UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	10,010.1	2-1-98

Microbiological Testing Program For *Escherichia coli* O157:H7 in Raw Ground Beef

I. PURPOSE

This Directive provides FSIS inspection personnel and compliance officers instructions for selecting, collecting, and submitting raw ground beef samples to be tested for *Escherichia coli* O157:H7. Also, attachment 1 provides the background of the testing program and questions and answers addressing issues such as the reporting of results and actions taken by the Agency.

II. CANCELLATION

FSIS Notice 50-94

III. REFERENCES

Federal Meat Inspection Act
FSIS Directives 10, 230.2 and 10,210.1

IV. RESERVED

V. TERMINOLOGY

The following terms apply for purposes of the testing program in this directive:

Sampled Lot All raw ground beef products produced between performance of complete cleaning and sanitization procedures for all equipment used in handling or processing a raw ground beef product.

Raw Ground Beef Products Raw comminuted (chopped or ground) meat food products made from cattle carcasses (beef and/or veal), such as ground beef, hamburger, veal patties, and beef patty mix, that may be distributed to consumers as such. (Sampled products may contain beef derived from advanced meat recovery systems and/or Mechanically Separated Beef, but these products are not to be sampled as such. Nor are products that contain another type of livestock product in addition to beef (for example, fresh beef and pork sausage).)

Positive Sample A sample is positive for E. coli O157:H7 when it is positive for E. coli O157 and (1) the H7 antigen test is positive or (2) the H7 antigen test is nonspecific or the culture is nonmotile and either toxin or one or more toxin genes are present.

VI. SAMPLE COLLECTION INSTRUCTIONS AT INSPECTED ESTABLISHMENTS

A. When the Office of Public Health and Science (OPHS) transmits FSIS Form 10,210-3 under sample project code MT03, inspection personnel collect samples in accordance with the instructions for MT03 found in FSIS Directive 10,210.1.

B. Unless otherwise directed by OPHS through supervisory channels or an establishment has had a positive test result within 6 months, inspection personnel should not collect samples at establishments that either:

1. Conduct routine daily testing of their raw ground beef products or boneless beef to be used in raw ground products for *E. coli* O157:H7,

2. Require suppliers of boneless beef to certify that each lot received has been tested and found negative for *E. coli* O157:H7, or

3. Use validated pathogen reduction interventions on beef carcasses, routinely verify the interventions effectiveness periodically through testing for *E. coli* O157:H7, and prevent the use of boneless beef or carcasses from outside sources.

C. To verify that establishments have implemented one or more of the above, inspection personnel ensure that establishments have a testing protocol on file, testing records documenting positive and negative results, or certificates. Inspection personnel also can observe the operation of pathogen reduction interventions and review related records. Upon receiving the FSIS Form 10,210-3, inspection personnel should review the records to determine that no positive results have been reported within 6 months. This record review should be done within the time period for sample collection indicated on the form.

D. If samples are not collected, inspection personnel complete block 33 of FSIS Form 10,210-3.

E. If notified that a sample is confirmed positive for *E. coli* O157:H7, inspection personnel:

1. Condemn the sampled lot, unless it is fully cooked in accordance with 9 CFR 318.23 or processed in an equivalent manner to that required by the regulations.

2. Collect subsequent samples from new lots on a daily basis in accordance with the instructions for MT04 found in FSIS Directive 10,210.1 until 15 consecutive ground beef samples have tested negative for *E. coli* O157:H7. OPHS will issue the necessary number of FSIS Form 10,210-3 under sample project code MT04 to the appropriate IIC.

F. Direct questions through supervisory channels to the Technical Center.

VII. SAMPLE COLLECTION INSTRUCTIONS AT RETAIL OUTLETS

A. OPHS will transmit FSIS Form 10,210-3 under sample project code MT05, to the Assistant District Manager for Enforcement at the appropriate District Office, for the week that samples are to be collected.

B. Compliance officers should randomly select the retail outlet from which a sample will be collected. An effort should be made to visit retailers at a time when the retail outlet is grinding product.

C. Compliance officers should collect samples in accordance with the instructions for MT05 found in FSIS Directive 10,210.1.

D. If samples are not collected, compliance officers complete block 33 of FSIS Form 10,210-3.

E. If notified that sample is confirmed positive for *E. coli* O157:H7, compliance officers collect samples on a daily basis in accordance with the instructions for MT06 found in FSIS Directive 10,210.1 until 15 consecutive ground beef samples have tested negative for *E. coli* O157:H7. OPHS will issue the necessary number of FSIS Form 10,210-3 under sample project code MT06 to the appropriate compliance officer.

VIII. RESPONSIBILITIES OF IMPORT INSPECTION PERSONNEL

A. When the import inspector is instructed to sample imported raw ground beef products for *E. coli O157:H7* testing, he/she should collect samples in accordance with instructions for project MT08 found in FSIS Directive 10,210.1, and submit FSIS Form 10,210-3 with each sample. The imported product subject to *E. coli* O157:H7 testing is represented by the following product codes: BABXK2 (ground fresh beef greater than 10 pounds), BABXK3 (ground fresh beef 10 pounds or less), and BABXK4 (beef patties).

B. If the sample is confirmed positive for *E. coli O157:H7*, the foreign establishment will be placed on intensified inspection. The import inspector will collect samples form the next 15 consecutive shipments of ground beef shipped to the United States from that establishment. In the case of shipments form Canada, the establishment may request the Canadian Food Inspection Agency to sample shipments prior to shipping and to certify negative results for *E. coli O157:H7* on the health certificate.

C. Import inspection personnel will not collect samples of imported raw ground beef if the shipment is accompanied by a health certificate containing the following statement: "This product has been subject to an *E. coli* O157:H7 prevention and/or testing program that was monitored by the inspection system of the exporting country." This certifies that the exporting establishment meets the criteria listed in paragraph VI. B, including the requirement that establishments have not had a positive test result within the last 6 months.

/s/ Maraget O'K. Glavin

Deputy Administrator
Office of Policy, Program Development and Evaluation

Attachment

BACKGROUND AND QUESTIONS AND ANSWERS

On October 17, 1994, FSIS began a microbiological testing program for *Escherichia coli* O157:H7 in raw ground beef and issued FSIS Notice 50-94, "Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef," on December 23, 1994. The objective of the testing program is to test for *E. coli* O157:H7, and to stimulate industry action(s) to reduce the presence of the pathogen in raw ground beef. Since the initiation of the FSIS testing program, a number of grinders have instituted their own programs and routinely test their ground beef products or raw materials used in ground beef products for *E. coli* O157:H7. Others have begun requiring suppliers of raw boneless beef to test for and certify that the organism is not present in the product.

There are approximately 1,900 plants under FSIS inspection that produce ground beef. There are approximately 100,000 retail outlets that grind beef on a regular basis. Each month, FSIS randomly selects an appropriate number of inspected plants and retail outlets for sample collection. Also, an appropriate number of samples are taken from imported ground beef product(s) upon FSIS Import Inspection and at state inspected establishments by state program personnel. FSIS bases its sampling plan on information from Centers for Disease Control and Prevention (CDC) sentinel sites, historic data of outbreaks of food borne illness, and information developed by Office of Public Health and Science (OPHS). If a plant or retail outlet initiates its own routine sampling program, has a certification from suppliers that the product was tested, or, in the case of inspected plants, uses in-plant validated pathogen reduction interventions on beef carcasses, FSIS will not collect samples.

When a sample is positive for *E. coli* O157:H7, subsequent samples from new lots are collected daily until 15 consecutive samples are negative. Additionally, if an FSIS inspected plant's or retail outlet's ground product is associated with an outbreak of food borne illness linked to *E. coli* O157:H7, FSIS will begin daily sampling until 15 consecutive samples test negative for *E. coli* O157:H7.

From time to time, FSIS evaluates the functioning of this program in relation to its objectives and makes changes as necessary to facilitate the achievement of current program objectives.

QUESTION AND ANSWERS

1. **Question:** What amount of ground product will be collected and tested?

   Answer: Compliance and inspection personnel will collect a one (1) pound sample of ground beef product. From this sample, 325 grams will be analyzed for *E. coli* O157:H7.

2. **Question:** How does the laboratory identify the presence of *E. coli* O157:H7?

   Answer: The laboratory analysis has two distinct steps. The first step can be accomplished in two days from collection of the sample. It is an immunochromatography-based screening test that identifies the presence of *E. coli* O157:H7 as well as some other cross-reacting bacteria that are not *E. coli* O157:H7. If the screening test is negative, *E. coli* O157:H7 is not present in the sample tested.

   If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7, and additional biochemical and serological testing is necessary to confirm the result. This second step, confirmatory testing, can usually be accomplished in 5 days from collection of the sample, but can sometimes take longer.

   Samples positive for *E. coli* O157:H7, where the H7 antigen test is positive or non-specific, or the culture is non-motile, will be tested for the presence of toxin and/or toxin genes. If the toxin and/or one or more toxin genes are present, the sample will be treated as positive for *E. coli* O157:H7 and regulatory action will be taken. The cultures will also be tested by pulsed-field gel electrophoresis (PFGE) for potential epidemiological association.

3. **Question:** Who will receive test results?

   Answer: The FSIS laboratories will electronically send negative results to the appropriate District Office by close of the second business day after collection. The District Office will inform the appropriate plants or retail outlets.

   If there are potentially positive (screen test positive) results, OPHS will notify the appropriate headquarters staffs and District Office by close of business the day the screening test is completed. The District Office will inform the appropriate plants or retail outlets.

   If the results are confirmed as positive, OPHS will notify the appropriate headquarters staffs and District Office to initiate enforcement actions. In addition, OPHS will notify the affected state/local food regulatory or health authorities for their follow-up actions.

4. **Question:** If a sample is confirmed to be positive for *E. coli* O157:H7, what products would be subject to voluntary recall?

   Answer: All raw, comminuted beef products produced on the shift represented by the positive sample would be subject to voluntary recall. If the raw, comminuted beef product was used as an ingredient in other raw products, those secondary products would also be subject to recall. If the positive product was used as an ingredient in cooked products or other further processed products, the FSIS Recall Committee will evaluate each situation and proceed on a case-by-case basis.

5. **Question:** Why will an entire shift's (clean-up to clean-up) production be subject to voluntary recall?

   Answer: *E. coli* O157:H7 contamination can enter the process at any point during a shift. The contaminant can then be widely disseminated throughout all the ground product by the grinding process itself. The potential for contaminating all subsequent handling, processing, and packaging equipment is also significant. The potential to contaminate product exists until an effective, complete cleaning and sanitization process has eliminated the source of the contamination and any subsequent cross contamination.

6. **Question:** If an establishment does more than one complete cleaning and sanitization a day, would the entire day's production still be subject to voluntary recall in the event of a confirmed positive?

   Answer: No. For the purpose of this program, a "shift" will be considered the period of production occurring between two complete cleaning and sanitization procedures. For example, if an establishment does a complete cleaning and sanitization procedure every 4 hours, the sample collected represents only the product produced during the time period between cleanups.

7. **Question:** If a retail sample is confirmed positive for *E. coli* O157:H7, what products will be subject to voluntary recall?

   Answer: The same factor that determines the scope of potential recall in a Federally inspected establishment must be considered in the retail environment. After a contaminant is introduced, the potential for contamination exists until an effective, complete cleaning and sanitizing process has eliminate the source of the contamination and any subsequent cross contamination. All meat or poultry products exposed to the same direct food contact surfaces as the sampled product would be subject to recall. These are products

exposed to those surfaces during a period between the two complete cleaning and sanitizing procedures. Additionally, individual store production procedures for repackaging or reworking such products would be evaluate to determine whether other production periods might be implicated.

8. **Question:** What other actions will be taken by FSIS in cases involving retail stores which have sample confirmed positive for *E. coli O157:H7?*

   Answer: District Enforcement will notify the retailer and the appropriate State and/or local food regulatory agency of the confirmed positive sample. The possibility of making an effective trace back of the source of contamination will be made on a case-by-case basis.

9. **Questions:** At retail stores, will compliance officers sample product that has been produced in Federally inspected establishments as "case ready" (bears the marks of inspection) and remains intact?

   Answer: No. Compliance officers will be sampling only product that has been processed at the retail store.

10. **Question:** Will coarse ground product be subject to sampling at Federally inspected establishments?

    Answer: Yes. All raw, comminuted beef products which bear the mark of inspection are subject to sampling at Federally inspected establishments. In cases where establishments produce a number of different products, the inspector should select the sample from the most consumer-ready type product produced. For example, if an establishment packs coarse ground beef in 10-pound chubs and finely ground beef in 1-pound packages, the line producing the 1-pound packages should be sampled.

11. **Question:** Will imported products be sampled for *E. coli* O157:H7?

    Answer: Yes. A samples of imported ground beef products will be collected for testing when the import inspector is directed to do so during import reinspection.

12. **Question:** How will State-inspected plants be sampled?

    Answer: State-inspected plants will be included in the national program. Each State inspection program will be provided with sampling instructions and request forms. State inspectors will randomly collect samples from plants producing ground beef products.

Sample results will be reported to the Director of Federal/State Relations Staff, who will report results to appropriate State Directors. The actions applicable to federally inspected product applies to State-inspected product.

13. **Question:** Must inspected establishments or retail outlets receive prior approval for their own testing programs?

Answer: Laboratories may use the testing procedures currently in use by FSIS or other methods for the detection of *E. coli* O157:H7. If rapid screening tests are used, they must meet or exceed the following characteristic: sensitivity > = 98%, false negative rate < = 2%, specificity > = 90%, false positive rate < = 10%, and efficiency > = 94%.