing this program over another.

These elements are critical to understanding the effectiveness of a given microbiological testing program and must be made public so that all stakeholders can adequately evaluate the program.

Increase FSIS and Industry Sampling

Currently, FSIS conducts sampling for pathogens to determine if an establishment's process controls are working effectively. However, FSIS sampling is often insufficient to this task. CFA encourages FSIS to increase its own level of sampling in both slaughter and processing plants. FSIS should identify specific goals for increased sampling and should set reasonable timelines for increasing sampling to meet those goals. FSIS should also periodically report to the public its progress in achieving those goals.

In addition, FSIS should undertake a program to collect continuous baseline data for E. coli, as well as other pathogens. This would provide the agency with the best available data, on an ongoing basis, on the prevalence of pathogens in the meat supply. Often, a significant lag time exists between baseline studies. This does not provide the agency or the industry with current information about the level of pathogenic contamination in the meat supply. If FSIS were to embark upon a program to collect baseline data on a continuous basis, the agency and the industry would be better able to implement adequate measures to reduce contamination rates.

Since FSIS' testing is limited, it is important that every meat processor conduct sampling to assure its controls are working effectively. FSIS should require each plant to sample trimmings and finished ground beef products, according to a more rigorous frequency than is being done currently. As the Inspector General at USDA pointed out in comments to FSIS "the recommended samples appear to be too infrequent to verify the effectiveness of control systems[2]." For small and very small plants, the sampling frequency identified in FSIS' Draft Compliance Guidance should be considered a starting point. FSIS should provide a calendar for increasing the frequency of sampling for all plants, starting after the first year of the program.

CFA recognizes that some smaller plants may not have the resources to develop adequate sampling plans on their own. Therefore, FSIS should make available sufficient resources and technical assistance to smaller plants to help them develop adequate sampling plans. All sampling should be consistent with a protocol established by FSIS.

Require Plants to Provide Sampling Results to Inspectors

FSIS inspectors must have sufficient information with which to determine whether a plant's process is in control. To assure that inspectors are provided this information FSIS should require its inspectors to request and receive each plant's most current sampling results. Plants should be required to provide those sampling results to the inspector. Each plant should be required to keep records that provide the source of the material sampled and should provide the supplier source to the FSIS inspector along with the results of the

[2] Letter from Phyllis K. Fong, Inspector General, U.S. Department of Agriculture, to the Docket Clerk, Food Safety and Inspection Service, "Comments on draft guidance for small and very small establishments on sampling beef products for E. coli O157:H7,"dated November 14, 2008.

sampling. Inspectors should be instructed to collect this list of suppliers for any lot of product that is sampled. Finally, FSIS must report aggregated or individual plant testing results to the public on a routine basis, but not less frequently than biannually.

Require Independent Third Party Approval of Sampling Plans
Developing a truly robust sampling plan can be challenging, but it is necessary to assure that an establishment is reducing, to the greatest possible extent, contamination of its products. In order to assure that each plant's sampling plan is adequate, CFA recommends that a plant's plan be certified by an independent certifying organization, such as ANSI. Approval by an independent organization can help provide assurance that each sampling plan is meeting the necessary specifications as established by FSIS.

Assure Proper Implementation of Sampling Plans
In order for any sampling plan to achieve the goals for which it was designed, it must be implemented properly. FSIS must identify standardized procedures for taking a sample and assure that FSIS inspectors are trained to carry out sampling procedures correctly. Inspectors should also routinely verify that industry employees are collecting samples appropriately.

FSIS should require each plant to keep records on the source(s) of material for each lot that it samples. The plant should be required to provide the most recent sampling results to FSIS inspectors immediately upon receipt of the results. The plant should provide FSIS with a list of the source suppliers to any lot from which FSIS collects a sample, at the time FSIS takes a sample. If a plant receives notice of a positive result, it must be required to notify the FSIS inspector immediately. If the inspector is not in the establishment, the plant must contact local officials.

Trace Back Every Positive Sample
An improved sampling program, as outlined above, must be coupled with a comprehensive program designed to trace contamination back to its source. If the results of in-plant sampling or FSIS testing, or an incident of foodborne illness, reveals product adulterated with *E. coli* O157:H7, FSIS must use data from the plant to work back up the line to the slaughterhouse.

FSIS notes in its Draft Compliance Guidance that plants should use sampling to assess whether their process controls are effective. The Guidance states that "For each positive result, there should be an investigation of its cause. Once a possible cause is identified, then appropriate action should be taken to make corrections and to eliminate the cause." In the October 14-15 meeting, both Tim Biela and Barbara Masters emphasized the importance of using sampling as part of a feedback loop to better understand a plant's process. They, and others noted, that the key to process control is tracking data over time and utilizing data to strengthen process control systems. They also emphasized that a lack of positives should be questioned as well. If a plant has no positives over a particular timeframe, the process should be investigated thoroughly to determine the reason.

CFA urges FSIS to follow its own advice as stated in the Guidance and initiate an investigation for every positive, whether found by FSIS sampling or industry testing, to identify the source of the contamination, all the way back to the slaughterhouse if necessary. The agency should then take the appropriate actions to assure that the contamination issues are resolved. FSIS should also recognize that a lack of positives does not necessarily mean that a plant is doing everything correctly and should investigate those situations as well.

Traceback is an essential element of effective process control. Microbiological testing can help identify whether a plant's process is in control. If a positive is found, the process may be out of control. In order to determine the cause and address the problem, the positive must be traced back through the system. The same principles apply to FSIS' regulatory responsibilities when a positive is found at a plant. FSIS must trace that positive back through the system in order to address the underlying problem. When a positive is found in a processing plant, traceback to the supplier is critical and must be done as quickly as possible so that other products in distribution can be identified.

A number of questions were raised about FSIS' activities regarding traceback during the October 14-15 public meeting. CFA strongly urges FSIS to hold a public meeting specifically on traceback to discuss the following issues, among others:

- How the agency has been conducting traceback since the beginning of HACCP;
- What specific factors FSIS will consider in taking traceback actions and what traceback activities will be pursued when a positive is found;
- Who is responsible for conducting the traceback; and
- Any reasons for not conducting a traceback.

Subsequent discussions with agency officials indicated that FSIS would be amenable to holding such a valuable meeting. CFA and other consumer groups would be happy to work with the agency to develop a productive meeting agenda.

Additional Funding is Warranted

CFA recognizes that the above recommendations will involve additional costs. However, we believe what we have outlined here has a public value that is worth an investment of public funds. The goal of meat and poultry inspection is to protect the public health by reducing the incidence of foodborne pathogens in these products. A strong microbiological testing program is an essential component of an effective regulatory program. FSIS needs to focus on improving its program as a whole, including identifying its public health objectives and designing a robust sampling plan to meet those objectives; increasing sampling frequency over time; developing requirements to provide inspectors with sampling results; properly implementing the testing program; and establishing a clear regulatory response when a positive is identified.

Finally, the October public meeting provided FSIS with a great deal of productive input from all stakeholders. FSIS should utilize this opportunity to substantially improve its microbiological testing program. As it moves forward, FSIS should keep the public fully informed on its progress in addressing these issues. FSIS should provide the public with a

progress report on how the agency is addressing these issues within six months, and then regular updates after that.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Chris Waldrop
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