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To	Whom It May Concern		Janice L. Wynn		
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Monfort, Inc.
Corporate Director Food Safety

March 22, 1999

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, **Monfort, 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.

¹ This data has been previously provided to FSIS.

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,



Janice L. Wynn
Corporate Director Food Safety

ATTACHMENT 1

The following data was collected from three manufacturers of ground beef patties and has been compiled and reported below by American Meat Institute (AMI), used with permission. Each establishment followed a raw material testing protocol and similar finished product protocols. Each manufacturer's protocol and results are briefly explained below.

Manufacturer A

Combo Testing

The combo testing protocol required that each load of twenty combos be divided into four (A, B, C and D) five-combo lots. A grab sample was taken from each combo (13 pounds or 5,897 grams). Each combo sample is ground and three (3) 25-gram samples are pulled. The three (3) samples are combined to make up a 75-gram composite for the combo. The five composites (75g each), one from each combo, are then combined to make a 325 gram composite sample for the lot. Each lot that tested positive for E.coli 0157:H7 was condemned. Each lot that tested negative was used for the manufacture of ground beef patties.

Finished Product Testing

This protocol has been designed to provide a 95% confidence level of detection at 1/500g in the specific facility.

Every 3000-pound batch of finished product is tested. 50-gram samples are collected at the final grinder head at three distinct points in the batch; front, middle and end. Half of each 50-gram sample is placed in a sterile sample bag to represent the specific batch. The other portion is placed in a sterile composite sample bag. Samples from 4 batches are composited into the sterile composite bag and analyzed as one sample. If a positive is obtained from the composite, representing four 3000-pound batches, then the independent samples for those four batches are analyzed.

Testing Methodology

Initial test is an ELISA based screen. Presumptive results are confirmed using standard cultural methods.

Results

The data summarized in the following three examples indicates that in those instances when a portion (lot) of a load has tested positive and the remaining portions (lots) tested negative, that the use of the negative lots did not show contamination in the finished product.

Example 1

In this example a load of boneless beef 50/50 trimmings was pre-screened following the above protocol for combo testing and only lot C from the load tested positive. That portion of the load was sent to a rendering company and the balance of the load was used for the production of ground beef patties. Lots A and B from the load were used to manufacture ground beef patties for a customer requiring serial sampling. Through the serial sampling no positive results were obtained.

Example 2

In this example a load of boneless beef 90/10 cow trimmings was pre-screened following the above protocol for combo testing and only lot C from the load tested positive. That portion of the load was returned to the slaughterer and the balance of the load was used for the production of ground beef patties. Lots A and B from the load were used to manufacture ground beef patties

that were tested under the above finished product testing protocol. Through the serial sampling no positive results were obtained.

Example 3

In this example a load of boneless beef 90/10 cow trimmings was pre-screened following the above protocol for combo testing and lot A from the load tested positive. That portion of the load was returned to the slaughterer and the balance of the load was used for the production of ground beef patties. Lot B and C from the load were used to manufacture ground beef patties that were tested under the above finished product testing protocol. Through the serial sampling no positive results were obtained.

Manufacturer B

Combo Testing

The combo testing protocol required that each load of twenty combos be divided into four (A, B, C and D) five-combo lots. A grab sample was taken from each combo (13 pounds or 5,897 grams). Each combo sample is ground and three (3) 25-gram samples are pulled. The three (3) samples are combined to make up a 75-gram composite for the combo. The five composites (75g each), one from each combo, are then combined to make a 325 gram composite sample for the lot. Each lot that tested positive for E.coli 0157:H7 was condemned. Each lot that tested negative was used for the manufacture of ground beef patties.

Finished Product Testing

This protocol has been designed to provide a 95% confidence level of detection at 1/500g in the specific facility.

Every fifteen minutes a sample of finished patties is taken. Each sample will contain two patties. One patty will be placed in a sterile sample bag to represent the fifteen-minute time frame and the second will be placed in a sterile sample bag to represent a composite for the hour. Every hour a composite sample will be analyzed. If a positive is obtained from the composite, representing the hour of production, the fifteen-minute samples will be analyzed.

Testing Methodology

Initial test is an ELISA based screen. Presumptive results are confirmed using standard cultural methods.

Results

The data summarized in the following example indicates that in one instance when a portion (lot) of a load tested positive and the remaining portions (lots) tested negative, the use of the negative lots did not show contamination in the finished product.

Example 1

In this example a load of boneless beef 50/50 trimmings was pre-screened following the above protocol for combo testing and only lot C from the load tested positive. That portion of the load was sent to a rendering company and the balance of the load was used for the production of ground beef patties. Lots A and B from the load were used to manufacture ground beef patties for a customer requiring serial sampling. Through the serial sampling no positive results were obtained.

Manufacturer C

Combo Testing

The combo testing protocol required that each load of combos be separated by establishment number and then by bone date. The following chart details the number and weight of samples taken from each combo.

# of Combos w/single Bone Date	Number of Samples From Each Combo	Total Analyzed
10+	Divide lot into two combo lots and take 37.5 grams per combo and composite into 75 grams per lot	750 g
9	Divide into four two combo lots and one single combo lot. Take 37.5 grams from each combo in the composite lots and 75 grams from the single combo lot.	375 g
8	Divide into three two combo lots and two single combo lots. Take 37.5 grams from each combo in the composite lots and 75 grams from the single combo lots.	375 g
7	Divide into two two combo lots and three single combo lots. Take 37.5 grams from each combo in the composite lots and 75 grams from the single combo lots.	375 g
6	Divide into one two combo lot and four single combo lots. Take 37.5 grams from each combo in the composite lots and 75 grams from the single combo lots.	375 g
5	One 75 gram sample per combo	375 g
4	One 75 gram sample per combo and one 75 gram sample from any one of the four combos (at random).	375 g
3	One 75 gram sample per combo and two 75 gram samples from any two of the three combos (at random).	375 g
2	Two 75 gram sample per combo and one 75 gram sample from any one of the two combos (at random).	375 g
1	Five 75 gram samples.	375 g

Finished Product Testing

This protocol has been designed to provide a 95% confidence level of detection at 1/500g in the specific facility.

Every two hours of production samples are taken at each grinder and on each line (total of eight samples). Each sample should weigh approximately 1 pound. From each sample 50 grams should be cut and placed into the first composite of the day. The first composite of the day will include all production up to 3:00 p.m. All samples pulled after 3:00 p.m. will be placed in Composite 2. If production ends prior to 6:00 p.m. then all samples from 3:00 p.m. to end will be included in the first composite. If production ends after 6:00 p.m. two composites for the day will be analyzed. The composite will be mixed well and five 75-gram samples will be analyzed per composite.

Testing Methodology

Initial test is an ELISA based screen. Presumptive results are confirmed using standard cultural methods.

Results

The data provided indicates that in those instances when a portion (lot) of a load has tested positive and the remaining portions (lots) tested negative, that the use of the negative lots did not show contamination in the finished product.

This manufacturer has run 7,580 tests on combos of beef raw materials following the above outlined protocol and obtained twenty-eight presumptive positives. Each of the lots represented by the twenty-eight presumptive results was either condemned or returned to the supplier. Subsequent testing of finished product, following the above protocol, obtained no positive results.