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April 28, 2000

FSIS Docket Clerk
 Docket No. 99-060N
 Room 102 Cotton Annex
 300 12th Street, SW
 Washington, DC 20250-3700

99-060N-294
 99-060N
 Ken Mastracchio
 Denise Bridges

Re: Docket No. 99-060N
Federal Register, Feb. 11, 2000,
 Vol. 65, No. 29, pg. 6881

Dear Sir:

National Meat Association (NMA) represents meat packers and processors throughout the United States. NMA respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) February 11, 2000 *Federal Register* notice providing the public with the opportunity to comment on FSIS' testing procedures and other issues on *E. coli* 0157:H7.

The majority of NMA's member firms process both intact and non-intact raw beef products, thus we are very concerned when FSIS seems to be proceeding with a program not fully based on sound science.

As an initial matter, we recognize the existing policy that *E. coli* 0157:H7 is an adulterant in raw comminuted beef products. Likewise, it seems logical that trimmings clearly intended to be used in such products would be adulterated if they contain *E. coli* 0157:H7. Our initial concerns with the expansion of the *E. coli* 0157:H7 policy to trimmings were based on the practicalities of implementation. These concerns have been resolved by the agency's current position that testing issues -- such as what product is represented by the sample and how tested product is to be handled -- are left to the establishment and will not be dictated by the agency. We trust that this position will be followed in the event FSIS itself samples trimmings. Finally, it seems that the new *E. coli* 0157:H7 testing procedure is a valid means of detecting the organism. We only request that any new test methods be publicly announced before they are used for regulatory purposes and that FSIS scientists work not only on increasing detection sensitivities, but on the speed of the analysis so that establishments holding fresh product can be advised of the results in the most timely manner possible.

Beyond the above, we are concerned with how FSIS is proceeding on this issue in three regards. First, its position with regard to tenderized meat is not supported by the science. Second, FSIS is relying on its own *E. coli* 0157:H7 incidence data, which is not consistent with other incident data. This difference may result in the agency taking

precipitous action. Third, FSIS has failed to take industry interventions and progress into account in developing or modifying policies.

THERE IS NO JUSTIFICATION FOR APPLYING THE POLICY TO TENDERIZED BEEF

At the same time FSIS issued its expansion of the *E. coli* 0157:H7 policy to trimmings, the agency also indicated it was expanding the policy to mechanically tenderized beef. However, such expansion is not logical nor supported by the science. We are unaware of any illness attributable to tenderized meat. When FSIS first adopted the *E. coli* 0157:H7 policy for raw comminuted beef in 1994, the single most determinative factor according to FSIS was that this pathogen on this product had caused actual illnesses. In the case of tenderized meat, that justification is lacking.

Likewise, there is no science to support the expansion. At the recent public hearing on *E. coli* 0157:H7, Dr. James Marsden and Dr. Randell Phebus, Department of Animal Science and Industry, Kansas State University presented their recent findings on *E. coli* 0157:H7 in blade tenderized steaks to USDA. While keeping in mind that the researchers inoculated beef cuts with a level of *E. coli* 0157:H7 that is much higher than what may be found on commercial product, the data shows that 3-4% of surface contamination was transferred into the interior of the muscle. However, the researchers pointed out that proper cooking to a specified time/temperature combination results in "... both intact and non-intact steaks [that] are safe for consumers." Therefore, the science does not support the policy expansion.

Finally, there are significant practical implementation problems. For example, if a individual item tests positive, what amount of production is implicated by that finding?

In short, the expansion is not necessary to protect the public health.

FSIS DATA MAY OVERESTIMATE O157:H7 INCIDENCE

As reported at the public meeting, FSIS' data estimates that 40% of ground beef from steers and heifers is contaminated with *E. coli* 0157:H7. Given this number was higher than expected, FSIS may be posed to revise and further expand its *E. coli* 0157:H7 policies. However, FSIS should not undertake any precipitous action.

There apparently is a dispute as to the actual prevalence. According to the Agricultural Research Service's most recent data taken during the peak *E. coli* 0157:H7 shedding season, the prevalence of *E. coli* 0157:H7 post processing was only 2%. In ARS' study, it states that, "Reduction in carcass prevalence from pre-evisceration to post processing suggests that sanitary procedures were effective within the processing plants," and furthermore that, "... current in-plant processing practices appear to reduce the level of carcass contamination with EHEC 0157." Given ARS' expertise in research generally, we strongly urge FSIS not to adopt any policy changes based on its own data that is not corroborated by data from USDA's Agricultural Research Service.

Dr. Ann Marie McNamara, former Director of Microbiology for the Office of Public Health and Science said on February 17, 1999, during the AMSA Western Science

Conference titled “Realities of *E. coli* 0157:H7 Part II,” the following about FSIS’ previous results of *E. coli* 0157:H7 testing.

“My pet peeve is that people try to make this data into more than it actually is and that’s because they try to make it into incidence data or say that this data shows the extent of the problem in ground beef and actually you can’t say that...there is no statistical design to this so there is no way to get incidence or prevalence data ... at best [the results] are just descriptive statistics.”

INDUSTRY INTERVENTION STRATEGIES SHOULD BE RECOGNIZED

According to a study done jointly by the industry and Colorado State University, the industry’s intervention strategies adequately address the risk of *E. coli* 0157:H7 in beef products. The study showed the dramatic effect that carcass decontamination interventions had on *E. coli* 0157:H7. For example, *E. coli* was reduced from 3.56 % for hide samples to 0.44% prior to carcass washing and then to 0.00% following decontamination interventions. Therefore, industry is currently doing everything within its means to reduce the prevalence of *E. coli* 0157:H7 on beef products. In light of this, additional policy measures may not be as desirable as measures to recognize those establishments that have implemented controls, such as with reduced agency *E. coli* 0157:H7 testing of the products from these establishments.

CONCLUSION

Currently, our industry is doing everything economically feasible to reduce and or eliminate the prevalence of *E. coli* 0157:H7. When science, based on sound practices, proves that the prevalence of *E. coli* 0157:H7 is already low when it leaves the processing plant, then FSIS should applaud the industry for its efforts. Instead, FSIS has chosen to salute the industry by implementing new expanded policies. If nothing more, at least reassure the industry that the data used as the basis for the new policy is scientifically accurate and unquestioned.

We appreciate the opportunity to provide our comments on the *E. coli* 0157:H7 policy and its derivatives.

Sincerely,



Ken Mastracchio
Director of Regulatory Issues



Denise Bridges
Regulatory Assistant