

golden state foods

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(51)

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

In response to the Policy on Beef Products Contaminated with *Escherichia coli* O157:H7, released for comment on January 19, 1999, and the Draft Questions and Answers on Beef Products Contaminated with *E. coli* O157:H7 published on February 26, 1999 we offer the following comments.

- In general, Golden State Foods supports the comments and proposal submitted by the American Meat Institute Industry Coalition.
- Golden State Foods is a diversified food supplier corporation; among other products that we produce and distribute are frozen ground beef patties for use by quick service restaurants.
- The Meat Industry has and continues to make great strides in addressing the issue of the presence of *E. coli* O157:H7 in raw ground beef. We believe the Policy Clarification expanding the adulteration status to products intended for ground beef products and non-intact beef products, as interpreted, will discourage current testing efforts by the Meat Industry. It should be noted however, that current sampling/testing methods of testing trimmings and/or finished products are statistically ineffective in isolating an organism of such a low incidence rate.

We believe that the FSIS current testing and sampling programs should not be expanded to include intermediate products, as such products are not distributed to consumers. In lieu of an expansion to the Agency's sampling and testing program we suggest some minor modifications to FSIS Directive 10.010.1 *Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef*.

- The Directive provides for three ways that establishments manufacturing ground beef can become eligible for reduced government sampling (Section VI, B).

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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* O157:H7 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, 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 resolution to this issue with the agency.

Sincerely,



Lynn Graves Delmore, Ph.D.
Beef Raw Material/Technical Specialist

cc: David Gilbert, Vice President of Beef Operation
Michael Hoppe, Vice President of Legal Counsel
Webber Neal, Assistant Vice President of Technical Services
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Bill Pyle, Food Safety and Regulatory Compliance Manager
Wayne Morgan, Ph.D., Beef Raw Material/Technical Specialist

ATTACHMENT 1

The following data was collected from three manufacturers of ground beef patties. 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.

1	Five 75 gram samples.	375 g
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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.