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March 22, 1999

97-068N
97-068N-41
Jerry Peterson
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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

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

To whom it may concern:

The undersigned, EA Miller Inc. , is an independent part of ConAgra, Inc., a $24 billion company with over 87,000 employees, most of which are in the United States. Many of ConAgra's businesses and employees are engaged in meat processing, from growers to slaughterers as processors, purveyors and distributors of meat and poultry products. As part of such an organization, the undersigned companies have a direct interest in the policy articulated in the above-referenced docket notice.

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 pronounced 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 three core issues and are divided into three sections. Section one discusses the policy's application to non-intact beef products (*e.g.*, mechanically tenderized steaks) that are not destined for ground beef manufacture and discusses recommendations for future risk assessment and potential future rulemaking. The second section discusses the FSIS Sampling and Testing Program. The final section of comments discuss the *Draft Questions and Answers on Beef Products Contaminated with E. coli O157:H7* published on February 26, 1999.

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

The notice changes the agency's long-standing policy by treating as adulterated non-intact meat products that have been subject 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. In doing so FSIS relied heavily in its briefs and at oral argument before the trial court 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.

In contrast, the agency's recent expansion of its *E. coli* does not enjoy that type of evidentiary support. 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. Moreover, the only scientific studies that have been conducted confirm that risks to the public health are not increased by such treatments.

Rather than expand by fiat the scope of products that are deemed to be adulterated, FSIS should withdraw that portion of the January notice pertaining to these types of non-intact products, conduct a complete risk assessment for these products and, if FSIS deems necessary, publish a proposed rule regarding that issue. In so doing FSIS would provide adequate notice and invite meaningful public comment on an issue that could have a very significant impact on the meat industry. To do so would bring the agency into compliance with the requirements of the APA by requiring that agency to set forth its rationale, for any such proposal and the evidence to support that rationale and it would provide an opportunity for all interested parties to participate in a process that has not been prejudged.

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. The protocol for that pilot will be provided to the Agency by April 7, 1999.

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&As) provided by the agency in the aftermath of the notice's publication on January 19, need amendment or further clarification. In that regard, consistent with the comments presented above pertaining to tenderized and similar non-intact products, questions twelve and thirteen and all other references throughout regarding those products, should be deleted.

We support 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, but the rest test negative, what is the probability that the negative units are not contaminated? Attached is a summary of industry testing data that 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.[1]

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 a positive result 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, the data provided in the attached demonstrates that any expanded notification is unnecessary.

Questions ten, eleven, and fourteen pertain to the Directive, for which changes have been recommended. However, question fourteen addresses notification of FSIS in the event there is a positive. Currently, industry is responsible for taking corrective actions and documenting those corrective actions when a positive occurs. A similar approach should be used under these circumstances as well.

We appreciate the opportunity to comment on the expanded policy and Draft Questions and Answers. We look forward to submitting industries protocol and working with the Agency on a solution to these issues.

Sincerely,

Jerry Peterson
Plant Manager

Jay Rawlings
Quality Control Manager

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1 This data has been previously provided to FSIS.