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Via Messenger

Docket No. 99-060N
c/o FSIS Docket Clerk
U.S. Department of Agriculture
Room 102 Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

99-060N-293
99-060N
George Green

**RE: Recent Developments Regarding Beef Products Containing *E. coli* O157:H7; Docket No. 99-060N**

Dear Sir or Madam:

The Food Marketing Institute (FMI) is pleased to respond to the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service's (FSIS's) request for comments on recent developments relevant to the Agency's policy on beef products that contain *Escherichia coli* O157:H7 (*E. coli* O157:H7). 65 Fed. Reg. 6881 (Feb. 11, 2000). As discussed more fully below, FMI strongly supports programs that prevent and eliminate food safety hazards. Accordingly, we urge USDA to adopt the program proposed by the Beef Industry Coalition under which the industry expects to conduct pathogen testing on 120,000 samples per year in conjunction with the application of vigorous decontamination steps at the slaughter stage. Adoption of the proposal will represent an increase in testing of nearly 20-fold from the current federal program levels. By focusing resources at the point of the distribution chain where they will be most useful in preventing the transmission of foodborne pathogens, we expect the program to increase overall food safety.

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and

independent supermarkets. Our international membership includes 200 members from 60 countries.

## I. Beef Industry Coalition Proposal

### A. Beef Industry Coalition Proposal Will Encourage Vigorous Use of Decontamination Interventions at Slaughter and Increase Pathogen Testing by Nearly 20-Fold from Current Federal Program Levels

#### 1. Current FSIS Testing Program

In conjunction with the original FSIS policy on *E. coli* O157:H7 in ground beef, FSIS instituted a microbiological testing program. At the very outset, the Agency noted that the "program is not statistically designed;" rather the stated purpose of the program was "to stimulate industry actions to reduce the presence of *E. coli* O157:H7 in raw ground beef." FSIS Notice 50-94 at 1, Attachment 1, Attachment 2 (Dec. 23, 1994). The Agency's most recent notice states that the end-product testing program was begun "as a means of spurring establishments into taking more aggressive action to control their processes." 65 Fed. Reg. at 6886.

Under the current program, FSIS directs inspection personnel and compliance officers to collect samples of raw ground beef products for testing to determine whether the samples test positive for *E. coli* O157:H7. Half of the samples are collected on a random basis from inspected processing establishments, retail outlets and imported products; the other half are "targeted" samples. Inspection personnel are instructed not to collect samples at processing establishments that meet one of the following criteria, unless the establishment has had a positive test result within the previous six months:

1. The plant conducts routine daily *E. coli* O157:H7 testing of raw ground beef products or boneless beef to be used in raw ground products;
2. The plant requires suppliers of boneless beef to certify that each lot received has been tested and found negative for *E. coli* O157:H7; or
3. The plant uses validated pathogen reduction interventions on beef carcasses, verifies their interventions' effectiveness through periodic testing for *E. coli* O157:H7, and prevents the use of boneless beef or carcasses from outside sources.

FSIS Directive 10,010.1 at 2. Under the policy as originally described, FSIS intended to collect approximately 5,000 samples per year, half at retail.

From 1995 through February, 2000, FSIS collected 19,317 samples from retail; 18 samples or 0.09% were found to contain *E. coli* O157:H7. Of the 14,819 samples collected at federal plants during this period, 40 samples or 0.27% tested positive for the pathogen. Thus, very low levels of *E. coli* O157:H7 were identified, although three times as many positive samples were found in plants as the Agency found at retail.

None of the positive samples found at retail has been linked to an outbreak or an illness. Even more significantly, follow up investigations demonstrate that *E. coli* O157:H7 found at retail was not caused at retail; that is, for the retail samples that tested positive, FSIS believes that the *E. coli* O157:H7 contamination occurred *before* the meat was received by the store.

2. Beef Industry Coalition Proposal

At a February 29 meeting, the Beef Industry Coalition presented the results of a carcass testing study in conjunction with a proposal to modify FSIS Directive 10,010.1.

a. The Study

The purpose of the study was to evaluate the feasibility of a carcass testing program that could be used to verify the efficacy of slaughter plant decontamination intervention controls on a routine basis. Twelve slaughter plants were selected to participate in the study, which was conducted for 30 days in September-October, 1999. Each plant tested one out of every 300 carcasses (or at least one each day) for the presence of *E. coli* O157:H7 at three points in the process: before hide removal; before carcass wash; and after final microbial intervention. Beef trimming samples were also collected and sampled, if available.

The study also provided carcass handling steps. Specifically, each carcass tested was treated as an individual lot and held until the plant received a confirmed negative for *E. coli* O157:H7. Carcasses with confirmed positive results for the pathogen were rendered or cooked. Upon finding a positive result, the plant was required to reassess the slaughter procedures and carcass intervention systems to ensure their efficacy.

*E. coli* O157:H7 was found on the hide at an average rate of 3.56% and prior to carcass washing at 0.44%. No samples tested positive for *E. coli* O157:H7 following the application of decontamination intervention steps, nor did any beef trimming samples test positive for the pathogen.

b. Proposed Modifications to Directive 10,010.1

The Beef Industry Coalition proposed that FSIS revise Directive 10,010.1 to modify the application of the Agency's current end product testing program to plants that perform interventions and routine carcass testing in keeping with the 1:300 program studied by the Coalition and retail stores that offer such products to consumers. Specifically, the Coalition recommended that FSIS remove the current limitation that subjects plants to testing for *E. coli* O157:H7 for six months if the pathogen is found. Given the serious penalties that attach to such a finding, continuing the current restriction would discourage processors from performing the 1:300 testing, despite the fact that any carcasses found with the pathogen under the proposed system would be diverted to applications in which they would be rendered or cooked.

In addition, the Coalition recommended that the eligibility for reduced FSIS testing follow carcasses that had been processed in accordance with the 1:300 testing program, and their subsequent products, through the distribution chain (*e.g.*, from slaughter to processing to retail or food service) by using an appropriate labeling or other identification mechanism. For example, a retailer who chose to offer consumers only meat that had been processed with enhanced interventions under the 1:300 testing program would be eligible for the reduced FSIS testing program.

### B. Coalition Plan Will Accomplish Stated Objective of FSIS's End Testing Program and Increase Food Safety

As noted above, FSIS did not design the current end product testing regimen on a statistical basis to "catch" any products contaminated with *E. coli* O157:H7 that had not been detected earlier in the system. As the program is not designed for this purpose and *E. coli* O157:H7 is an infrequently occurring organism, the program would not be effective for this purpose, either. Rather, the stated purpose of the program is to encourage industry to undertake actions to reduce the presence of *E. coli* O157:H7 in beef.

The study conducted by the Beef Industry Coalition demonstrates that the Coalition's plan would achieve the purpose of the current end testing program if adopted. Specifically, under the 1:300 carcass testing program, plants will be encouraged to use vigorous decontamination interventions to reduce and eliminate *E. coli* O157:H7 from meat products. Effective interventions will have the added benefit of reducing other pathogens, as well. Furthermore, the 1:300 testing program will increase the amount of pathogen testing from the approximately 5,000 samples per year that are now being collected to more than 120,000 per year. The use of increased interventions that can be expected as a result of the 1:300 testing program, coupled with the information and added assurance provided by the carcass testing, will increase the safety of food that retailers can offer to consumers.

### C. Retailers Need the Highest Assurances Possible that Meat Entering Stores Will Not Contain Pathogens

The FSIS end product testing program at retail has shown that *E. coli* O157:H7 contamination does not originate in grocery stores. Moreover, unlike slaughter plants and processors, retailers do not have any effective prevention or intervention tools (short of cooking) available to them to improve the safety of meat received at retail. *See, e.g.*, AMSA, "The Role of Microbiological Testing in Beef Food Safety Programs," (1999). Therefore, food retailers cannot eliminate or reduce pathogens in meat that enters the store. Rather, the proper food safety role of the retailer is to maintain the quality of the meat through proper sanitation methods and to minimize the possibility of cross-contamination that may result from meat that contains a pathogen. Retailers cannot, however, make meat any safer than when it is received.

Therefore, retailers are dependent on their suppliers to provide meat products that are as free from pathogens, such as *E. coli* O157:H7, as possible. Preventing microbial contamination before the meat enters the grocery store is essential to providing consumers with safe food. The Beef Industry Coalition proposal will provide added assurance that meat entering stores is as safe as possible.

### D. Need for End Product Testing Will Be Obviated at Stores that Purchase Meat Processed under 1:300 Testing System

#### 1. Indiscriminate Pathogen Testing at Retail Was Not Intended To and Does Not Serve as a Food Safety Tool

As noted above, the random retail testing program was not designed to serve as a food safety tool, but to encourage the use of stronger food safety practices by plants and processors. Moreover, indiscriminate testing for *E. coli* O157:H7 at retail is not an effective food safety tool for the following reasons.

First, *E. coli* O157:H7 occurs in the end product at an extremely low incidence. Accordingly, it cannot be used as an effective marker to verify that the production process is performing properly to reduce and eliminate pathogens.[1] Moreover, as there are no effective interventions that can be applied at retail, there is no process to verify in the first place.

Second, despite the emotional appeal that random retail testing holds for some, the FSIS testing program of 5000 or so samples per year for *E. coli* O157:H7 does not serve as a "safety net" to "catch" any pathogens that might not have been detected at the processing stage. As noted, above, the program is not statistically designed or scientifically supported. *See*, AMSA, "The Role of Microbiological Testing in Beef Food Safety Programs," (January, 1999); Gill, "Interventions for Assuring the Microbiological Safety of Raw, Red Meats" (2000). Moreover, even if it was, the practical reality is that most of the beef products have been sold and consumed by customers before a confirmed positive for *E. coli* O157:H7 can be obtained. Thus, end product testing at retail is akin to the old maxim of "closing the barn door after the horse has escaped."

Comments presented by the Center for Science in the Public Interest (CSPI) have only the following to offer on the subject of sampling at retail versus slaughter:

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[1] Indeed, the Agency's February notice states that "end-product testing alone is ineffective for ensuring process control." 65 Fed. Reg. at 6885. *See, also*, Tarr, et al., "*Escherichia coli* O157:H7 in Retail Ground Beef in Seattle: Results of a One-year Prospective Study," 62 J. Food Protection 133 (1999); AMSA, "The Role of Microbiological Testing in Beef Food Safety Programs: The Scientific Perspective," (January, 1999).

> Retail testing 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.

CSPI, "FSIS Policy on *E. Coli* O157:H7: Reviewing the Role of Pathogen Testing in HACCP," at 7 (Feb. 29, 1999). We agree that plant testing is more efficient and effective as a public health tool for the reasons CSPI has stated. However, for the reasons that we have set forth above, retail testing is *not* effective for catching "problems that fall through the cracks." CSPI's unsupported assertion to the contrary is contradicted by the Agency's own analysis and by the scientific evidence.

### E. Proposal Would Conserve Important Food Safety Resources that Can Be Used for Truly Effective Food Safety Activities

Based on the discussion above, it is clear that eliminating retail testing at stores that purchase meat prepared under the 1:300 system will not decrease food safety.[2] It will, however, allow FSIS to conserve important food safety resources; these resources could then be better directed toward activities that can truly enhance food safety and aid in the fight against *E. coli* O157:H7. For example, the resources could be used to conduct a comprehensive study of the ecology of the pathogen or to establish the effectiveness of controls and interventions that will reduce the pathogen before it enters the food supply. Alternatively, the resources might be directed to points along the food chain that have been affirmatively identified as needing resources to effect a positive and significant improvement in food safety. *See, e.g.*, GAO, "Food Safety: Opportunities To Redirect Federal Resources and Funds Can Enhance Effectiveness" (GAO/RCED-92-994, August 1998); "Improving the Safety of Food Imports: Hearing before the Senate Permanent Subcommittee on Investigations," 105th Congress, 2d Sess. (1998) (statement of Tim Hammonds, President and CEO, FMI).

## II. FSIS Applied Incorrect Legal Standard To "Clarification" That *E. coli* O157:H7 Is an Adulterant in Non-Intact Beef Products

In the Federal Meat Inspection Act (FMIA), Congress specifically defined the term "adulterated" to distinguish between substances that are naturally occurring in a food product and substances that are added to the food. Specifically:

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[2] It would also not completely eliminate the retail testing program. Retail stores that did not purchase meat processed under the 1:300 system or monitor trimming lots would still be eligible for the federal testing program. Testing would also need to be performed in public health investigations in case of an outbreak.

> (m) The term "adulterated" shall apply to any . . . meat . . .
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health.

21 U.S.C. § 601(m). The separate standards reflect the Congressional recognition that foods may naturally contain substances that may be harmful to consumers, but that those foods should not be considered adulterated, and, thereby, subject to the condemnation procedures of the Act, unless a finding has been made that the food, when in the state in which it will be consumed, will be harmful. That is, if the quantity of the substance at the point of consumption will not *ordinarily render* the food injurious to health, then the food should not be considered adulterated, even though some might describe the substance itself as "poisonous or deleterious."

As *E. coli* O157:H7 occurs naturally in the host animal, and is not added by humans, meat that contains the bacteria should not be considered adulterated if the quantity of the substance in the meat "does not ordinarily render" the food injurious to health. *See Am. Pub. Health Ass'n v. Butz*, 511 F2d 331 (D.C. Cir. 1974) (concluding that salmonellae are not adulterants under the non-added substance standard); *cf. Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994) (applying added substance standard without comment to *E. coli* O157:H7 in beef).

In the January, 1999 notice, FSIS did not cite either adulteration standard, but stated instead that "the status under the FMIA of beef products contaminated with *E. coli* O157:H7 must depend on *whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed.*" 64 Fed. Reg. 2803 (January 19, 1999) (emphasis added). The Agency offered no data to support such an assertion, but stated only that, "Pathogens may be introduced below the surface of these products as a result of the processes by which they are made." Id. at 2804.

In the most recent notice, FSIS recites both the non-added substance and added substance standards in the "adulteration" definition, but does not indicate which, if any, standard that the Agency is applying. 65 Fed. Reg. at 6884. The Agency's entire analysis is as follows:

> Because beef products contaminated with *E. coli* O157:H7 are often cooked in a manner that may not prevent illness, this pathogen is a substance that renders "injurious to health" even products that many consumers consider to be properly cooked.

65 Fed. Reg. at 6884, citing *Texas Food Industry Association v. Espy.*

As noted above, the proper standard is whether the quantity of the substance *ordinarily* renders the food injurious to health. At the February 29 public meeting, data were presented regarding the levels of *E. coli* O157:H7 that might be translocated into the center of beef products as a result of the blade tenderization process. Specifically, a Kansas State University study analyzed intact beef subprimals that were inoculated on the surface with *E. coli* O157:H7 and then processed by a blade tenderizer. Approximately 3-4% bacteria were translocated into the center of the subprimal. However, cooking the subprimal to a minimum internal temperature of 140°F, which corresponds to rare or medium rare, resulted in a 5-log reduction in the translocated pathogens. Accordingly, the quantity of *E. coli* O157:H7 present in blade tenderized meat will not ordinarily render the meat injurious to health. Therefore, FSIS has an insufficient legal basis for the policy "clarification" announced in January, 1999.

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We appreciate the opportunity to provide you with our comments on this very important subject. If we may be of further assistance on this matter, please do not hesitate to let us know.

Sincerely,

George Green
Vice President
General Counsel