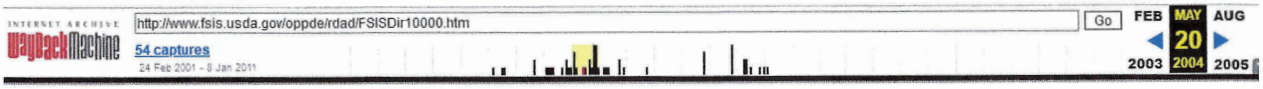
Exhibit 1056
Mullins Decl. Appendix L-1
(FSIS Website from Wayback Machine)

Screen capture completed by J L Mullins from Wayback Machine, Internet Archive, on November 18, 2023, capturing screen from May 20, 2004 from the webpage for FSIS Regulations and Directive Development at URL:
https://web.archive.org/web/20040520135754/http:/www.fsis.usda.gov:80/oppde/rdad/FSISDir10000.htm



FSIS

United States Department of Agriculture
Food Safety and Inspection Service
Office of Policy and Program Development
Washington, DC 20250-3700

REGULATIONS AND DIRECTIVES DEVELOPMENT

- Home
- Rulemaking
- Federal Publications
- OPPD Home Page

FSIS DIRECTIVES

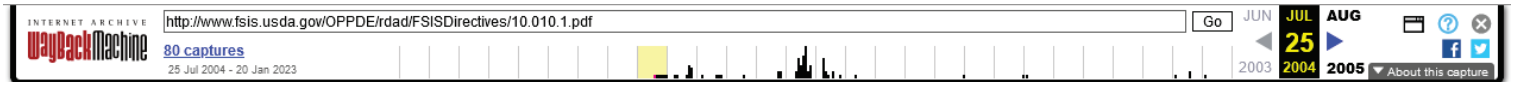
10,000 SERIES - Laboratory Services

SERIES	TITLE
10,001.1	Sample Reserves Requested by the Food and Drug Administration (9 pp)
10,010.1 Rev 1	Microbiological Testing Program for *Escherichia Coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components (28 pp) New!

- Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program And Other Verification Activities For *Escherichia coli* O157:H7 (PDF Only, 16 pp)

Exhibit 1056
Mullins Decl. Appendix L-2
(FSIS Directive from Wayback Machine)

Screen capture completed by J L Mullins from Wayback Machine, Internet Archive, on November 18, 2023 at URL:
https://web.archive.org/web/20040725051246/http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf



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

FSIS DIRECTIVE	10,010.1, Revision 1	3/31/04

MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR *Escherichia coli* O157:H7 IN RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS

NOTE: *FSIS PESONNEL ARE NOT TO IMPLEMENT THIS DIRECTIVE UNTIL MAY 17, 2004*

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

FSIS DIRECTIVE

10,010.1, Revision 1 | 3/31/04

MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR *Escherichia coli* O157:H7 IN RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS

NOTE: ***FSIS PESONNEL ARE NOT TO IMPLEMENT THIS DIRECTIVE UNTIL MAY 17, 2004***

Part I – General

I. PURPOSE

This directive provides Food Safety and Inspection Service (FSIS) inspection program personnel, program investigators, and import inspection personnel instructions for sampling raw beef products as part of verification testing for *Escherichia coli* O157:H7 (*E. coli* O157:H7) to ensure the protection of public health. It also outlines actions FSIS will take when a raw ground beef product sample, raw ground beef component sample, or raw beef patty component sample is found to be positive for *E. coli* O157:H7. Attachment 1 provides questions and answers for further clarification.

II. CANCELLATION

FSIS Directive 10,010.1, dated 2/1/98
FSIS Notice 11-03, dated 4/18/03
FSIS Notice 47-02, dated 11/20/02

III. REASONS FOR REISSUANCE

This directive has been rewritten in its entirety to be consistent with the Agency's current policies regarding *E. coli* O157:H7. No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. This directive provides new instructions: 1) for the policy that non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated; 2) for follow-up actions taken after an initial FSIS sample tests positive; and 3) for verifying the control of beef products that are presumptive positive or positive for *E. coli* O157:H7.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC;Import Offices

OPI: OPPD

IV. REFERENCES

Federal Meat Inspection Act
9 CFR 318.2, 325.10, 416, 417, and 500
FSIS Directives 5000.1, Revision 1, 5000.2, and 8080.1, Revision 3
Federal Register Notices: Policy on Beef Products Contaminated with *E. coli* O157:H7 (64 FR 2803, 1/19/99); Recent Developments Regarding Beef Products Contaminated with *Escherichia coli* O157:H7; Public Meeting (65 FR 6881, 2/11/00); Availability of and Request for Comment on FSIS Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef (66 FR 55912, 11/05/01); and *E. coli* O157:H7 Contamination of Beef Products (67 FR 62325, 10/7/02).

V. BACKGROUND

Non-intact raw beef products contaminated with *E.* coli O157:H7 are adulterated. Non-intact beef products include ground beef; beef that has been injected with solutions; beef that has been mechanically tenderized by needling, cubing, Frenching, or pounding devices; and beef that has been reconstructed into formed entrees. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated. Establishment records and HACCP documents (e.g., the flow chart and hazard analysis) should identify the intended use of intact raw beef products. Manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts are removed) are an example of intact raw beef product that may be intended to be used for non-intact product. Raw beef products contaminated with *E. coli* O157:H7 may, however, be further processed at official establishments to destroy the pathogen.

On October 7, 2002, FSIS published a notice requiring establishments that had not already reassessed their Hazard Analysis and Critical Control Point (HACCP) plans for raw beef products in light of relevant *E. coli* O157:H7 data to do so to determine whether *E. coli* O157:H7 contamination was reasonably likely to occur in their production process for raw beef products (67 FR 62329). In that notice, FSIS advised that it intended to scrutinize very closely the hazard analyses and HACCP plans of those slaughter or deboning establishments that had conducted a reassessment and decided that an intervention was not necessary. Also in that notice, FSIS stated that establishments receiving product for grinding should address *E. coli* O157:H7. FSIS explained that these establishments could employ validated Critical Control Points (CCPs) in their HACCP plans to address *E. coli* O157:H7, or the establishments could incorporate purchase specifications in their HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs to prevent *E. coli* O157:H7-contaminated product from entering their establishments.

This directive focuses on raw ground beef products and the beef products that are used to produce raw ground beef products. These products will be the focus of FSIS' verification sampling program for *E. coli* O157:H7. Products that FSIS may sample are listed in Parts II and VI.

This directive discusses the significance of a finding that a sample is "presumptive positive." A sample is presumptive positive when analytical steps of microbiological analysis indicate the strong possibility that *E. coli* O157:H7 is present, but additional steps are needed to confirm the presence or absence of the organism.

A sample is confirmed to contain the bacterial isolate of *E. coli* O157:H7 through testing by either FSIS or non-FSIS laboratories when biochemical, serological, or genetic testing results in a finding of *E. coli* Serotype O157:H7, O157:H7:NM (nonmotile), or O157:H7-indeterminate.

FSIS recognizes that many establishments test their raw ground beef products, raw ground beef components, and raw beef patty components for *E. coli* O157:H7. The Agency applauds and encourages this practice. FSIS points out, however, that if an establishment finds a sample of one of these products to be presumptive positive for *E. coli* O157:H7, that product would only be allowed to move off site under appropriate controls for proper disposition at official establishments, landfill operations, or renderers. If the establishment's confirmation testing finds the sample negative for the pathogen, that product may be shipped in commerce under normal procedures. Product that is confirmed positive for *E. coli* O157:H7, through FSIS or establishment testing, may also be moved off site under appropriate controls for proper disposition. If product is confirmed positive, or is presumptive positive and no additional testing confirmed the product negative, such product destined for an official establishment for further processing that will destroy the pathogen would have to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1). Such product destined for a landfill operation or renderer would have to move under company control.

According to 9 CFR 325.10, if product is found to be adulterated or misbranded after it has been transported from an official establishment, transportation back to the establishment that originally produced the product or to another official establishment must be authorized. According to 9 CFR 318.2(d), inspection program personnel must place a U.S. retained tag at the time of reinspection on all products suspected of being adulterated. FSIS will allow product that is positive or presumptive positive for *E. coli* O157:H7 to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1), rather than as required in 9 CFR 325.10 and 318.2(d) to facilitate proper disposition of product that may be adulterated with *E. coli* O157:H7. FSIS intends to modify these regulations to reflect this policy.

Part II -- Inspection Program Personnel Responsibilities for Collecting Raw Ground Beef Product Samples from Official Establishments

A. What comprises raw ground beef products?

Raw Ground Beef Products: Raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix. A raw ground beef product that contains any amount of beef product derived from advanced meat recovery (AMR) systems is considered a raw ground beef product. Raw product comprised only of beef from AMR systems is not considered a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component (see Part VI of this directive). Ground or chopped products made from both beef and other meat or poultry products and beef sausage products are not subject to FSIS' *E. coli* O157:H7 sampling and testing.

B. How is raw ground beef product sampling conducted at official establishments?

1. When the Office of Public Health and Science (OPHS) schedules samples to be taken at an establishment, OPHS will send the Inspector-in-Charge (IIC) FSIS Form 10,210-3, "Requested Sample Programs." OPHS will send the form electronically in the near future. Specific information for the sample to be collected will be included on the sample request or in revisions to FSIS Directive 10,210.1, under the appropriate project.

2. Inspection program personnel may be instructed to collect more than one sample per lot in certain circumstances (e.g., if FSIS has reason to believe that product is at high risk of being contaminated with *E. coli* O157:H7 because of illnesses or outbreaks that may have been associated with the establishment, or because the establishment or its suppliers have previously produced product that tested positive in FSIS-collected verification samples for *E. coli* O157:H7).

3. Before collecting samples, inspection program personnel are to notify official establishment management that they will be collecting a sample and are to provide enough time for the establishment to hold the sampled lot. Inspection program personnel are to inform the establishment of the reason they are taking the sample (e.g., routine FSIS verification testing, follow-up sampling in response to an *E. coli* O157:H7 positive, traceback sampling, or follow-up sampling in response to an *E. coli* O157:H7 outbreak).

4. Inspection program personnel collect samples from the current day's production, and the samples should be, whenever possible, in their final packages. Samples should not be sent to the laboratory until the establishment has completed pre-shipment review for that lot. If product from final packages is not available for sampling, inspection program personnel should collect an aseptic sample. Products should be held under security following established Agency controls.

5. If a sample must be held overnight, it must be refrigerated. If a sample must be held longer than overnight, it must be frozen.

6. After the establishment completes the pre-shipment review, inspection program personnel should prepare the sample to be sent to the laboratory on the first available Federal Express pick-up.

Part III – Supplier Information

A. What actions does FSIS take when there is an FSIS presumptive *E. coli* O157:H7 positive for a raw ground beef product sample?

1. Every FSIS verification sample that is eventually confirmed positive by FSIS for *E.* coli O157:H7 goes through three stages of analysis. The results of each stage are reported to IIC's on LEARN. These samples are initially screened and, as appropriate, are reported as "Potential Positives." At the next stage, based on laboratory results, some samples are reported as "Presumptive Positives." Because most "Presumptive Positives" are eventually confirmed, the contact person in the District where the establishment is located needs to immediately inform the establishment that the sample is a "Presumptive Positive." At the same time, the District contact person also informs the establishment management that if the results are confirmed positive, FSIS will collect the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

a. name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment;

b. supplier lot number; and

c. production date, name of supplied material, and any additional information to clearly identify the material used to the management of the supplying establishment.

2. If the source materials are from a foreign establishment, the District contact person should inform the establishment that FSIS will also collect the following information, should the product be confirmed positive for *E. coli* O157:H7:

a. country of origin;

b. foreign establishment number;

c. shipping mark;

d. I-house; and

e. barcoding or any other information that identifies the origin of the product.

3. The District contact person advises the establishment that it should begin to gather the information above, along with distribution information.

B. What information does FSIS collect when a raw ground beef product sample collected by FSIS for verification testing at an official establishment is confirmed positive for *E. coli* O157:H7, and whom does FSIS notify concerning the positive?

1. When a sample is confirmed positive, inspection program personnel collect from the establishment the information in Part III. A. Inspection program personnel make note of any information that the establishment is unable to provide.

2. Inspection program personnel forward the information by e-mail to the designated DO contact, with a "cc" to the front-line supervisor.

3. The DO will access the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), open a case file for the incident, and follow STEPS procedures.

4. STEPS automatically e-mails the DO that has jurisdiction over the supplying establishment. The DO notifies the IIC at the supplying establishment to perform a HACCP 02 and other activities described in Part VI.

5. The DO notifies all of the supplying establishments in the District, by telephone, of the positive finding and provides the suppliers the production date for the product that the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot. The DO documents the date and time of this oral notification in the STEPS system.

6. After all necessary information on the supplying establishment has been entered into the STEPS system, the DO reviews the information in the STEPS system and sends an e-mail notification to the supplier about the *E. coli* O157:H7 positive product.

7. The supplier information is maintained within the STEPS system and is maintained on FSIS' network. Users must be given access to this site.

NOTE: If the confirmed positive sample came from product which was made, in whole or in part from imported product, the DO provides information about the supplier to the Office of International Affairs (OIA), Import-Export Programs Staff, by telephone, and documents the date and time of this oral notification in the STEPS system. The DO then provides information about the supplier to OIA, Import-Export Programs Staff, through an e-mail message to importexport@fsis.usda.gov. OIA, in turn, forwards this information to the head of the inspection service in the country where the supplying establishment is located.

Part IV – Enforcement Actions in Official Establishments

A. What actions do inspection program personnel take if an FSIS sample taken from an official establishment is confirmed positive for *E. coli* O157:H7?

1. The DO is notified of a positive through the Biological Information Transfer and E-mail System (BITES).

2. Inspection program personnel, the DO, and Recall Management Staff (RMS) work together to determine the necessity of product retention, detention, or recall. The Technical Services Center (TSC) and OPHS may also serve as technical resources to assist in the decision making process. The DO will contact inspection program personnel and program investigators as necessary (see FSIS Directive 8080.1, Revision 3).

3. As set out in FSIS Directive 5000.1, Revision 1, inspection program personnel are to:

a. issue an NR under the appropriate 03 ISP code using the "verification" trend indicator; and

b. as soon as possible after the establishment has implemented its corrective action, perform a HACCP 02 procedure for the specific production that tested positive for *E. coli* O157:H7 and verify that the establishment implements corrective action that meets the requirements of:

i. 9 CFR 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan;

ii. 9 CFR 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan or if it is addressed in prerequisite programs; or

iii. 9 CFR 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the Sanitation SOPs.

4. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product.

5. If product disposition is to occur off site, inspection program personnel are to verify that the establishment that produced the positive product maintains appropriate control of the product by conducting the following activities when performing the 02 procedure:

a. obtaining the identity of the official establishment or obtaining the name and address of any renderer or landfill that will receive the product;

b. notifying, through e-mail, the contact person in the District that covers the establishment that produced the positive product that adulterated product is being transferred and providing the DO contact person the establishment number of the establishment where disposition will occur or the name and address of the landfill operation or renderer. The District contact person will notify the District where the establishment that will further process the product, landfill operation, or renderer is located, if the establishment, landfill operation, or renderer that is to receive the product is located in another District;

c. for product being transferred to a landfill operation or renderer, verifying that the establishment will maintain control of the positive product while it is in transit (e.g., through company seals);

d. for product being transferred to an official establishment, verifying that either 1) the establishment that produced positive product will maintain control of the product while it is in transit (e.g., through company seals) or 2) the product will move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1); and

e. verifying that records are available that show that the positive product received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, landfill operation, or renderer where disposition occurred. The HACCP 02 procedure at the establishment that produced the positive product cannot be completed for this specific production until the establishment has conducted pre-shipment review of the corrective action record and has received documentation evidencing proper disposal from the official establishment where disposition occurred or landfill operation or renderer where disposition occurred.

6. If inspection program personnel find noncompliance with paragraph 5, they are to contact the DO. The DO will investigate to determine whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

Part V – Follow-up Sampling

A. Are FSIS follow-up samples taken at official establishments after an FSIS-sample of raw ground beef is confirmed positive for *E. coli* O157:H7?

1. If inspection program personnel identify no significant problems through the HACCP 02 procedure (see Part IV. A. 3. b.), inspection program personnel are to contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up verification sample. Inspection program personnel should copy (CC) their front-line supervisor and the DO designated representative on their e-mail message. The request must include the establishment number, the number of forms (in this case 1), the type of sample to be collected (i.e., a product sample), the purpose of the request (i.e., follow-

up sampling in response to a confirmed positive in raw ground beef), the sample form number of the original positive sample triggering this request, and the DO official approving the request. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, Requested Sample Programs, or in revisions to FSIS Directive 10,210.1, under the appropriate project. Inspection program personnel should collect the follow-up sample as soon after the establishment has taken its corrective action as possible. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

2. If inspection program personnel identify regulatory noncompliance, they should document the noncompliance in accordance with FSIS Directive 5000.1, Revision1, Chapter IV. If inspection program personnel find that the establishment may have moved positive product without appropriate controls or if they find the establishment may not have records showing that positive product received proper disposition, they should contact the DO. Inspection program personnel should also collect one follow-up sample as soon after the establishment has taken its corrective action as possible. Inspection program personnel are to contact OPHS so a form can be sent for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

3. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine when it would be appropriate to collect the follow-up sample and how to work with the establishment to ensure proper and timely disposal of the product.

4. If the inspection program personnel have concerns regarding whether the design of the HACCP system is adequate to ensure food safety, they should not collect a follow-up sample. They should notify their front-line supervisor, who will determine whether it is necessary to bring in an Enforcement Investigations and Analysis Officer (EIAO) to the establishment to conduct a comprehensive assessment of the food safety systems. If the EIAO determines that the establishment's corrective actions appear to be appropriate and effective, the EIAO will contact OPHS so a form can be sent to inspection program personnel for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. Inspection program personnel are to take the sample as soon as possible after they receive the form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

5. If a follow-up sample is found positive, the DO is notified through BITES, and the DO will determine the appropriate follow-up action.

6. If the EIAO determines that the corrective actions are inappropriate or ineffective, the EIAO will recommend an enforcement action as described in 9 CFR 500.3 or 500.4 (e.g., Notice of Intended Enforcement (NOIE), withholding, or suspension).

7. If the District Office decides to either defer a decision on suspending the establishment, or a suspension action is taken and then put into abeyance (see FSIS Directive 5000.1, Revision 1, Chapter IV), FSIS will conduct follow-up sampling to verify that the corrective action taken by the establishment is appropriate and effective. The DO will determine the number of follow-up samples. Guidance on how to determine the number of follow-up samples will be provided to the DO. The DO should contact OPHS so the appropriate number of forms can be sent to inspection program personnel for the collection of follow-up verification samples. See Part V. A. 1., for information on e-mailing OPHS to request follow-up sampling forms. The guidance is designed to provide enhanced statistical confidence for finding low levels of *E. coli* O157:H7 but is not designed to provide validation of the establishment's food safety system.

PART VI - FSIS' Verification Activities at Establishments Producing Raw Ground Beef Components or Raw Beef Patty Components

A. If FSIS confirms raw ground beef product at an official establishment or retail facility positive for *E. coli* O157:H7, and a second official establishment supplied the product used to produce the ground product, what verification activities does FSIS conduct at the supplying establishment?

The IIC at the supplying establishment ensures that the inspection program personnel perform a HACCP 02 procedure to verify that the establishment met the applicable regulatory requirements at all CCPs in the HACCP plan (monitoring, verification, recordkeeping, corrective actions, and reassessment) for the production lots sent to the establishment or retail facility where FSIS found the positive. If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision1, Chapter IV.

B. If a grinding establishment or retail facility receives incoming product for grinding, and FSIS finds the raw ground product positive for *E. coli* O157:H7, will FSIS test product from suppliers? If so, how do inspection program personnel collect samples?

1. When FSIS conducts sampling at official establishments or at retail, and a sample tests positive for *E. coli* O157:H7, FSIS may test raw ground beef components and raw beef patty components at the supplying establishment.

2. If inspection program personnel are requested to collect raw ground beef components or raw beef patty component samples, they are to follow the instruction in Part II of this directive and collect samples as described in Attachment 2. The types of product inspection program personnel may collect are:

Raw Ground Beef Components: These components include raw esophagus (weasand) meat, head meat, and cheek meat; beef manufacturing trimmings (e.g., 90/10, 85/15, 75/25, 65/35, 50/50); boneless beef; beef from AMR systems; and lean finely textured beef (LFTB).

Raw Beef Patty Components: These components include all the components listed above in Raw Ground Beef Components, as well as partially defatted chopped beef (PDCB), finely textured PDCB; heart; and partially defatted beef fatty tissue (PDBFT).

3. Also, inspection program personnel are to only collect samples of raw ground beef components or raw beef patty components that are intended for use in raw non-intact product. To determine the intended use of the products, inspection program personnel are to review establishment records and HACCP documents. In cases where the establishment records and HACCP documents (e.g., flow chart and hazard analysis) are unclear about the intended user, FSIS will handle the product as if it were intended for use in raw non-intact product. If the establishment has not identified the intended use or consumers of the finished product, the establishment is out of compliance with 9 CFR 417.2(a)(2).

C. If FSIS finds raw ground beef product at an official establishment positive for *E. coli* O157:H7, and the ground product was derived from raw ground beef components produced at the same establishment, would FSIS sample raw ground beef components at that establishment?

FSIS may sample and test raw ground beef components at an establishment that produces raw ground beef products from such components if FSIS finds the ground beef product positive. If instructed to sample such products, inspection program personnel should follow the sampling procedures in Part VI. B.

D. What enforcement actions do inspection program personnel take if FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7?

Inspection program personnel are to follow the instructions in Part IV. A. The enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7 are the same as the enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef product positive for *E. coli* O157:H7. Similarly, the controls necessary for movement of presumptive positive or positive raw ground beef products are also necessary for movement of presumptive positive or positive raw ground beef components or raw beef patty components.

.

PART VII – Inspection program personnel responsibilities related to an establishment's testing of product for *E. coli* O157:H7

A. Can establishments conduct pre-shipment review for product that is not at the producing establishment?

FSIS has taken a consistent position that establishments can conduct pre-shipment review when the product is at locations other than at the producing establishment provided that the product does not leave the control of the producing establishment. Some establishments analyze samples for *E. coli* O157:H7 while the product is being moved but is still under the establishment's control. FSIS is providing the establishments the flexibility to move this product prior to pre-shipment review being conducted when the establishment is conducting testing for *E. coli* O157:H7 and maintains control of the product. FSIS has instructed inspection program personnel that they have access to the results of any testing and of any monitoring activities that are performed that may have an impact on the establishment's hazard analysis (FSIS Directive 5000.2). Inspection program personnel must review these results on at least a weekly basis.

B. What do inspection program personnel verify if an establishment conducts verification testing for *E. coli* O157:H7?

1. Inspection program personnel are to review the records associated with any *E. coli* O157:H7 testing conducted by an establishment. If inspection program personnel find a presumptive positive or confirmed positive *E. coli* O157:H7 result in the testing records, they should verify that the establishment is implementing corrective actions that meet the regulatory requirements as part of a HACCP 02 procedure as described in Part IV.

2. If establishment records show that the establishment transports product that it has found presumptive positive or positive for *E. coli* O157:H7 to another establishment for appropriate disposition, or if establishment records show that the establishment moves product before *E. coli* O157:H7 test results become available, inspection program personnel should verify that the establishment—

a. maintains records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;

b. maintains records identifying the official establishment that is to receive product for which results are pending;

c. maintains control of product that is destined for a landfill operation or renderer while the product is in transit (e.g., through company seals);

d. maintains control of product that is destined for an official establishment while the product is in transit (e.g., through company seals) or ensures such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

e. maintains records that show that presumptive positive or positive product, including product that moved pending test results, received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, renderer, or landfill where disposition occurred; and

f. completes pre-shipment review for product from a lot that has tested positive or presumptive positive and that was moved pending test results only after it has the records described in paragraph e. for that particular product.

3. If inspection program personnel are aware that an establishment has found product presumptive positive or positive for *E. coli* O157:H7, and that the establishment is currently moving the product for further processing to destroy the pathogen or for destruction, they should verify that the establishment moves the product using the appropriate controls identified in Part VII. B. 2. Inspection program personnel should also notify the DO where the establishment that produced positive or presumptive positive product is located, through e-mail, of the establishment number or name and address of the renderer or landfill operation that is to receive the product. The DO contact person will notify the contact person in the District where the establishment, landfill operation, or renderer that is to receive the product is located, if that establishment, landfill operation, or renderer is located in another District.

4. If inspection program personnel find noncompliance with Part VII. B., 1., 2., or 3., they should contact the DO. The DO will investigate to determine whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

5. The HACCP 02 procedure for a specific production at the establishment that produced the positive or presumptive positive product cannot be completed until that establishment completes pre-shipment review, including review of the corrective action record, and has received documentation evidencing that product has been properly disposed of from the official establishment where disposition occurred or renderer or landfill operation where disposition occurred.

NOTE: When an establishment tests product, a presumptive positive or positive result alone does not warrant an NR. Inspection program personnel are only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions to meet the requirements in 9 CFR 417.3.

PART VIII – Receiving raw ground beef products, raw ground beef components, and raw beef patty components that are positive for *E. coli* O157:H7

What should inspection program personnel do at an establishment that receives raw ground beef products, raw ground beef components, and raw beef patty components that FSIS or an establishment has found positive for *E. coli* O157:H7*?*

When inspection program personnel perform a HACCP 01 or 02 procedure at an establishment that has received product from a lot that was found positive for *E. coli* O157:H7 product, they are to verify that:

1. the establishment documents the receipt of presumptive positive or positive product, as required under 9 CFR 417.5;

2. the establishment maintains control of the product; and

3. *E. coli* O157:H7 is addressed in the establishment's hazard analysis and HACCP plan, so that the positive product will receive an adequate lethality treatment to destroy the pathogen.

If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision 1, Chapter IV.

Part IX -- Verification Procedures Involving Instructional or Disclaimer Statements Concerning *E. coli* O157:H7

A. What is an instructional or disclaimer statement concerning *E. coli* O157:H7?

1. An <u>instructional statement</u> concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples of instructional statements concerning *E. coli* O157:H7 in raw ground beef components, raw beef patty components, and raw ground beef products may include, "for full lethality treatment" or "for cooking only." "Cooking" is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate *E. coli* O157:H7 or reduce the pathogen to an undetectable level, and "full lethality treatment" may be cooking or another process that eliminates *E. coli* O157:H7 or reduces the pathogen to an undetectable level, such as fermentation or salt curing.

2. A <u>disclaimer statement</u> concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were NOT used in the production of the product. An example of a disclaimer statement concerning *E. coli* O157:H7 is, "product has not been tested for *E. coli* O157:H7."

B. What type of products can bear these labeling statements?

Establishments can only place these statements on product for use at other official establishments. When the Labeling and Consumer Protection Staff (LCPS) approves the use of instructional labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that ensure these products receive adequate lethality treatment. When LCPS approves the use of disclaimer labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plan. Establishments' use of these statements is entirely optional.

C. What verification activities should inspection program personnel conduct at establishments that place instructional or disclaimer statements concerning *E. coli* O157:H7 on the labeling of raw ground beef products, raw ground beef components, or raw beef patty components?

1. When conducting an 04B04 procedure, inspection program personnel are to verify that the establishment has received sketch approval from LCPS and that it is maintained in the company's required labeling records (see 9 CFR 317.4(a)).

2. If inspection program personnel find that the establishment did not receive sketch approval or does not maintain that sketch approval in its official labeling records, they are to document the noncompliance on an NR under the Inspection System Procedure (ISP) code 04B04, and they are to document noncompliance with 9 CFR 317.4(a).

3. When performing a HACCP 01 or 02 procedure to verify the HACCP regulatory requirements are met for the production of such products, inspection program personnel are to verify that:

a. the instructional or disclaimer statement does not serve as a control or CCP to address *E. coli* O157:H7;

b. the establishment has not used the statement to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in the production of these products;

c. the use of any instructional statements is reflected in the establishment's decisionmaking documents (9 CFR 417.5) or hazard analysis (9 CFR 417.2(a)(1)); and

d. the establishment's HACCP plan for products on which it places a disclaimer statement includes a validated intervention for *E. coli* O157:H7.

4. If inspection program personnel find that the establishment's use of instructional statements does not meet the criteria in paragraph 3. a., b., or c. or that the establishment's use of disclaimer statements does not meet the criteria in paragraph 3. a. or b., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

5. If inspection program personnel find that the establishment's HACCP plan for product on which it places a disclaimer statement does not include an intervention for *E. coli* O157:H7, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV, using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. If inspection program personnel are concerned about product moving outside the establishment, they should initiate a regulatory control action (9 CFR 500.2).

D. What verification activities should inspection program personnel conduct at establishments receiving raw ground beef components, raw beef patty components, or raw ground beef products with instructional or disclaimer statements concerning *E. coli* O157:H7?

1. When performing an 01 or 02 procedure to verify the HACCP requirements are met for products produced using such incoming products, inspection program personnel are to verify that establishments that receive such incoming products:

a. have addressed the use of incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with *E. coli* O157:H7; and

b. are following any instructional statements on the incoming products.

2. If inspection program personnel find that the establishment has not met the criteria in paragraph 1., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

3. Inspection program personnel should retain product produced using such incoming products under the following conditions:

a. the establishment is not following the instructional statement, or the establishment is receiving product bearing a disclaimer statement and its hazard analysis or decisionmaking documents do not address the use of the incoming product as if it were contaminated with *E. coli* O157:H7;

b. the establishment's process may not be adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels; and

c. the product is not intended for further processing that would destroy the pathogen.

4. If inspection program personnel retain product, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. Inspection program personnel should also notify the DO through supervisory channels of the conditions observed in association with the use of instructional or disclaimer statements. The DO may send an EIAO into the establishment to conduct a comprehensive food safety assessment or invoke an enforcement action as described in 9 CFR 500.3 or 500.4.

PART X -- Retail Sampling

A. How is raw ground beef product sampling conducted at retail?

1. Retail sampling continues to be an important part of FSIS' *E. coli* O157:H7 sampling program. The likelihood that a specific retail facility will be sampled will depend on what the Agency learns about how raw ground beef product is handled at that facility.

2. When OPHS schedules samples to be taken at retail facilities, OPHS will send OPEER offices FSIS Form 10,210-3, "Requested Sample Programs." Specific information will be provided for the samples to be collected.

3. Program investigators are to make an effort to notify the retail facility the day before they plan to collect the raw ground beef product samples, so that the retail facility can prepare to hold the expected sampled lot. However, in cases when this is not possible, program investigators should try to get to the retail facility as close to the beginning of the grinding operation as possible.

4. Program investigators do not collect raw ground beef product that is received and sold as case-ready product or raw ground beef product that is only re-packaged at the retail store. Program investigators also do not collect raw ground beef product that is ground at retail if the retail facility only regrinds product previously ground at official establishments and does not conduct any practices that would introduce *E. coli* O157:H7 in the product (examples of situations in which samples should be taken include when the store mixes irradiated and un-irradiated beef; adds store trim; or grinds case-ready coarse ground product in a grinder also used to grind store trim if the sanitation program is not well documented, monitored, and verified for effectiveness).

5. When they collect the sample, program investigators obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of raw ground beef product sampled.

NOTE: When the source material for the sampled product is store-generated trim, the program investigator obtains and records the names and establishment numbers of the establishments that produced the product from which the store-generated trim was derived.

6. The supplier information is recorded on the retail worksheet that is used specifically for collection of raw ground beef products at retail.

7. In addition, the program investigator records the supplier lot number, production date, and other identifying information that would be useful to the supplier if it is later notified of a positive sample.

B. If a sample of raw ground beef product from a retail facility is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

The retail facility is notified of the positive *E. coli* O157:H7 result by the program investigator. FSIS will request a recall if any product in the sampled lot has been made available for retail sale. Program investigators and RMS are to work together to determine the necessity of product retention, detention, or recall. (See FSIS Directive 8080.1, Revision 3).

C. Whom does FSIS notify when a raw ground beef product sample at a retail facility is confirmed positive for *E. coli* O157:H7, and how is the notification given?

1. OPEER is notified of a retail positive through the Biological Information Transfer and E-mail System (BITES) and enters supplier information into the STEPS system.

2. The OPEER contact person accesses the STEPS system site with the list of suppliers for the sampled product that tested positive and follows the procedures for notifying suppliers in Part III. B.

D. If FSIS finds raw ground beef product produced at retail positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling at the retail facility?

After an FSIS sample tests positive, program investigators should contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up sample. The request must include the retail facility name and address, the number of forms (in this case, 1), the type of sample to be collected (i.e., product sample), the purpose of the request (i.e., follow-up sampling in response to a confirmed *E. coli* O157:H7 positive in raw ground beef), the sample form number of the original positive sample triggering this request, the date by which the form is needed, and the program investigator's name and work address. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, "Requested Sample Programs" or in revisions to FSIS Directive 10,210.1, under the appropriate project. In addition, when feasible, FSIS will schedule

verification activities, including testing, at the supplying establishment following an FSIS positive sample from a retail facility.

PART XI -- Import Sampling

A. How is raw ground beef product sampling conducted at import establishments?

1. OPHS works with the Office of International Affairs (OIA) to send import inspection personnel FSIS Form 10,210-3, "Requested Sample Programs." Certain information will be provided specific to the sample to be collected. Import inspection personnel are to follow the corresponding instructions found in the Import Manual of Procedures (Part 3, Section 5). When OPHS begins sending the form electronically, the Automated Import Information System (AIIS) will schedule samples and send the form electronically to import inspection personnel.

2. Import inspection personnel notify the import establishment management of the reason a sample is being collected for *E. coli* O157:H7 testing (routine FSIS verification testing, increased sampling, or intensified sampling). Imported products may be under increased sampling if OIA has determined that product may be at risk of being contaminated with *E. coli* O157:H7. When a shipment is to be sampled for FSIS testing, the importer, broker or applicant has an opportunity to voluntarily hold the product until the results are reported. Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. When a foreign establishment is under intensified sampling for *E. coli* O157:H7, FSIS holds the product to be sampled until negative results are reported by the laboratory.

B. If a sample of imported raw ground beef product collected from an import establishment is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

1. If the product is on hold at the import establishment, whether on FSIS hold or voluntary hold, import inspection personnel will initiate refused entry procedures on the entire lot.

2. FSIS will request a recall if any product in the sampled lot has been released into commerce. Program personnel, including OIA, the DO, and RMS, work together to determine the necessity of product retention, detention, or recall. OIA will coordinate with the DO to provide information to inspection program personnel and program investigators as necessary.

C. Whom does FSIS notify when an imported raw ground beef product collected at an import establishment is confirmed positive for *E. coli* O157:H7, and how is notification given?

1. If the lot has not moved into commerce, import inspection personnel notify establishment management, which is responsible for notifying the importer of record. Import inspection personnel should refer to Part 4, Section 11 of the Import Manual of Procedures for guidance on refused entry procedures.

2. If the lot has moved into commerce from the import establishment:

a. the import inspection personnel should send a copy of FSIS Form 9540-1 and the foreign health certificate via facsimile to OIA/Import Inspection Division.

b. OIA notifies the head of the inspection service in the country of origin of the sample that has been confirmed positive for *E. coli* O157:H7 and requests that appropriate action be taken.

D. If FSIS finds raw ground beef product collected at an import inspection establishment positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling of product from the foreign establishment?

Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. An intensified level of sampling is automatically generated by the AIIS for the next 15 consecutive shipments of product from the foreign establishment presented at port-of-entry anywhere in the United States. Under an intensified level of sampling, the shipment is placed on FSIS hold when the sample is collected, until results are reported. Import inspection personnel should follow the procedures outlined in the Import Manual of Procedures (Part 3, Section 5) for guidance.

All questions related to this directive should be directed through normal supervisory channels.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy and Program Development

Attachment 1

Questions and Answers

1. Will FSIS sample trimmings and other ground beef and beef patty components?

FSIS may sample and test beef manufacturing trimmings and other raw ground beef and beef patty components at a supplying establishment when that establishment has supplied product to grinders that tested positive for *E. coli* O157:H7 after it was ground. In the future, FSIS intends to develop a random sampling and testing program for raw ground beef components and beef patty components and non-intact beef products other than ground beef, such as mechanically tenderized and injected steaks and roasts.

2. Will an establishment that has incorporated testing of trimmings and ground beef products for *E. coli* O157:H7 into its HACCP plan as a verification procedure be exempt from FSIS sampling and testing?

No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. However, FSIS' verification testing will become more risk-based. Establishments that have designed and implemented sampling and verification testing, with a high degree of confidence of finding the pathogen in both trim and finished ground product, presumably present a lower risk for producing adulterated product than one that conducts this activity only on trim or only on finished ground product and, therefore, will be sampled less frequently than other establishments.

3. What factors will be considered by FSIS in establishing risk-based verification testing for *E. coli* O157:H7 in federally-inspected establishments?

FSIS will weight its sample scheduling process so that an establishment producing a large volume of raw ground beef products will be sampled more frequently than an establishment with a lower volume of production of raw ground beef products. In addition, FSIS will also consider seasonality of *E. coli* O157:H7 prevalence and other factors, such as the number of suppliers, in developing a sampling plan based on risk. FSIS will also sample ground beef product at inspected establishments that form ground beef patties but do not grind the product. However, FSIS will also sample ground beef product at these establishments less frequently than at a plant that grinds product.

4. What factors are considered by FSIS in ensuring that retail sampling focuses on the highest risk product?

Retail sampling focuses on higher risk products by focusing on product that either includes store-generated trim or was ground using equipment that had been used to grind store-generated trim without being adequately cleaned.

5. Can an establishment have a CCP for product disposition based on finished product testing?

If a grinder has internal controls for *E. coli* O157:H7 and receives product from suppliers (both slaughter and fabrication establishments) that have controls for *E. coli* O157:H7, and the grinder and its suppliers conduct rigorous verification testing at multiple points during the production process, a CCP for disposition based on finished product testing for *E. coli* O157:H7 may be appropriate. A CCP for disposition based on finished product *E. coli* O157:H7 testing should employ testing at a level sufficient to find the organism if present at very low frequency. Corrective and preventive action in response to a positive in finished product testing should accompany an examination of the whole system, not merely disposition of the product.

6. Can the FSIS guidance materials suffice for supporting documentation for validation of CCPs, or does FSIS expect the scientific supporting documents to be more specific than a copy of the FSIS guidance materials?

The guidance materials that FSIS has developed for slaughter establishments, grinders, and suppliers on minimizing the risk of *E. coli* O157:H7 contamination included the parameters of certain studies. If establishments can demonstrate that their process meets the parameters of those studies, the FSIS guidance materials would be sufficient documentation of their validation. However, if the process parameters in the establishment differ from those in the FSIS guidance materials, in-house validation would be necessary.

7. If the establishment or FSIS tests raw ground beef products, raw ground beef components, or raw beef patty components for *E. coli* O157:H7 and finds more than one positive, do these findings signify a HACCP failure?

The establishments' or FSIS' finding more than one positive would not alone be a HACCP failure. However, FSIS would expect the establishment to identify *E. coli* O157:H7 as a hazard reasonably likely to occur (if it has not already done so). In addition, the establishment should attempt to determine the cause of the positive findings and would likely need to examine its intervention methods to determine why they are not working. Some establishments have adopted intensive raw material and finished product testing and supplier controls within their Sanitation SOPs and HACCP systems. In these situations, inspection program personnel should verify that the establishments control procedures to determine whether a HACCP failure is occurring. In other situations, the establishment may decide to conduct carcass mapping to identify areas of carcass contamination (if the establishment conducts slaughter or fabrication). In addition, if FSIS testing finds *E. coli* O157:H7, the establishment may decide to intensify its verification program or may decide to ensure that the sensitivity of its testing method is equivalent to FSIS' testing method.

8. Can an inspector collect and submit a ground beef sample prior to pre-shipment review being performed by the establishment?

Inspection program personnel should become familiar with the production process and provide notification to the establishment that a sample will be collected in time for the establishment to hold the sampled product. Some establishments have an extensive verification testing program, sample every "lot" of ground beef product produced, and have a CCP for product disposition. In this scenario, the establishment cannot conduct pre-shipment review until the result from the sample has been received. If the establishment has no interventions in place after the product is sampled that address the presence of the pathogen of concern, the establishment could conduct a pre-shipment review on this product up to this point with a note indicating that the product is being held pending laboratory analysis. Inspection program personnel could verify that the establishment meets the corrective action requirements of 9 CFR 417.3, if a positive result is received by the establishment. If disposition of product is delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product. When the results for both samples (FSIS sample and the establishment sample) have been received, the establishment could then conduct a "final" pre-shipment review. In a scenario similar to this, inspection program personnel could submit the sample prior to the final pre-shipment review being conducted.

9. If an establishment makes case-ready product and requests that the inspector give it notice the day before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, should the inspector accommodate the request?

Yes. The purpose of FSIS sampling is to provide verification that the establishment's process is producing product that is not adulterated by *E. coli* O157:H7. It is not to compromise the establishment's ability to fill its orders.

10. What is the purpose of follow-up sampling by FSIS after FSIS finds that a sample of product is positive for *E. coli* O157:H7?

FSIS generally always will collect at least one supplemental verification sample of product immediately following corrective actions by the establishment when FSIS finds a sample of product from an official establishment positive for *E. coli* O157:H7. This follow-up verification sample is expected to be larger (e.g., double the size of the regular verification sample), and FSIS expects to double the number of sub-samples that it analyzes. The results will be reported as either positive or negative, like other routine verification sample results. FSIS' follow-up sampling is one of several activities FSIS conducts to verify the adequacy of the establishments' corrective actions following an FSIS positive *E. coli* O157:H7 finding.

11. Is FSIS notified of *E. coli* O157:H7 positive Agriculture Marketing Service (AMS) results? If so, what actions do inspection program personnel take in response to such notification?

Yes, FSIS is notified of *E. coli* O157:H7 positive AMS results. AMS reports potential positives and confirmed positives to FSIS. When the DO is notified of an AMS potential positive, FSIS reacts as if the product were found presumptive positive by FSIS (see Part III, A.). If the product is confirmed positive by AMS, the establishment needs to ensure its proper disposition and to conduct appropriate corrective actions. An AMS result is an official government result.

12. Why must establishments obtain sketch approval from FSIS to use labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components?

The labeling of ground beef products, single-ingredient raw ground beef components, or single-ingredient raw beef patty components that includes special instructions or disclaimer statements concerning *E. coli* O157:H7 cannot be generically approved because FSIS considers these special instructions or disclaimers to be special claims (see 9 CFR 317.5(b)(2)).

13. If FSIS finds that establishments have been using labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components without sketch approval from FSIS, will FSIS request that the establishments recall the product?

No. FSIS will not request that establishments recall product that has already been shipped with unapproved labels because use of such product will not result in adverse health consequences. However, FSIS will rescind such labels, and the establishment would need to submit them to FSIS for sketch approval.

14. Can instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7?

Labeling is not a means to prevent, eliminate, or reduce pathogens. Therefore, instructional or disclaimer statements cannot be used as CCPs or interventions for *E. coli* O157:H7. If the establishment has determined that *E. coli* O157:H7 is a hazard reasonably likely to occur in its production of raw ground beef products, raw ground beef components, or raw beef patty components, the establishment must have an intervention to address the hazard.

15. Can establishments use instructional or disclaimer labeling statements to justify a determination that *E. coli* O157:H7 is not a hazard reasonably likely to occur in their production of beef products?

No. Because labeling is not a means to control pathogens, establishments may not use these labels to justify their determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in their production of these products.

16. Can product labeled "for cooking only" go to an establishment that cooks product intended for additional further processing?

Yes. Even if the product will undergo further processing after it leaves the cooking establishment, as long as the cooking establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

17. How should the placement of instructional statements be reflected in HACCP plan documents?

The placement of any instructional statement addressing *E. coli* O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty components must be reflected in an establishment's decisionmaking documents and hazard analysis.

For example, if an establishment is placing the statement "for cooking only" or "for full lethality treatment" on raw ground beef products, raw ground beef components, or raw beef patty components, the establishment's hazard analysis should show how the establishment is ensuring that the product will go for cooking only or for other full lethality treatment only. If the establishment places a "for cooking only" statement on the product and cooks the product in the establishment, the establishment's flow chart should show the cooking steps the product will undergo. If the establishment places a "for cooking only" statement on the product and ships it to outside establishments, the shipping establishment should have controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that is not intended for cooking, it should have controls in place to segregate product intended for cooking from product not intended for cooking. If an establishment places the statement "for cooking only" on its finished product, but the establishment has not addressed the intended use of its finished product in its decisionmaking documents or hazard analysis, the establishment's hazard analysis and decisionmaking documents would not be consistent with the information contained in the instructional statement, and the establishment would not be in compliance with 9 CFR 417.5.

18. Why are establishments that place labels on raw beef products that include a disclaimer statement concerning *E. coli* O157:H7 required to have an intervention for the pathogen in their HACCP plan?

An establishment may use a disclaimer statement, such as, "not tested for *E. coli* O157:H7," on labels of raw ground beef products, raw ground beef components, or raw beef patty components only if it has an intervention for the pathogen in its HACCP plan for these products. A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (9 CFR 417.6).

19. How are inspection personnel to document noncompliances involving labeling and disclaimer statements?

Inspection program personnel are usually to cite 9 CFR 417.5 and to use the recordkeeping trend indicator when documenting on an NR most of the possible noncompliances involving labeling and disclaimer statements. Under 9 CFR 417.5, required records documenting the establishment's HACCP plan include: a written hazard analysis, supporting documentation of the hazard analysis, a written HACCP plan, and decisionmaking documents associated with selection and development of CCPs and critical limits.

a. If the establishment's use of instructional statements concerning *E. coli* O157:H7 is not reflected in its decisionmaking documents or hazard analysis, the establishment is not in compliance with 9 CFR 417.5, because its records do not show that the establishment has considered its use of these instructional statements in its hazard analysis or HACCP plan.

b. If the instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7, the establishment is not in compliance with 9 CFR 417.5 because the establishment's decisionmaking documents or hazard analysis cannot support its use of instructional or disclaimer statements as controls or CCPs.

c. If the establishment has used instructional or disclaimer statements to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur, the establishment is not in compliance with 9 CFR 417.5 because the establishment's decisionmaking documents or hazard analysis incorrectly concluded that labeling statements would prevent *E. coli* O157:H7 from becoming a hazard reasonably likely to occur in the establishment.

d. If an establishment receiving product with instructional or disclaimer statements has not addressed the use of such products in its decisionmaking documents or hazard analysis, or does not have data to validate that these products will receive adequate lethality treatment, the establishment is not in compliance with 9 CFR 417.5 because its records do not show that the establishment has adequately addressed the use of these incoming products in the hazard analysis for those products in which such incoming products will be used.

Attachment 2

PROCEDURES FOR SAMPLING RAW GROUND BEEF COMPONENTS AND RAW BEEF PATTY COMPONENTS:

Refer to the page in FSIS Directive 10,210.1 that corresponds to the project code in Block 14 of FSIS Form 10,210-3, Requested Sample Programs, for further collection instructions.

Sample Size:
The FSIS laboratory requires approximately 1.5 pounds (24 ounces or 680 grams) but no less than 1.25 pounds (20 ounces or 570 grams) of product.

Sample Chilling:
If the sample is warmer than 40°F/4.4°C when the sample is taken, place it in a cooler to chill it before shipping.
Prior to shipping the sample, pre-chill the shipping container in a refrigerated cooler that is between 28°F and 45°F for at least 8 hours.

Randomized or Representative Sampling:
As best as practical, select a representative sample by one of the two following procedures:

1. **Time**: Throughout the production lot, as defined by the establishment, as boxes or combo bins are filled, collect samples at random times. Use standard procedures for identifying "random times".
   If random times are not practical use the "Space" option below.

2. **Space**: At or toward the end of the production lot, as defined by the establishment, note the number of boxes or combo bins containing the requested product types. Take the square root of that number and round up to the next whole number (i.e., if the number of boxes is 29, the square root is 5.38; the next whole number is 6). That number, or no more than 10, is the number of containers to be sampled.
   Use a standard random number procedure to select which containers to sample. Select representative samples from the top of the filled boxes or combo bins. These pieces should have collected representative bacteria from the product contact surfaces during the course of production.

Sampling Procedure:
There will be three basic sampling procedures based on size of sample pieces:

1. Very small pieces less than the size of an ordinary thumb, such as AMR, or LBT/LFTB.
   For very small pieces, use the laboratory-supplied scoop or spoon to collect the sample.

2. Small pieces less than the size of an ordinary palm, such as head meat or trimming.
   For small pieces, use the laboratory-supplied scoop, tongs, or hook to collect the sample.

3. Chunks and pieces larger than an ordinary palm, such as chucks and plates:
   Call for help from an establishment employee with an establishment knife and laboratory-supplied hook. Have the employee sanitize knife and hook in the same manner as is done on the boning/trim line. From each of the designated containers (or during the day) "Grab sample" pieces with the hook. From each piece, slice a thumb to palm-sized piece of surface, no thicker than ½ inch (or 1 cm). Place the samples into the sterile sample bag, using the hook or laboratory-supplied tongs.