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FSIS Docket Clerk
Docket #98-068N
U.S. Department of Agriculture, Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

Re: **Policy on Beef Products Contaminated with *E. coli* O157:H7; Industry Protocol for *E. coli* O157:H7 Testing**
64 Fed. Reg. 2803 (January 19, 1999); FSIS Constituent Update: May 14, 1999

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the protocol for *E. coli* O157:H7 testing of beef carcasses submitted by the American Meat Institute (AMI) on behalf of a group of beef-industry companies. CSPI is a nonprofit consumer organization representing over one million members in the U.S. and Canada that focuses primarily on nutrition and food safety issues.

CSPI applauds the industry's efforts to develop a protocol and pilot study for *E. coli* O157:H7 testing of beef carcasses in slaughterhouses. Data from the study could offer valuable insight into both the prevalence of the deadly pathogen in slaughterhouses and the ability of existing intervention technologies to eliminate it from beef carcasses. If the study data are widely disseminated, they could help plants throughout the industry to take important steps to reduce the risk consumers face whenever they cook raw beef products.

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Although CSPI strongly supports the industry's effort to conduct the proposed pilot study, we have several reservations concerning both the testing protocol itself and the very significant changes to the Food Safety and Inspection Service's *E. coli* O157:H7 testing program urged by the meat industry. In examining the industry's proposal, FSIS must be guided by a fundamental principle as it assesses the data generated by the pilot study and considers whether to make the proposed revisions to its sampling program: ***no change should be made to the program absent scientific evidence demonstrating that the change will yield a greater degree of safety for ground and non-intact beef products than that provided by the current program.*** As explained more fully below, CSPI will oppose any alteration of the existing sampling program that weakens public-health protections provided by random FSIS sampling at both the slaughterhouse and retail establishments, as well as the agency's authority to deem adulterated all raw, comminuted beef products from the production shift represented by a positive sample.

I. FSIS Should Immediately Implement the Clarification of Its *E. coli* O157:H7 Policy

FSIS should not await the results of the proposed industry pilot study before fully implementing the policy, set forth in its January 19, 1999, *Federal Register* notice, that extends the definition of adulteration to all *E. coli* O157:H7-contaminated non-intact beef products.[1] Full implementation of that policy, which affords consumers a greater degree of protection against beef products contaminated with the pathogen, does not depend upon any data generated by the industry's proposed study. The agency therefore should act without delay in revising both its

[1] U.S. Department of Agriculture, Food Safety and Inspection Service, "Beef Products Contaminated with *Escherichia coli* O157:H7," *Federal Register*, Vol. 64, No. 11 (1999), pp. 2803-2805.

regulations and FSIS Directive 10,010.1[2] as necessary to reflect the policy clarification. Any further revisions, including those urged by the beef industry, may be made at a later date if supported by sound scientific data from the pilot study.

We are encouraged by industry's assurances that purchasers of trimmings from plants participating in the pilot study will continue to sample those trimmings in accordance with their existing protocol. The agency, too, should conduct random sampling of non-intact beef products to enforce the expanded definition of adulterated beef under its policy clarification, even while the pilot study is underway.

II. The Meat Industry's Testing Protocol

A. The Industry Should Adopt All Revisions to the Testing Protocol Suggested by FSIS

In its response to the April 5, 1999, letter in which AMI set forth the proposed pilot study, FSIS expressed its general approval of the testing protocol but strongly recommended that several changes be made.[3] CSPI is not aware of any response from AMI to FSIS's comments, so it is unclear whether the industry has revised the protocol to reflect the agency's suggestions. We emphasize, however, that incorporation of FSIS's recommended changes into the study is critical to its ability to yield important information about how *E. coli* O157:H7 contamination can be eliminated from beef products. Moreover, without the additional data sought by FSIS, the study

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[2] U.S. Department of Agriculture, Food Safety and Inspection Service, "Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef," FSIS Directive 10,010.1 (February 1, 1998) [hereinafter cited as *Directive 10,010.1*].

[3] Letter from Thomas J. Billy, Food Safety and Inspection Service, to Kimberly K. Rice, American Meat Institute, dated May 13, 1999 [hereinafter cited as *FSIS Response to AMI*].

may not provide a valid scientific basis for the changes to Directive 10,010.1 sought by the industry.

CSPI is especially concerned that all data from the pilot study be presented on a plant-by-plant basis (although blinded), rather than as larger data sets incorporating the results from several plants. In addition, sufficient information should be provided about the individual plants (e.g., size, number of lines and line speed, location, type of products produced, type(s) of intervention technologies employed, etc.) so that variability among plant types can be taken into account in assessing the data.

Moreover, CSPI urges the industry to facilitate interpretation of the study results by providing both a thorough statistical analysis of the data and any conclusions that may be drawn therefrom. In addition, the industry should act on FSIS's recommendation that plants test the trimmings from carcasses sampled during that day's production and correlate both sets of test results. Without such a correlation, it will be difficult to gauge the relative effectiveness of carcass testing in identifying a contamination problem.

B. Other Changes Should be Made to the Testing Protocol

In addition to the changes suggested by FSIS, there are several additional revisions that the industry should make to strengthen the proposed testing protocol. First, the industry should ensure that the plants involved in the study are representative of the variations that exist among slaughterhouses that produce raw ground and non-intact beef products. The 12 plants should include various sizes, locations, processes, and products, so that the data generated in the study may be as broadly applicable as possible.

Second, the industry should ensure that the raw data and statistical analysis from the study are disseminated widely, both throughout the beef industry and to all interested parties outside of the industry and the government, including consumer groups. Because the data will be blinded as to the specific plant from which they were obtained, participating plants should have no need to shield the data from disclosure to third parties.

Third, the industry should assess, upon completion of the study, whether its short duration (only four weeks) is adequate to account for seasonal fluctuations in microbial contamination rates of carcasses. If, at the conclusion of the four-week study, significant questions remain about whether the results reflect changes in contamination patterns associated with the different seasons of the year, testing should be extended for an appropriate period of time.

Finally, it is not clear from the industry's testing protocol whether the post-intervention data will be presented as a function of the *specific type* of intervention employed. In other words, under the protocol it appears that all interventions will be lumped into a single category, and data will be presented simply as "post-intervention" incidence rates. The utility of the data generated by the study would be significantly enhanced if post-intervention rates of *E. coli* O157:H7 contamination are labeled as to the specific intervention measure employed by the plant (e.g., "incidence rate after steam vacuum application = X"; "incidence rate after organic acid spray = X"; "incidence rate after both steam vacuum and organic acid spray = X"). Organizing the pilot-test results in that manner could provide valuable information about the relative efficacy of the various validated intervention measures available to beef slaughterhouses, information that would be lost if all intervention methods were combined into a single, undifferentiated category.

III. Revisions to Directive 10,010.1 Proposed by the Industry

As summarized in FSIS's response to AMI's letter, in addition to its request that the agency refrain from making any changes in its *E. coli* O157:H7 sampling program until the proposed pilot study has been completed, the industry seeks two significant changes to Directive 10,010.1, which sets forth the agency's current sampling program. Specifically, the industry requests that the agency extend the Directive's exemption from FSIS sampling to purchasers of boneless beef from suppliers that use validated interventions in their production process, and that FSIS eliminate a clause in the Directive that requires establishments to achieve no positive tests for six months to earn an exemption from agency sampling.[4] CSPI's comments concerning those proposed changes are set forth below.

A. Extension of the Sampling Exemption to Purchasers of Boneless Beef from Suppliers Using Validated Interventions

Under FSIS's Directive 10,010.1, establishments producing raw ground beef products are exempt from FSIS sampling if they "[u]se validated pathogen reduction interventions on beef carcasses, routinely verify the interventions' effectiveness periodically through testing for *E. coli* O157:H7, and prevent the use of boneless beef or carcasses from outside sources."[5] In proposing its pilot study of a carcass-testing-based system, the industry has asked FSIS to consider extending that sampling exemption to purchasers of boneless beef from suppliers that use validated interventions. The industry expects that data from the pilot study will enable it and FSIS to develop a system for verifying validated interventions at slaughterhouses based upon carcass testing. Then, after such a system is in place, the industry would like FSIS to exempt

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[4] *FSIS Response to AMI*, p. 1.

[5] *Directive 10,010.1*, p. 2.

from agency sampling the beef products of purchasers of boneless beef from plants that use validated interventions and conduct carcass testing as a verification tool.[6]

In theory, carcass testing should provide an effective means of detecting *E. coli* O157:H7 contamination in beef and of verifying that slaughterhouse intervention measures are working. As the industry explained at the March 8, 1999, public meeting during which it first presented its carcass-testing proposal, it is far more efficient -- and protective of public health -- to detect and eliminate microbial contamination in the slaughterhouse, rather than at subsequent stages of the distribution process when the beef has been more widely distributed.

However, for slaughterhouse carcass testing to afford a level of protection that is at least as strong as that provided by the existing system, numerous safeguards must be built into the carcass-testing program. Although it is premature to discuss in detail the form that such a program should take, and FSIS should await the data from the industry pilot study before undertaking any efforts to design a program based upon carcass sampling, CSPI offers the following preliminary observations about the industry's proposal.

1. Concerns About Sampling Frequency and Lot Size

CSPI is concerned that the sampling frequency proposed by the industry, namely that only one out of every 300 beef carcasses will be tested, together with the industry's intention to treat each sampled carcass as representing a lot size of one, would not be adequately protective of public health. Under the industry proposal, only the particular post-intervention beef carcass that tests positive for *E. coli* O157:H7 would be considered adulterated and subject to the requirement

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[6] American Meat Institute, *Pilot Test Protocol for E. coli O157:H7 on Beef Carcasses*, p. 1 [hereinafter cited as *AMI Pilot Test Protocol*].

that it be rendered or subjected to thermal processing that destroys the pathogen.[7] No other carcass, including those immediately adjacent to the contaminated carcass or any others that were processed during the same production shift, would be subjected to closer scrutiny or additional processing.

The adequacy of that system, apparently proposed by the industry for reasons of convenience, must be assessed in light of FSIS's current *E. coli* O157:H7 testing program, under which the agency treats samples of ground beef that test positive for pathogen in a very different manner. Specifically, the agency deems all raw, comminuted beef product produced on the same shift as the positive sample -- that is, the entire production from the previous cleaning/ sanitization to the subsequent cleaning/sanitization -- to be potentially adulterated and subject to voluntary recall.[8] That policy reflects the agency's recognition that *E. coli* O157:H7 contamination can enter the production process at any point during a shift, and that the potential for the contamination to spread, through grinding or other processing, exists until the next cleaning and sanitization step takes place.[9] Under the industry's proposal, by contrast, for plants that conduct carcass sampling in lieu of ground-product testing the large lot size now represented by a single positive sample would shrink to a lot comprising just a single carcass.

While CSPI recognizes that a carcass that tests positive for the pathogen presents a different food-safety problem than a sample of ground product or manufacturing trimmings that tests positive, we are not convinced that FSIS should depart from its current treatment of

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[7] *Ibid.*, p. 3.

[8] *Directive 10,010.1*, pp. 1-2; *Directive 10,010.1*, Attachment 1, pp. 7-8.

[9] *Directive 10,010.1*, Attachment 1, pp.7-8.

contaminated product to the degree urged by the industry. In essence, the industry's proposal fails to recognize that the implications of a positive sample on a carcass extend beyond that particular carcass, and that such a positive may indicate that other carcasses from the same production shift also harbor the pathogen, which could find its way -- undetected -- into ground and non-intact cuts of beef if testing is limited to carcasses alone.

There are numerous alternatives available to address that problem. For example, plants could be required to conduct more frequent carcass testing, perhaps in combination with some amount of product testing. In addition, expansion of the size of the lot represented by each sampled carcass beyond that particular carcass, so that further corrective action would have to be taken with respect to some number of additional carcass from the same production shift, would also enhance the public-health protection afforded by the proposed carcass-testing system.

Under one possible scheme, FSIS could require 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. 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.

Of course, the foregoing examples are offered only to illustrate how FSIS could encourage establishments to increase the frequency of carcass testing. The agency would have to examine carefully the data obtained during the industry pilot study, as well as other information concerning *E. coli* O157:H7 contamination of carcasses and beef products, to ascertain the relative importance of sampling frequency, lot size, and product testing in protecting consumers from contaminated beef. In any event, FSIS should only consider adopting those schemes that would enhance, not decrease, the safety of raw ground and non-intact beef products.

2. Concerns About the Adequacy of Corrective Actions

CSPI has a second, related concern about the industry's request. Specifically, we question whether the response by industry and FSIS to a finding that a carcass has become contaminated with *E. coli* O157:H7 will be adequately protective of public health. According to the industry proposal, if a carcass tests positive for the pathogen after application of the microbial intervention measures, in addition to rendering or thermally treating the contaminated carcass all that will be required is that the plant "investigate the cause by reviewing [its] slaughter

procedures and carcass intervention systems."[10] That response fails to account for the possibility that other carcasses from the same production shift as the contaminated carcass also harbor the pathogen. We would expect that the plant, as part of a carcass-testing system designed to afford a measure of protection that meets or exceeds that provided by the existing system, would undertake, at a minimum, the following steps upon detection of a positive carcass sample:

- if possible, test other carcasses from the same production lot to determine if they are also contaminated;
- if such carcasses already have been processed, conduct extensive tests of raw ground and non-intact product derived from the carcasses from the same production shift, if such product is available at the plant;
- alert purchasers of raw boneless beef from the affected production shift of the positive test, and advise them to test or increase their testing of that raw beef; and
- increase sampling of both carcasses and raw ground and non-intact product at the slaughterhouse to ensure that the problem has been adequately addressed.

Moreover, because the presence of *E. coli* O157:H7 on a post-intervention carcass signals a failure of the intervention system(s) in place at a plant, the review of those systems must be swift and thorough. In some circumstances, for instance where more than a single positive is detected in a short period of time, reassessment of whether the interventions used are fully "validated" should take place. In addition, FSIS should be vigilant in inspecting plants' records to facilitate detection of intervention systems that are or have become ineffective at eliminating *E. coli* O157:H7 contamination.

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[10] *AMI Pilot Test Protocol*, p. 3.

3. Concerns About Potential Commingling of Beef

Finally, CSPI has one additional concern about the industry's request that the exemption from FSIS sampling flow down the distribution channels from the slaughterhouse to its customers. Such an extension of the exemption would be acceptable only if sufficient safeguards are built into the regulations to ensure that there is absolutely no commingling of raw beef products derived from different sources, some of which may employ carcass testing and validated intervention measures and others that may not, at any stage in the distribution process. Retailers and other purchasers of raw ground and non-intact products should be exempted from FSIS sampling only if they can demonstrate to the agency's satisfaction that such commingling has not occurred, and that they have effective systems in place to prevent cross-contamination of their products. To that end, we applaud FSIS's commitment, as stated in its response to AMI's proposal, to refrain from reducing its sampling at retail establishments absent data showing that such establishments are not mixing raw materials that have been produced as set forth in the industry testing protocol with other beef.[11]

B. Elimination of the Six-Month "No Positives" Clause

The industry has also asked FSIS to eliminate the requirement in Directive 10,010.1 that establishments achieve six months of positive-free testing for *E. coli* O157:H7 to remain eligible for the exemption from FSIS testing. CSPI agrees that the six-month "no positives" clause may be somewhat counterproductive because it penalizes plants whose testing programs have successfully uncovered problems, but we cannot support complete elimination of the clause. Instead, reducing the length of the requisite no-positives period may be appropriate for plants that

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[11] *FSIS Response to AMI*, p. 2.

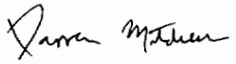
combine validated interventions with frequent carcass testing for verification, provided those plants act swiftly to correct any problems indicated by a positive test. The six-month clause should continue to apply to those establishments that do not employ carcass testing and validated interventions, however.

IV. Conclusion

Although CSPI is hopeful that the pilot study proposed by the beef industry will contribute significantly to our understanding of *E. coli* O157:H7 contamination in beef slaughterhouses, we caution FSIS that any change to the existing program for product sampling should be supported by sound scientific evidence indicating that it will yield safer beef products. We urge the industry to distribute the data and analysis from its pilot study to all interested parties, so that this information may provide a basis for further dialogue among the industry, the government, and other groups, including consumer representatives, about how best to address the serious health threat posed by the pathogen. In addition, we ask FSIS to refrain from instituting any change in sampling policy based upon the pilot-test results without first providing for public input concerning the proposed change by means of notice and comment rulemaking.

Thank you for your consideration of CSPI's comments.

Very truly yours,



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*Lucy Alderton, CSPI Project Coordinator, provided significant assistance in the preparation of these comments.