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292

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FSIS Docket Clerk
Docket #99-060N
U.S. Department of Agriculture, Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

Re: **Recent Developments Regarding Beef Products Contaminated With *Escherichia coli* O157:H7; Public Meeting 65 Fed. Reg. 6881 (February 11, 2000)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food Safety and Inspection Service's (FSIS) policy regarding *E. coli* O157:H7 in light of new developments and the agency's recent white paper on the subject. CSPI is a nonprofit consumer organization representing nearly one million members in the U.S. and Canada that focuses primarily on nutrition and food safety issues. These comments are endorsed by the American Public Health Association, the Consumer Federation of America, and Government Accountability Project.

The time is ripe for FSIS to thoroughly revise its safety program for *E. coli* O157:H7 in raw beef products to maximize public health protection. Now that the agency's Pathogen Reduction/HACCP program has demonstrated that microbial testing can help to reduce the prevalence of *Salmonella* in raw meat and poultry products, the lessons drawn from the HACCP

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experience should be applied to other pathogens, including *E. coli* O157:H7. Equally important, new information showing that *E. coli* O157:H7 is significantly more prevalent in incoming cattle than previously thought and that the foodborne illness rate from the pathogen is much higher than CDC had previously reported makes it imperative that FSIS act quickly to develop a new testing program for *E. coli* O157:H7 -- one that will give consumers greater confidence that the hazard can be identified before contaminated products leave the slaughter or processing plant.

In the comments below, we first discuss the shortcomings in FSIS's current testing program for *E. coli* O157:H7 and then describe our vision for an improved, comprehensive program that would include both industry and government testing for the pathogen. Next, we respond to the specific questions set forth in FSIS's *Federal Register* notice on its *E. coli* O157:H7 policy. Finally, we comment on the changes to FSIS's testing policy proposed by the beef industry based upon its carcass-testing pilot study.

I. A Comprehensive Testing Program for *E. coli* O157:H7 in Beef Products

A. Shortcomings in the current program

FSIS's current testing program for *E. coli* O157:H7, though well intentioned, suffers from numerous shortcomings. It is too limited, with an inadequate number of tests conducted each year. It is reactive rather than prevention-oriented, because it relies solely upon a small number of end-product tests. And it is not systematic, leaving gaping holes in the safety net for consumers.

The current system must be converted to one that is more systematic, more prevention-oriented, and one that gives consumers greater assurance that it is actually catching the hazards in

the food supply. In short, FSIS should bring the *E. coli* O157:H7 testing program into the HACCP era.

The pathogen-testing scheme that is a cornerstone of the pathogen reduction/HACCP rule should serve as a model for a redesigned *E. coli* O157:H7 testing program. Under the pathogen reduction/HACCP rule, microbial testing occurs at multiple levels and is conducted by both the industry and the government. FSIS requires all beef, pork, and poultry slaughter plants to test their own products for generic *E. coli,* while the government tests these slaughter operations and some beef, pork, and poultry processors for *Salmonella.*

This program has markedly improved *Salmonella* contamination levels across the meat and poultry industry, with reductions in many meat products ranging from one-half to one-quarter of previous contamination levels.[1] Unfortunately, it has also shown that control of one hazard does not result in control of all hazards. In fact, recalls for other hazards in meat continued at a high level last year. *Listeria*-contaminated meat and poultry products were recalled 33 times and products containing *E. coli* O157:H7 were recalled 10 times.[2] In addition, consumers suffered one of the most deadly outbreaks ever linked to meat products in 1998-99 when *Listeria monocytogenes* in a processed meat product sickened 100 and killed 21.

That the HACCP program, though successful at reducing *Salmonella* contamination, apparently has not improved the beef industry's ability to control for *Listeria* and *E. coli*

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[1] U.S. Department of Agriculture, "FSIS Reports Continued Decline of *Salmonella*," *FSIS News Release*, March 21, 2000, available at <http://www.fsis.usda.gov/OA/news/salmrel2.htm>Internet.

[2] U.S. Department of Agriculture, "Meat and Poultry Product Recalls: News Releases and Information for Consumers," available at <http://www.fsis.usda.gov/OA/news/xrecalls.htm>Internet.

O157:H7 should come as no surprise: these pathogens are legal adulterants in certain products, but the government uses a pathogen-testing scheme that is far less thorough and systematic than that required under the HACCP regulation. Specifically, FSIS conducts only limited random sampling for the pathogens and asks companies to recall the affected products when it is found in food.

FSIS should respond to the grave public-health threat posed by *E. coli* O157:H7 by transforming the current testing program into one that is more consistent with the modern HACCP approach. More thorough and systematic testing is necessary to help ensure that breakdowns in hazard-control systems and resulting contamination problems are detected before food reaches consumers' tables.[3]

B. Objectives of an Improved Testing Program for *E. coli* O157:H7

Before embarking upon the process of devising a new testing program for *E. coli* O157:H7 in raw beef products, FSIS should have a clear understanding of the food-safety objectives that such a program should satisfy. CSPI believes that an effective microbial-testing program for *E. coli* O157:H7 would achieve all of the following objectives:

- First and foremost, it would serve a verification role. Specifically, microbial testing would enable the government to verify that plants' HACCP systems are effectively controlling *E. coli* O157:H7 contamination on an ongoing basis and to identify problems so that corrective actions can be taken.

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[3] Similar action should be taken regarding FSIS's safety program for *Listeria monocytogenes* in ready-to-eat meat and poultry products. To that end, CSPI has petitioned FSIS to require companies producing such products to test both their plant environments and products for the presence of the pathogen. Center for Science in the Public Interest, "Petition for Regulatory Action to Require Microbial Testing By Industry for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Products," January 13, 2000.

- Second, an effective microbial-testing program would enhance the likelihood that contaminated products are detected before they can sicken or kill consumers. Positive test results should be available early enough to enable companies to destroy or further process contaminated products to eliminate the pathogen, or, if necessary, to recall and destroy product that has already entered commerce.
- Third, a well-designed program would provide incentives for companies to implement effective interventions against *E. coli* O157:H7, both on the farm and during the slaughter process, and to conduct their own thorough testing. If end-product testing is sufficiently comprehensive and systematic, the specter of positive test results that require massive recalls would provide the industry with a strong incentive to take every step necessary to eliminate the pathogen from its products.
- Finally, testing would facilitate acquisition of data concerning the prevalence of *E. coli* O157:H7 as a function of product type, season, and geography; the efficacy of various pathogen-intervention measures implemented by industry; and other issues important in developing effective regulations. In short, systematic microbial testing would better enable FSIS to create a dynamic testing program that can be tailored in response to trends in the latest prevalence data.

C. Elements of an Effective Testing Program

FSIS should recognize that neither government sampling nor industry sampling alone would achieve those objectives. Instead, FSIS should develop a comprehensive *E. coli* O157:H7 strategy that includes systematic microbial testing by both the government and the industry. By requiring each slaughterhouse to test for the pathogen, the agency would greatly expand the

scope of the existing program, while continued (but modified) government testing would serve as a means of verifying the efficacy of industry testing. The result would be a significant expansion of the safety net provided by the federal government's testing program.

1. Industry Testing

FSIS should require all slaughterhouses to conduct ongoing, systematic testing for *E. coli* O157:H7. Until sufficient data exist to demonstrate that thorough carcass testing obviates the need to test trimmings, companies should be required to test both carcasses and trimmings for the presence of the pathogen.

Some questions should be resolved before implementing a program that includes carcass testing, including how frequently carcasses should be sampled and how lot size should be determined. Post-intervention carcasses that test positive for *E. coli* O157:H7 signal a breakdown in a slaughterhouse's intervention systems and indicate that other carcasses subjected to the flawed processes may also harbor the pathogen. To maximize public-health protection, the lot size represented by each sampled carcass should be sufficiently large to ensure that all other potentially contaminated carcasses -- or meat from those carcasses -- are treated appropriately.

The industry's proposal that one out of every 300 carcasses be tested and that each contaminated carcass represent a lot of one is unacceptable. Under that scheme, the testing would be too infrequent and the probability is high that other contaminated carcasses would escape further treatment. CSPI recommends that FSIS consult an independent, expert body to establish a testing frequency and lot size that would truly protect consumers.

Under the new testing program, industry should be required to immediately report to FSIS any positive test results. Positives from industry testing should be treated in the same

manner as positives from FSIS testing -- that is, the contaminated meat should be treated as adulterated if shipped in interstate commerce, and the agency should take all appropriate actions, including asking for product recalls.

In addition, any positive test results should trigger appropriate corrective actions by the company, including stepped-up sampling in the plant. FSIS should carefully review data from industry testing to identify and investigate persistent problems. Companies with repeated positives should be required to re-validate their interventions against *E. coli* O157:H7 and to change their slaughter processes if necessary to produce safer products.

2. Government Testing

In addition to requiring companies to test for *E. coli* O157:H7, FSIS should revamp its random-sampling program for the pathogen to ensure that it provides both an additional layer of protection against the distribution of contaminated products and better enables the agency to independently evaluate the efficacy of plants' process controls.

Initially, FSIS should target establishments that do not conduct their own testing and/or do not employ validated interventions against *E. coli* O157:H7. However, once the entire industry is required to perform its own testing, FSIS sampling should be focused on those plants and raw-meat products that historically have posed the greatest risk. In determining where to sample, at least until sufficient testing data are obtained from plants, FSIS should consider, among other things, results from *Salmonella* and generic *E. coli* testing.

Once industry testing is fully implemented, all plants should be subject to random government testing, in a pooled system similar to the one used for *Salmonella* testing under the pathogen reduction/HACCP rule. However, FSIS's program should be dynamic, not static: the

agency should alter its testing program based on data derived from both government and industry testing. The focus should be on identifying the riskiest plants and products and taking appropriate measures to assure their safety.

FSIS should also evaluate how its sampling program can best serve as a tool to verify the accuracy of industry testing and the ongoing efficacy of the hazard-control systems employed by plants. FSIS should seek the assistance of an independent expert body in developing a testing scheme that achieves those goals.

II. Answers to Specific Questions Posed in FSIS's White Paper

Having set forth CSPI's vision for a comprehensive *E. coli* O157:H7 testing program, we now turn to the specific questions posed by FSIS in its *Federal Register* notice.

Question 1: *E. coli* O157:H7 and HACCP:

E. coli O157:H7 should be considered a "hazard reasonably likely to occur" for all beef slaughter and processing operations, given recent data from the USDA Agricultural Research Service (ARS) showing an unexpectedly high prevalence of *E. coli* O157:H7 contamination of beef-cattle carcasses during processing.[4] Beef slaughter and processing establishments should be required to institute technological controls that address this hazard. If a company believes that it should be exempted from identifying *E. coli* O157:H7 as a hazard in its HACCP plan because the pathogen is not a hazard for the particular type of cattle that it slaughters, the burden should be

[4] Robert O. Elder, *et. al.*, "Correlation of Enterohemorrhagic *Escherichia coli* O157 Prevalence in Feces, Hides, and Carcasses of Beef Cattle During Processing," *Proceedings of the National Academy of Sciences*, Vol. 97, No. 7 (2000), pp. 2999-3003 [hereinafter cited as *E. coli Prevalence in Beef Cattle*]; presentation by Dr. Mark Powell of FSIS at the FSIS public meeting on "Recent Developments Regarding Beef Products Contaminated with *Escherichia coli* O157:H7," Arlington, VA, February 29, 2000.

on the company to seek a formal exemption from the general policy and make all supporting data available to FSIS.

Establishments should address *E. coli* O157:H7 in their HACCP plans by employing interventions that have been validated specifically for their ability to reduce or eliminate the pathogen from raw beef products. FSIS should require plants to reassess their HACCP plans in light of the new prevalence data to ensure that they effectively address *E. coli* O157:H7. The agency can provide support and guidance to the industry by collecting and then disseminating to the entire industry specific information concerning validated interventions that have proven effective against the pathogen.

The recent ARS survey also points out the critical importance for plants to prevent cross-contamination of carcasses during processing.[5] As part of the reassessment of HACCP plans, FSIS should require that plants examine the efficacy of the measures they take to stop the dissemination of the pathogen during processing, especially when large numbers of *E. coli* O157:H7-contaminated animals are being processed.

Question 2: Redesign of FSIS's Testing Program for *E. coli* O157:H7:

FSIS's overall testing program for *E. coli* O157:H7 should be fundamentally redesigned. Rather than relying solely on random testing of a small number of samples by government inspectors, the agency should develop a program that incorporates mandatory, systematic testing by industry and risk-based testing by the agency, as described above.

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[5] *E. coli Prevalence in Beef Cattle*, p. 3003.

If FSIS takes such action, other elements of the current policy, including the requirements under FSIS Directive 10,010.1, must be changed or eliminated. For instance, if all beef slaughter and most processing plants are required to conduct systematic testing, the trade offs currently reflected in FSIS Directive 10,010.1 would become obsolete. Under the comprehensive system proposed by CSPI, FSIS would focus its testing on the plants and products posing the greatest risk of *E. coli* O157:H7 contamination, as determined by analyzing a combination of factors, including plant testing history, changes in a plant's processes, seasonal variation, etc. Although the question of whether a plant has had a positive sample within the past six months could play a role in this analysis, it would not be the sole determinant of whether the plant should be subjected to sampling.

FSIS would have to address additional questions in designing the testing program set forth above. The agency would have to decide whether industry testing should be done on carcasses only, trimmings only, or some combination of the two. At least initially, CSPI recommends that slaughterhouses be required to sample both carcasses and trimmings for *E. coli* O157:H7. FSIS should review industry data to assess whether one type of sampling is superior or if both should be employed.

In addition, the agency would have to determine whether to change the proportion of tests it conducts on in-plant versus retail samples under the redesigned program. Retail testing is useful because it can help the agency detect problems that fall through the cracks of plant testing. But testing earlier in the process (at plants) should be the focus of FSIS's program, because it is far more efficient -- and protective of public health -- to detect and eliminate microbial contamination before products are widely distributed. After the industry-testing program is

underway, FSIS should be in a better position to determine the optimal ratio of in-plant to retail testing.

As part of Question 2, FSIS asked for suggestions regarding alternatives to the current testing system that would encourage industry to institute *E. coli* O157:H7 interventions. CSPI believes that more systematic testing, by both the agency and industry, would greatly increase the likelihood of detecting positive samples, which would in turn encourage companies to avoid costly recalls by using the best available interventions against the pathogen.

Questions 3 and 4:

Consideration of *E. coli* and *Salmonella* Results In Deciding Whether To Test For *E. coli* O157:H7; Effects of a Plant's Testing/Verification Program On FSIS Testing:

As FSIS moves forward with its testing program, it should target establishments that do not conduct their own testing and/or do not employ validated interventions against *E. coli* O157:H7 initially, but once the entire industry is required to perform its own testing, FSIS sampling should be focused on those plants and raw-meat products that historically have posed the greatest risk. Until sufficient data from industry testing is available, FSIS should consider, among other things, results from *Salmonella* and generic *E. coli* testing in determining where to sample.

Question 5: Treatment of Non-Intact Product?

CSPI continues to maintain that at the present time FSIS policy should not distinguish between blade-tenderized beef and other non-intact beef. The data generated by Kansas State University show that small amounts of contamination are transported to the interior of the meat

during the tenderizing process.[6] While the number of *E. coli* O157:H7 organisms transported to the interior of the meat is lower than that found on the surface, any introduction is troubling because the bacteria can grow in the interior of the meat in the time between tenderizing and consumption. In addition, the infectious dose for *E. coli* O157:H7 is very low. The Kansas State study also shows wide variations in pathogen reduction during cooking of blade-tenderized steaks, further confirming that meat companies should explore alternative methods for tenderizing meat.

Question 6: Voluntary Producer Actions To Provide Animals With Reduced *E. coli* O157:H7 Levels:

CSPI does not have any specific information to share with FSIS regarding voluntary producer actions to provide slaughter operations with animals having reduced levels of *E. coli* O157:H7 contamination. However, we urge the agency to mount a serious effort to explore ways to encourage on-farm reforms that will yield food animals significantly less likely to harbor the pathogen. Specifically, FSIS should identify producers that use innovative *E. coli* O157:H7-control programs and ask them to provide the agency with data regarding their programs, so that the information can be shared in a "best-practices" or similar document and ultimately used to develop mandatory on-farm regulations. Until effective on-farm controls are made mandatory, the agency should develop incentives that would encourage producers to adopt such controls voluntarily. In addition, FSIS should fund additional research aimed at eliminating the problem of *E. coli* O157:H7 contamination on the farm.

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[6] Randall K. Phebus, et al., "*Escherichia coli* O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steaks," Kansas State University (unpublished), presented at the USDA-FSIS Public Meeting, Washington, DC, March 8, 1999.

Once on-farm controls become mandatory, the agency should assess the data from *E. coli* O157:H7 testing in plants and consider whether to revise the testing program based upon any resulting changes in relative risk posed by animals from sources that use different control strategies. For example, if particular on-farm controls are shown to consistently result in the production of feedlot cattle having extremely low *E. coli* O157:H7 contamination levels, slaughterhouses obtaining animals exclusively from feedlots using such controls could be sampled less frequently than other establishments. The testing program advocated by CSPI would be sufficiently flexible to account for changing patterns of risk.

III. The Beef Industry's Carcass-Testing Pilot Study

At the February 29, 2000 public meeting on FSIS's *E. coli* O157:H7 policy, representatives of the beef industry presented the results of a pilot study of carcass sampling in 12 beef packing plants. Before the study was conducted, CSPI submitted written comments to FSIS suggesting various changes in the protocol designed to enhance the utility of the data to be collected.

The industry study does provide some useful information concerning the prevalence of *E. coli* O157:H7 on slaughter animals during various stages of the production process and it confirms that, at least under the limited test conditions, interventions used by some plants are effective at reducing *E. coli* O157:H7 contamination on carcasses. It also suggests that carcass sampling could play a significant role in a comprehensive *E. coli* O157:H7 testing program, as described above. However, the study itself is too small and the data are too limited to support the fundamental changes in the testing program urged by the industry. Specifically, the data do

not indicate that sampling of one in 300 carcasses would adequately protect human health or that FSIS Directive 10,010.1 should be revised as requested by the industry.

As CSPI emphasized in its written comments on the industry study, we are concerned that the sampling frequency proposed by the industry, together with its intention to treat each sampled carcass as representing a lot size of one, would be less protective of consumers than FSIS's current testing program, in which all raw, comminuted beef product produced during the same shift as a positive sample is considered potentially adulterated and subject to voluntary recall. By asking the agency to shrink the lot size to a single carcass, the industry ignores the fact that a positive carcass may indicate a breakdown in a plant's hazard-control system and that other carcasses from the same production shift may also harbor the pathogen. Such concerns are made even more salient by the recent ARS data showing surprisingly high contamination rates of incoming cattle.

As previously stated, CSPI urges FSIS to consult with an independent body of experts in determining an appropriate sampling frequency and lot size for carcass testing in slaughterhouses. Nothing in the industry study indicates that the one-in-300 sampling frequency, especially when combined with a lot size of one, is as protective as the existing random sampling program for ground and other non-intact cuts of beef. FSIS and its outside experts should consider a number of options, including:

- Requiring that establishments conduct both carcass testing *and* product testing for *E. coli* O157:H7, making the frequency of product testing dependent upon the frequency of carcass testing. For instance, the agency could require frequent product testing if the establishment opts to sample carcasses at the proposed rate of one-in-300, fewer product

tests if carcasses are sampled at a frequency of one-in-100, and no product testing at all if carcass sampling is performed on one out of every 50 carcasses.[7] Such a scheme would encourage plants to step-up their testing of carcasses to alleviate the need to conduct a large number of tests on raw products.

- Alternatively, FSIS could vary the lot size represented by the sampled carcasses as a function of the frequency of sampling. For instance, under such a system each carcass in a plant that samples one out of every 300 carcasses could represent a lot size of 101 carcasses (the sampled carcass, and the previous and subsequent 50 carcasses on the line), while a sampled carcass in a plant that tests one out of every 100 carcasses could represent just 31 carcasses (the sampled carcass plus the previous and subsequent 15 carcasses). Such a system would also encourage more frequent carcass testing because the number of carcasses requiring corrective action upon detection of a positive sample would decrease as the frequency of carcass testing increased.

Regarding the changes in FSIS Directive 10,010.1 advocated by industry, rather than tinker with the current policy, FSIS should immediately begin the process of developing the comprehensive testing program described above. Once a program that includes both systematic industry testing and risk-based testing by FSIS is put in place, the trade-offs reflected in the directive will be obsolete and the directive should be discontinued.

Finally, CSPI would like to address one additional issue pertaining to the beef industry's proposals. In reporting their data at the public meeting, industry representatives once again

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[7] CSPI provides those potential sampling/lot size schemes for illustrative purposes only. An analysis of data on contamination rates in slaughterhouses would have to be conducted to develop an appropriate scheme.

stated their opposition to the use of pathogen testing as a means of ensuring beef safety. The industry's position is based on its assertion that "pathogen contamination is an infrequent, unpredictable event [and] 'zero-risk' is unachievable." Rather than test for pathogens, the industry argues, industry and government should focus on indicator organisms to assess process control.

CSPI agrees that microbial testing for process control is critical to the success of HACCP as a food-safety system and that indicator-organism testing can play a role in verifying process control. However, we cannot agree that pathogen testing is an ineffective method to help assure the safety of raw beef products. Rather, we believe that systematic sampling for pathogens that are considered adulterants in certain foods is a critical -- and irreplaceable -- element in the federal food-safety program. This is especially true now that ARS has documented the high prevalence of *E. coli* O157:H7 on cattle entering slaughter plants.

Food contaminated with *E. coli* O157:H7 at the time of consumption is a known killer. That indisputable fact must guide the federal government's approach to raw-beef safety. What is less well understood is how effectively other bacteria perform as indicator organisms for the presence of *E. coli* O157:H7 in raw beef. Consequently, it would be premature and irresponsible in the extreme to replace tests for the pathogen itself with tests that target an indicator organism instead. Unless and until scientists demonstrate with certainty that testing for an indicator

organism instead of *E. coli* O157:H7 itself results in an equivalent measure of protection, FSIS should refuse to change the focus of its testing program from the pathogen to an indicator.

Thank you for your consideration of CSPI's comments.

Very truly yours,

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On Behalf of:

American Public Health Association

Consumer Federation of America

Government Accountability Project