AMERICAN MEAT INSTITUTE
Serving The Industry Since 1906.

Mark D. Dopp
Senior Vice President
Regulatory Affairs
and General Counsel

(3)

April 11, 2000

99-060N-5
99-060N
Mark D. Dopp

FSIS Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
Room 102 Cotton Annex Building
300 12th Street SW
Washington D.C. 20250-3700

RE: Supplemental Comments Pertaining To Recent Developments Regarding Beef Products Contaminated with *Escherichia coli* O157:H7

To whom it may concern:

The American Meat Institute (AMI) submits these comments to supplement the information presented by the Beef Industry Coalition at the Food Safety and Inspection Service's (FSIS or the agency) February 29, 2000, public meeting regarding recent developments concerning beef products contaminated with *Escherichia coli* O157:H7 (*E. coli*). AMI represents slaughterers and processors of more than 70 percent of the meat and turkey products sold in the United States. As such, AMI has a direct interest in the policy articulated in the above-referenced docket and the various issues raised by the agency in this matter.

The agency's February 11, 2000, notice announced a public meeting about the agency's significant expansion of its policy governing beef products containing *E. coli,* which was originally implemented in 1994 and applicable only to raw ground beef. Since 1994 industry has made great strides in addressing the issues involving the presence of *E. coli* in raw ground beef. As AMI stated in its comments submitted in March 1999, it is incumbent on all segments of the industry to become more aggressive in their efforts to reduce the incidence of *E. coli* in the beef supply, with the ultimate goal being elimination of the pathogen. In that regard, the coalition's research efforts

and the suggestions provided in the recent public meeting evidence significant progress by industry, as well as providing an innovative solution to issues raised by the agency's testing program. Mindful of the common goal and the notable progress that has been made in developing additional obstacles to microbiological contaminants, the following comments are submitted.

The FSIS Testing and Sampling Program should not be Expanded, but Refocused on Verifying the Industry's Process Control.

FSIS currently samples and tests raw ground beef products for *E. coli*. That testing program, however, is of extremely limited value. Indeed, the type of sampling engaged in by FSIS "may successfully mislead the consumer or regulatory agency regarding the safety of ground beef" and "it cannot accomplish the greater goal of predicting the safety of this product."[1]

In the wake of the agency's March 8, 1999, meeting, the coalition conducted a survey regarding the incidence of *E. coli* on incoming cattle and the effectiveness of one or more interventions in cattle slaughter plants. In that survey cattle carcasses were sampled at the rate of one of every 300 for *E. coli*. The results of that survey were submitted at the February 29, 2000, meeting. The survey's results provide compelling evidence that the incidence of *E. coli* on cattle entering a slaughter plant is not very high and, more importantly, that the various interventions utilized by a significant percentage of the cattle slaughtering industry are very effective in reducing and controlling *E. coli*. The survey and its results provide useful and persuasive information against any expansion of FSIS sampling and testing program. Indeed, the survey fully supports the coalitions recommended changes to the FSIS Directive 10, 010.1 *Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef* (the directive).

The directive currently provides three ways establishments manufacturing ground beef can become eligible for reduced government sampling. Establishments can: (1) conduct daily routine testing of raw ground beef products or boneless beef; (2) require suppliers of boneless beef to certify that each lot has been tested and found negative, or (3) use validated pathogen reduction intervention on beef carcasses, routinely verifying intervention effectiveness periodically and preventing the use of boneless beef or carcasses from outside sources. However, the directive provides that an

---

[1] *The Role of Microbiological Testing in Beef Food Safety Programs: Ground Beef*; Dr. Gary Acuff; at 13. Presented at the American Meat Science Association Symposium, *The Role of Microbiological Testing in Beef Food Safety Programs*, January 20-22, 1999.

establishment with a positive test result within a six-month period loses its eligibility for reduced sampling.

As the coalition recommended in the February 29 meeting, the directive should be changed in the following manner. The third option should be amended to allow plants that engage in sampling cattle carcasses at the recommended rate of one per 300 to be eligible for reduced sampling status. The coalition also urged the agency to amend the directive to eliminate the provision precluding a plant from eligibility if it has had a positive within the last six months. Furthermore, eligibility for reduced sampling should follow the carcass through the distribution channels (slaughter - processing - retail or food service), with the utilization of an appropriate identification mechanism.

The coalition's proposal, including testing one of every 300 carcasses is far preferable to the current system because it identifies problems farther upstream, thereby helping to limit the possibility of *E. coli* contamination. Moreover, amending the directive as suggested will provide a notable incentive for establishments, regardless of size, to conduct their own testing. The three options provide flexibility for facilities of all sizes to qualify for reduced sampling and enable the agency to refocus its sampling and testing.

The Policy should not be Implemented to Apply to Tenderized and Similar Non-intact Products

The 1999 notice changed the agency's long-standing policy by treating as adulterated non-intact meat products that have been subjected to various treatments, such as needling or other tenderizing methods, if those products test positive for *E. coli*. This position is markedly different from the position taken by FSIS in 1994 concerning raw ground beef and, from the best evidence available, is without a substantive foundation in science or fact.

The agency argued in the 1994 litigation challenging its announcement that *E. coli* in raw ground beef was an adulterant that FSIS not bound by the notice and comment process provided by the Administrative Procedure Act (APA). Indeed, FSIS made much of the fact that evidence existed that a percentage of the consuming public ate its ground beef in a state that presented a health risk, *i.e.*, ground beef that was not cooked thoroughly. FSIS relied heavily on the fact that there was evidence of illnesses related to the consumption of ground beef, coupled with studies that many persons do not cook ground beef thoroughly enough to kill the pathogen. Moreover, the court's holding was based on that evidence and was limited to the presence of *E. coli* in raw ground beef.

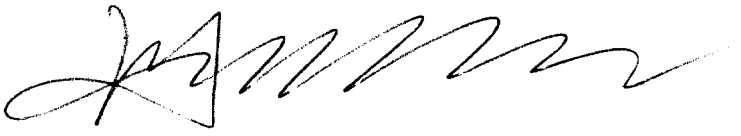
The agency's expansion of its *E. coli* policy last year was not then, and is not now, based on any scientific fact. There is no evidence that needled or otherwise tenderized or non-intact products that contain *E. coli* present any public health risk and there is no evidence of any illnesses attributed to such products. Indeed, the only scientific studies that have been conducted confirm, as was discussed at the March 8, 1999, meeting and again at the February 29, 2000, meeting, that risks to the public health are not increased by such treatments.

Questions Exist regarding the Agency's *E. coli* Risk Assessment Modeling

After attending the February 29 meeting, AMI is concerned about the validity of the risk assessment models that have been developed by the agency and any reliance in decisionmaking based on those models. In that regard, the National Advisory Committee for Microbiological Criteria for Food (NACMCF) was critical of this project and AMI suggest that before utilizing any other information gleaned from the project that the NACMCF be given an opportunity to review the results and the recommendations produced by the risk assessment.

AMI appreciates the opportunity to submit these supplemental comments and looks forward to working with the agency regarding this matter. If you have any questions or concerns about this letter, or anything else regarding this matter, please contact me.

Sincerely,



Mark D. Dopp

cc: J. Patrick Boyle
Jim Hodges
Kim Rice
Randy Huffman