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March 22, 1999

97-068N
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Tim Hammonds

Via Messenger

FSIS Docket Clerk
Docket No. 97-068N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

Re: Comments on Clarification of Policy on Beef Products Containing *E. coli* O157:H7; Docket No. 97-068N

Dear Sir or Madam,

The Food Marketing Institute (FMI) appreciates the opportunity to provide the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) with comments on the Agency's clarification of its policy on beef products containing *Escherichia coli* O157:H7 as explained in the January 19, 1999 *Federal Register* notice and as further developed in the March 8, 1999 public meeting. As discussed more fully below, FMI's members are pleased to provide consumers with the safest food in the world. Although we have been glad to assist the government in all reasonable and responsible efforts to augment the safety of our food supply, we are disappointed in the current policy "clarification," which we believe is not supported by sound science and, therefore, does not enhance efforts to protect public health. We are looking forward to reviewing the proposal the meat industry outlined at the March 8 public meeting and agreed to submit formally to the Agency in the next few weeks. We encourage USDA to consider carefully the clear merits of the plan.

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 store 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.

A. FSIS Has Presented Insufficient Evidence To Support the Policy Clarification Described in the January 19 *Federal Register* Notice

In a January 19 *Federal Register* notice, FSIS announced the expansion of the Agency's current policy concerning the adulteration of beef products with *E. coli* O157:H7. 64 *Fed. Reg.* 2803 (Jan. 19, 1999). The current policy dates to 1994 when FSIS notified the public that raw ground beef products that contained *E. coli* O157:H7 would be considered adulterated within the meaning of the Federal Meat Inspection Act (FMIA), unless the ground beef was further processed to destroy the pathogen.

FSIS developed this policy for raw ground beef products because the Agency believes that *E. coli* O157:H7 that may originally be on the surface of the meat may be introduced below the product's surface by the chopping or grinding that converts the raw product into ground beef. If the resulting ground beef product, such as hamburger, is only cooked to a rare or medium rare state, any *E. coli* O157:H7 organisms that are in the center of the food may not be destroyed before the food is consumed. 64 *Fed. Reg.* at 2803.

According to the recently announced "clarification," FSIS proposes to expand the policy so that non-intact beef products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption that contain *E. coli* O157:H7 will also be considered adulterated under the FMIA,[1] unless the newly specified meat products are further processed to destroy the bacteria. In support of the expansion, FSIS notes that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) stated the following with respect to *intact* meat products:

> Due to a low probability of pathogenic bacteria being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle

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[1] Congress specifically defined the term "adulterated" in the FMIA to distinguish between substances that are naturally occurring in a food product and substances that are added to the food:

> (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). 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 "does not ordinarily render" the food injurious to health. *See Am. Pub. Health Ass'n v. Butz*, 511 F.2d 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). The FMIA definition reflects 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. FSIS has made no such determination in the case at hand.

> (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces.

64 *Fed. Reg.* at 2803-04. FMI agrees that intact cuts of meat should be safe when cooked as described, even if the pathogen was originally present on the food. However, the NACMCF statement quoted above does not provide any indication regarding the Committee's conclusions with respect to non-intact beef products. The Agency simply avers that the Committee's conclusion is only directed to intact products, a point that the Committee made in its statement.

FSIS further argues that "pathogens may be introduced below the surface of [non-intact beef] products as a result of the processes by which they are made," such as injection with solutions, mechanical tenderization by needling, cubing, frenching or pounding. 64 *Fed. Reg.* at 2804. However, again, the Agency offers no further explanation for its belief nor does the Agency provide any factual or scientific basis in support of its supposition regarding the presence of bacteria below the surface of the meat products processed in the manner described or its inherent belief that those bacteria will ordinarily render the food injurious to health at the time that the food is consumed.

We submit that it is a disservice to public health to promote the idea that naturally occurring bacteria can be eradicated from the food supply by federal mandates or administrative fiat. As FSIS is well aware, the only known methods of eliminating *E. coli* O157:H7 are cooking the meat product to an appropriate temperature or irradiating the meat product. As the latter is not yet lawfully permitted and processors ultimately have no control over the former,[2] blanket condemnation of a large segment of the food supply without evidence to support the existence of a public health problem is not appropriate.

B. FSIS *E. coli* O157:H7 Sampling and Testing Program Should Be Re-Focused in Accordance with the Tenets of the Meat Industry Proposal Outlined at FSIS's March 8 Public Meeting

The January 19 *Federal Register* notice states that FSIS is not expanding its current sampling and testing program through the January 19 notice, but that the Agency may decide to reconsider its current sampling and testing program, as well as the scope of products deemed adulterated, in response to any comments received pursuant to the notice. 64 *Fed. Reg.* at 2804. As explained more fully below, we recommend that the current FSIS sampling and testing program be modified in accordance with the tenets of the proposal outlined at the March 8 public meeting by representatives of the meat industry, including the American Meat Institute (AMI).[3]

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[2] As you know, FMI is part of the Partnership for Food Safety Education, a government-industry coalition that works to educate consumers on proper food handling measures.

[3] Although a broad coalition was involved in the development and presentation of the proposal, for simplicity, we will refer to the suggestions as the "AMI proposal" here. We understand that AMI intends to

In conjunction with the original policy outlined in 1994, 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 policy 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).

Under the program, FSIS directed inspection personnel and compliance officers to collect samples of raw ground beef products for testing to determine whether the sample tested positive for *E. coli* O157:H7. Samples were to be collected on a random basis from inspected processing establishments, retail outlets and imported products. Inspection personnel were instructed not to collect samples at processing establishments that met one of the following criteria, unless the establishment had had a positive test result within the previous six months:

1. The plant conducted routine daily testing for *E. coli* O157:H7 of raw ground beef products or boneless beef to be used in raw ground products;
2. The plant required suppliers of boneless beef to certify that each lot received had been tested and found negative for *E. coli* O157:H7; or
3. The plant used validated pathogen reduction interventions on beef carcasses, verified their interventions' effectiveness through periodic testing for *E. coli* O157:H7, and prevented 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. In practice, the majority of sampling has been from retail stores. FSIS Notice 50-94 (Dec. 23, 1994).

During the March 8 public meeting, AMI recommended some modifications to the testing program described in Directive 10,010.1 that we believe will significantly increase the safety of all raw beef products that are sold to consumers at retail stores in keeping with the stated purpose of the testing program, *e.g.*, to encourage the development of industry actions to reduce *E. coli* O157:H7 in beef. In this regard, AMI estimated that implementation of the modifications discussed below would result in close to 100,000 tests for *E. coli* O157:H7 conducted on an annual basis at the slaughter plants, which is the most effective place in the chain of production to prevent *E. coli* O157:H7 from entering the meat supply.

Specifically, AMI recommended that the third criterion for reduced establishment testing in Directive 10,010.1, discussed above, should be amended to require the efficacy of pathogen reduction intervention steps on beef carcasses to be verified through carcass testing for *E. coli* O157:H7 at an appropriate interval, *e.g.*, one in every 300 carcasses. Once the efficacy of the pathogen reduction intervention steps was established as described, the eligibility for reduced sampling would follow the carcass and subsequent products through

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provide FSIS with a written proposal shortly, at which time the Agency may opt to re-open the comment period for further consideration of AMI's recommendations. We urge the Agency to give full and fair consideration to AMI's proposal.

the distribution channels (*e.g.*, from slaughter to processing to retail or food service) by using an appropriate labeling or other identification mechanism. AMI expects to provide FSIS with a protocol for a pilot study to provide data to support this change shortly.[4]

FMI believes that amendments in this regard would be consistent with the original purpose and design of the microbiological testing program and would increase food safety for the following reasons. First, the microbiological testing program was not designed to prevent food that contained *E. coli* O157:H7 from reaching consumers. As FSIS stated, the program was "not statistically designed;" that is, the Agency did not conclude that if 5,000 samples were obtained and tested, the Agency would "catch" all unsafe food products that would otherwise enter the market. Rather, the stated purpose of the program was "to stimulate industry action to reduce the presence of *E. coli* O157:H7." FSIS Notice 50-94. In light of the forthcoming AMI proposal, it appears that the FSIS program's purpose may well have been satisfied.

Second, testing food products at retail is not intended to serve as a "safety net," nor is it effective as one. Indeed, of the 16,000 retail samples of raw ground beef that have been taken to date under the policy, only seven have resulted in confirmed positive results of *E. coli* O157:H7. Furthermore, none of these results has been linked to an outbreak or illness. As the results of testing food products offered to consumers at retail are only obtained after the remaining food products have been sold to and, in most cases, consumed by the public, retail testing, *per se*, is not an effective means to ensure food safety not to protect the public.

Third, adoption of a program along the lines suggested by AMI would undoubtedly conserve significant federal resources that might then be better utilized to fight *E. coli* O157:H7 by, for example, conducting a comprehensive study of the ecology of the pathogen or establishing 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).

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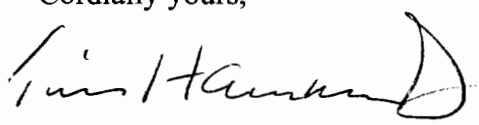
[4] AMI also noted that the current requirement in Directive 10,010.1 that establishments lose their eligibility for the reduced sampling program for six months after a single positive test result serves as a disincentive to "find" products with *E. coli* O157:H7. Since the purpose of testing under the Hazard Analysis Critical Control Point (HACCP) system adopted by FSIS is to ensure that existing controls are effective and to make process modifications if they are not, it is important not to discourage processors from "finding" *E. coli* O157:H7.

We appreciate your consideration of our comments and we look forward to our continuing partnership to provide the public with the safest possible food supply.

Cordially yours,



Tim Hammonds
President and CEO