Consumer Federation of America

cfi THE CENTER FOR FOODBORNE ILLNESS RESEARCH & PREVENTION

September 27, 2013

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Ave SW
Mailstop 3782 Room 8-163B
Washington, DC 20250-3700

Re: Docket No. FSIS-2012-0038

To Whom It May Concern:

Consumer Federation of America[1] and the Center for Foodborne Illness Research & Prevention[2] appreciate the opportunity to comment on the notice from the Food Safety and Inspection Service (FSIS) on the *Salmonella* Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing *Escherichia coli* and *Salmonella* (Docket No. FSIS-2012-0038).

FSIS should use sampling data to regularly update performance standards.

CFA and CFI support FSIS' intention to begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim and other raw ground beef components that the agency collects for Shiga toxin-producing *E. coli* analysis. FSIS states that it intends to use the results from its sampling program to develop new *Salmonella* performance standards for ground beef. This is particularly important as the current standards were first developed as part of the PR/HACCP final rule in 1996 and have not been updated since.

The *Salmonella* performance standard for ground beef is currently 7.5% and is based on the industry average estimated from baseline studies conducted before the PR/HACCP rule was

[1] Consumer Federation of America is a nonprofit association of 300 consumer groups, representing more than 50 million Americans, that was established in 1968 to advance the consumer interest through research, education and advocacy.

[2] The Center for Foodborne Illness Research & Prevention (CFI) is a national non-profit organization dedicated to advancing a stronger, more science-based food safety system that prevents foodborne illness and protects public health.

implemented. At the time, USDA claimed the system would spur continuous improvement because new baseline studies would be performed regularly and the standard would be adjusted over time to reflect the industry's increasing capacity to control contamination and pathogens:

> *The Salmonella standards being established are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards for raw products. FSIS plans to repeat its baseline surveys and collect substantial data through other means and, on that basis, adjust the Salmonella targets and possibly set targets for additional pathogens, as appropriate.*[3]

That was seventeen years ago, and to date, no new performance standards have been developed. The lengthy delay in developing new performance standards has resulted in numerous missed opportunities to reduce pathogen contamination in raw ground beef products so that consumers have continued to remain at risk of illness from *Salmonella*.

FSIS should provide additional information about its proposed approach.

While CFA and CFI generally support FSIS' proposed approach, the goal of the proposal should be to provide greater efficiency and precision of the agency's sampling program, not just efficiency for the sake of achieving cost-savings. To that end, FSIS needs to provide additional information about the sampling program so that stakeholders can understand how the program will be improved. Specifically, FSIS should inform stakeholders of the program's sample size. FSIS should specify the number of samples it intends to collect and sample annually and should identify what statistical power that sample size provides.

In 2012, FSIS analyzed nearly 15,000 raw ground beef (RGB) samples for *Salmonella* and over 10,000 RGB and almost 5,000 raw ground beef component (RGBC) samples for *E. coli* O157:H7. In 2011, FSIS analyzed over 13,000 RGB samples for *Salmonella* and just over 13,000 RGB and 3,400 RGBC samples for *E. coli* O157:H7.

	2012	**2011**
Number of RGB samples analyzed for *Salmonella*	14,655	13,161
Number of RGB samples analyzed for *E. coli* O157:H7	10,519	13,076
Number of RGBC samples analyzed for *E. coli* O157:H7	4,927	3,403

It is not clear how many samples FSIS plans to collect under this new testing strategy. Does FSIS plan to analyze approximately 15,000 samples for *Salmonella*, *E. coli* O157:H7 and non-O157 STEC each year? If so, what power does that provide? Increasing the sample size would improve both the efficiency and the precision of the agency's sampling program and provide the agency and stakeholders with better results. FSIS should provide details on the sample size and statistical power when it finalizes the proposal and when it reports sampling results. And the agency should consider increasing the sample size in order to improve the precision of the program.

[3] Food Safety and Inspection Service, "The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems," July 1996.

FSIS also states that it is considering a "moving window" sampling plan to evaluate whether establishments are maintaining process control. This approach has merit, but the agency needs to provide additional details for stakeholders to be able to adequately assess it. For example, it is unclear how big the window would be and how often the agency expects an establishment will be sampled. We note that assessing data through a moving window approach requires adequate analytic capacity, both in terms of laboratory capacity and data analysis as well as appropriate IT infrastructure. FSIS should detail the extent of the agency's capacity in this regard to provide assurances that this approach could be appropriately used.

FSIS should ensure that its sampling program is risk-based and random.

CFA and CFI are pleased to see that the agency conducted an evaluation of its sampling programs to determine whether they could generate prevalence estimates. Appropriately, FSIS identified the data and statistical requirements for the use of verification data to compute prevalence estimates and evaluated each testing program against these requirements. However, in its determination that the raw ground beef verification sampling program (MT43) can be used to estimate prevalence, the agency failed to address two critical statistical requirements: sampling representative of population and sampling provides desired precision. While the agency states that MT43 testing program meets these two requirements, FSIS did not provide the details necessary to evaluate this conclusion. Further, FSIS describes its MT43 program as "risk-based" but it is unclear if this allows the agency to achieve samples that are representative of the population. While the agency may reasonably wish to target certain strata of plant performance in terms of risk, the agency should randomly sample establishments within each risk category (i.e. stratified random sampling). This should allow the agency to achieve its dual objectives of verifying process control and estimating prevalence.

We appreciate the opportunity to provide these comments.

Sincerely,

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Director, Food Policy Institute	CEO and Director of Research
Consumer Federation of America	Center for Foodborne Illness Research & Prevention