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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

97-068N
97-068N-57
Ken Andros
Katrina Laube

RE: FSIS Docket No. 97-068N *Beef Products Contaminated with Escherichia coli O157:H7*

To whom it may concern:

Pabst Meat Supply, Inc. is a meat processing company that has a direct interest in the policy articulated in the above-referenced docket.

The agency's January 19, 1999, notice significantly expanded the scope of the FSIS policy governing beef products containing *Escherichia coli* O157:H7 (*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. It is incumbent, however, on all segments of the industry to become even 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. It is with that goal in mind that the following comments regarding the agency's notice are submitted.

The comments address two core issues that directly affect our company, and are divided into two sections. The first section discusses the FSIS Sampling and Testing Program and the second section comments on the *Draft Questions and Answers on Beef Products Contaminated with E. coli O157:H7* published on February 26, 1999.

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.* The current testing program does not include intermediate products because they are used in formulating other products, such as hamburger, but those intermediate products are not distributed to consumers. In lieu of the agency's expansion of its sampling and testing program the following suggested changes to the FSIS Directive 10, 010.1 *Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef* (the Directive) are submitted.

The Directive 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 requires that an establishment with a positive test result within a six-month period loses its eligibility for reduced sampling.

The Directive should be changed in the following manner. First, the third option, in the directive for eligibility for reduced sampling, should be amended to specify that intervention steps on beef carcasses are verified through carcass swabbing for *E. coli.* Furthermore, eligibility for reduced sampling should follow the carcass and subsequent products through the distribution channels (slaughter - processing - retail or food service), with the utilization of an appropriate identification mechanism. As the agency is aware an industry coalition intends to conduct a pilot test that will provide data to support this change.

Amending the Directive as suggested above 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 enables the agency to refocus its sampling and testing.

The Questions and Answers Provided by FSIS should be Modified to ensure Consistency in Agency Policies.

Several of the Questions and Answers (Q&A's) provided by the agency in the aftermath of the notice's publication on January 19, need amendment or further clarification.

The industry supports the approach articulated in question one. Specifically, it provides that establishments conducting testing must determine, prior to sampling and testing, the lot that each sample and subsequent test represents. Establishments should prevent cross contamination between lots represented by each sample and subsequent test and sampling schemes should identify the appropriate number of units to be sampled and how many total units the sample represents.

However, the answer to question three is inconsistent with the answer to question one. Specifically, the Q&A's ask that in those instances when a number of units is broken into smaller groups and one of the smaller groups tests positive, with the remaining testing negative, what the probability is that the negative units are, in fact, not contaminated. Industry testing data previously provided to FSIS supports the use of negative portions of loads, of raw materials, in which the finished product manufactured from those subgroups testing negative were subjected to intensive sampling and did not yield any subsequent positive results.

Question two, which pertains to appropriate testing protocols for *E. coli,* **should be reevaluated**. Although FSIS is trying to provide guidance to establishments, the agency should not issue guidance that inadvertently hinders the development and use of alternative methodologies that are more rapid, yet equally effective and sensitive. **Question two could be misconstrued to provide such a hindrance.**

Questions five, six, seven, and eight concern actions to be taken by industry when a positive result for *E. coli* is found in raw materials destined for ground beef manufacture. The answers referencing notification of other establishments in the event of positive should be reconsidered. The information provided above regarding question three and the logic underlying the agency's answer to question one are inconsistent with the suggestion that the supplying establishment notify other customers of the supplying plant about test results in other facilities. Although notifying the supplying establishment may provide that facility with useful information to reexamine its processes, expanded notification is unnecessary as long as receiving establishments are following their established protocol.

We appreciate the opportunity to comment on the expanded policy and Draft Q&A's.

Sincerely,

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Vice President of Operations

Katrina Laube
QA Laboratory Manager