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NMA

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March 22, 1999

FSIS Docket Clerk, U.S. Department of Agriculture
Food Safety & Inspection Service
Rm. 102 Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

97-068N
97-068N-69
Rosemary Mucklow

Re: *Federal Register* Notice January 19, 1999 Policy Beef Products Contaminated with *Escherichia coli* O157:H7 Docket No. 97-068N

Gentlemen:

The Administrator of the Food Safety & Inspection Service (FSIS) informed the industry in a briefing on Friday, January 15, 1999 that FSIS was publishing a sweeping change in its policy regarding beef products contaminated with *Escherichia coli* O157:H7 effective with the next business day, Tuesday, January 19, 1999. The agency's announcement expanding its interpretation of the adulteration provisions of the Federal Meat Inspection Act, without any dialogue about a rationale for doing so, seriously impacted commercial business relationships between sellers and buyers of meat and meat food products.

At a meeting on January 21, FSIS Administrator Tom Billy informed the industry that the Department would withhold implementation of the new policy until after a sixty day comment period. A public meeting was subsequently held on Monday, March 8 in Washington, DC.

National Meat Association was represented at the March 8 public meeting by its Executive Director Rosemary Mucklow. Other leaders from across the industry attended the meeting. A copy of the formal comments that Mucklow presented at the public meeting are enclosed herewith. The beef industry worked collectively to respond to the concerns stated by FSIS in its January 19 Notice. These comments supplement those submitted by the industry group of which NMA is a party.

FSIS offered no data to support its intentions with respect to the many products that are scored or injected for tenderizing purposes. Without scientific data, especially risk analysis data, it is NMA's recommendation that the agency's thesis is not supported by science and that the intended expansion of the adulteration policy to needle-tenderized products should be withdrawn.

A comprehensive proposal for carcass sampling and testing for *E. coli* O157:H7 was presented by beef industry representatives at the March 8 meeting. There was much dialogue between representatives of consumer organizations and industry representatives regarding a carcass testing program for *E. coli* O157:H7. In fact, representatives of consumer organizations expressed great interest in seeing a written proposal providing the details of the oral presentation

so that they could comment with more specificity. The Administrator indicated that he was amenable to providing more comment time, but he subsequently determined not to extend the time for such comments.

Beef slaughterers have been required, pursuant to the Final Rule published July 25, 1996, to test for generic *E. coli* on beef carcasses after they have moved into the holding cooler but before they are divided into cuts. This testing involves the collection of samples from three sites on one side of a beef carcass, and compositing them for testing. Certain requirements have been established for follow-up in the event of positive findings. Three major beef slaughterers presented recommendations at the March 8 public meeting to take a matching three-site sample from the other side of the same beef carcass sampled under the generic *E. coli* program and run the resulting sample for *E. coli* O157:H7. The carcasses so sampled would be identified as a single point source lot and held until test results were available. In the event of a confirmed positive result, the carcass would be appropriately identified, handled separately from all other carcasses to avoid cross contamination and passed for cooking and appropriate corrective action initiated.

This proposal met with considerable interest and was received as a positive step by many parties. The industry representatives said they would provide a written proposal for the record. Much work needs to be done to develop protocols, and it simply could not be done to meet the March 22 date set by agency. Industry is also going to conduct tests over sixty days on this proposal. It would be best to wait until the tests are completed and the data summarized and available for evaluation which would be expected to take a total of ninety days.

National Meat Association is committed to work with the other farm-to-table industry organizations to assist in developing an improved sampling and testing scheme. It is extremely important that FSIS recognize that the industry's commitment to testing carcasses be linked to assigning the principle of point source location to the sampled carcass which will be held for testing results through confirmation if necessary before release into commerce.

It is necessary, once again, to consider the incentives and disincentives of testing for pathogens that occur rarely. Several presentations at the public meeting discussed various sampling and testing schemes that are in use by different buyers and sellers. It needs to be understood, clearly and unequivocally, that no testing procedure is available to give statistically valid confirmation of the absence of a rarely occurring pathogen, including *E. coli* O157:H7, from a sampled lot.

What the united industry presented in concept at the March 8 meeting, a systematic sampling and testing of carcasses before they are disassembled into primal and sub-primal cuts and trimmings, will provide an improvement in statistical confidence, simply because of the sheer numbers of tests that will be run, but once again it is no absolute guarantee of absence of the pathogen. The industry's proposal to undertake a systematic sampling and testing of *E. coli* O157:H7 of finished carcasses is a huge step towards collecting data that will be important to future efforts to eliminate this pathogen from beef. Developing the protocols to undertake this work will take time and commitment. It needs to be done with joint involvement of FSIS technical experts and

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industry representatives in full cooperation. It should not be a regulatory requirement, but rather be a collection of data by industry, with the full support and cooperation of FSIS. If the specific point source carcass being tested is held for results, and only released into commerce based on negative results, there should be no regulatory or reported action by agency officials.

In summary:

These comments supplement those that are being submitted by the united industry group of which NMA is a strong supporter. NMA recommends that USDA hold in abeyance its intentions to expand the adulteration provisions of the Federal Meat Inspection Act as announced on January 15, 1999. This abeyance action is supported by (1) The agency's own testing program for *E. coli* O157:H7 initiated in 1994 which has yielded 26 positive findings out of 27,430 samples (latest data available as of 2/18/99) and does not justify an expansion; (2) The agency does not have data to support the inclusion of scored and needled cuts of meat within this definition of adulteration; (3) The agency has initiated a risk assessment process and the results of this should be completed before any expansion is considered; (4) The industry has expressed its willingness to engage in a cooperative sampling and testing program with input from the agency's technical staff that will develop data that should help focus future efforts to eliminate the pathogen closer to its source.

In its good faith commitment to this effort, National Meat Association is prepared to recommend to its members that they immediately initiate a voluntary carcass sampling and testing program for *E. coli* O157:H7, with the intent that the level of testing be increased when the agency responds to the industry's proposal. The carcass tested will be a lot (both sides) for the purpose of determining point source.

The next step in the process is confirmation by the Agency that it is prepared to work cooperatively with the industry in this effort. We hope that the agency can announce its intent as soon as possible so that the complex work on developing sampling and testing protocols can be started.

Sincerely,

Rosemary Mucklow
Executive Director

enclosure

COMMENTS BY ROSEMARY MUCKLOW, NMA EXECUTIVE DIRECTOR, FOR PUBLIC MEETING MARCH 8, 1999 ON USDA/FSIS PROPOSED *E.COLI* POLICY

Today beef packers, processors and distributors have presented important recommendations to orient sampling and testing towards the prevention of illness and recalls, and away from the after-the-fact sampling and testing of inspected and passed product. This type ofafter-the-fact testing has proved to be oriented more to punishment and prosecution than to the prevention of illness and recalls.

In the past five years, beef packers have invested hundreds of millions of dollars in sophisticated hot water, steam and organic acid intervention systems and in HACCP-based process controls, all designed to make beef safer for consumers. The recommendations proposed by a united industry today are designed to provide on-going verification that those interventions and controls are effective on a day-by-day, plant-by-plant basis.

In January, when the agency proposed to expand its definition of adulteration, there were serious concerns within the industry that this legal step would expand the agency's capacity for punishment and prosecution, while at the same time impairing the ability of companies and inspectors to prevent the shipment of USDA inspected and passed product which could later be the subject of recall and prosecution.

The key to using sampling and testing to prevent illness and recalls is to provide test methods which are sufficiently rapid and to sample lots which are sufficiently well-defined that the sampled product can be held back from shipment until test results become available. The sampling procedures that have been proposed today meet these goals.

This orientation to prevention, and away from punishment, is in the interests of consumers, the industry and government regulators.

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