

October 13, 2009

RAW BEEF PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

1. Identify the pathogen of concern for raw beef products.
2. Select, from a list, those raw beef products subject to sampling.
3. State where to find FSIS's raw beef product sampling instructions.
4. Explain the use of FSIS Form 10,210-3, Requested Sample Programs.
5. List, in order, the five steps of raw beef product sampling.
6. Describe how to determine which raw beef product to sample.
7. State how sample results are received.
8. State when to mail samples to the FSIS laboratory.
9. List the actions associated with positive pathogen results.
10. List the requirements for transportation of raw beef product which has tested positive or presumptive positive for a pathogen.
11. Identify the PBIS procedure performed when collecting and submitting a raw beef product sample to the FSIS laboratory.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused food borne illness. FSIS works with other governmental agencies, academia, industry, and consumer groups to set policy and establish guidelines and performance standards to reduce or eliminate pathogens from meat and poultry products. Each package of federally inspected product bears the mark of inspection, which the public has come to trust as a sign that the product is safe. FSIS intends to maintain that public trust. Currently, FSIS is concerned with the presence of *E. coli* O157:H7 in beef slaughter and raw beef product processes because of its public health significance. *E. coli* O157:H7 is a food safety hazard that establishments need to consider in their hazard analysis if slaughtering, receiving, grinding, or otherwise processing raw beef products.

Non-intact raw beef products (e.g., ground beef and mechanically tenderized beef) contaminated with *E. coli* O157:H7 are adulterated. 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 (i.e., the flow chart and hazard analysis) should identify the intended use of intact raw beef products. Beef manufacturing trimmings (e.g., pieces of meat remaining after an establishment removes the steaks, roasts, and other intact cuts from the carcass) are an example of an intact raw beef product that is intended to be used for non-intact product such as ground beef.

Raw Beef Product Sampling

FSIS microbiological sampling programs are part of FSIS verification activities to ensure the protection of public health. HACCP systems integrate science-based controls into food production processes. These controls must be combined with some means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. Sampling programs are designed to verify that HACCP systems are effective in controlling harmful microorganisms in meat and/or poultry products. Establishments may also include a microbiological sampling program in their HACCP system in order to verify that the system is performing as intended, i.e., controlling, reducing or eliminating the identified food safety hazards.

FSIS also protects public health by keeping pace with changes, such as emerging pathogens, new products and processes, and new laboratory analyses methods. FSIS is continuously improving its sampling protocol and techniques, updating sampling and testing programs, and developing more rapid means of reporting results. In 2007 and 2008, FSIS made changes to its testing program to increase the likelihood of detecting *E. coli* O157:H7. For instance, FSIS began:

- Sampling beef manufacturing trimmings and other raw ground beef components (including raw beef patty components) for *E. coli* O157:H7 on a routine basis. The samples of beef manufacturing trimmings, and other raw ground beef and raw beef patty components are collected at the **slaughter establishment** that produced the trimmings or component,
- Collecting multiple follow-up samples of raw ground beef, beef manufacturing trimmings, and other raw ground beef and raw beef patty components in response to an FSIS positive *E. coli* O157:H7 result or another Federal or State entity's positive *E. coli* O157:H7 result,
- Tracing positive samples of raw ground beef back to the establishment that slaughtered the cattle used to produce the source materials, and
- Submitting samples to the FSIS laboratory without waiting for the establishment to complete pre-shipment review.

In 2009, as set out in FSIS Notice 51-09, FSIS began sampling bench trim designated for use in raw ground beef, beef patties and other non-intact raw beef products and derived from cattle **not** slaughtered at the establishment. FSIS will continue its sampling and testing for *E. coli* O157:H7 in raw ground beef products, beef manufacturing trimmings, and raw ground beef and beef patty components intended to be used in non-intact product. An objective of FSIS's verification sampling program is to test for *E. coli* O157:H7 and, as a result, stimulate industry actions to reduce the presence of that pathogen in raw beef products.

Raw Beef Product Sampling

FSIS directives contain policy details specific to sampling projects and programs (see Attachment 1). Policy changes rapidly; amendments and new issuances are developed to keep you informed. You are responsible for properly selecting products and using appropriate sample collection techniques to ensure the integrity of samples received by the laboratories. You must review the updated resources **each** time you take a sample. You should review new issuances when they are issued.

FSIS Directive 10,010.1, Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products, contains key concepts and instructions regarding the testing of raw beef products for *E. coli* O157:H7. These include:

- Collecting and submitting samples of raw ground beef, and other non-intact raw beef products and intact beef products intended for use in raw ground beef products,
- FSIS actions after an *E. coli* O157:H7 positive sample result,
- Verifying *E. coli* O157:H7 positive product disposition when product is shipped to a renderer, landfill operation or another federal establishment,
- Procedures for follow-up sampling after an *E. coli* O157:H7 positive sample result,
- Responsibilities related to plant generated *E. coli* O157:H7 samples, and
- Verifying instructional and disclaimer statements on labels.

Terminology

Aseptic Sampling Techniques

An aseptic technique implies that you do not add any organisms to the sample when it is collected. It does **not** imply that the **sample** is aseptic or free of microorganisms. Extraneous microorganisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological analysis are necessary; therefore, the use of aseptic sampling techniques and clean and sanitized equipment is of utmost importance.

The purpose of aseptically collecting a sample is to prevent contamination of the sample **or** the surrounding product/product contact area. For raw beef products collected in their final package (intact), such as ground beef, you are to clean and sanitize your hands before collecting the sample. For non-intact samples, such as beef manufacturing trimmings and bulk packaged ground beef products, you are to clean and sanitize your hands to the mid-forearm and put on sterile gloves before collecting the sample. The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected and the sterile sampling equipment. The outside surfaces of the sample container (Whirlpak® bag) are not sterile. Follow the procedure in FSIS Directive 10,010.1 for putting on the sterile gloves. Good

Raw Beef Product Sampling

personal hygiene is **essential** anytime a sample is collected, whether it is in the final package or not.

Beef Manufacturing Trimmings

Raw beef manufacturing trimmings subject to FSIS sampling for *E. coli* O157:H7 are 2-piece chucks (i.e., the blade portion and an arm roast from the forequarter individually packaged and placed into the same container), raw beef source materials from sub-primal cuts (e.g., steaks and roasts) or primal cuts (e.g., round, loin, rib and other primals listed in 9 CFR 316.9), or boxed boneless beef parts that establishments frequently use as components of raw ground beef and beef patties.

Bench Trim

Bench trim subject to FSIS sampling for *E. coli* O157:H7 is defined as large or small pieces of beef manufacturing trimmings or any other cuts from the boning of whole or half carcasses or primals (e.g., chuck, loin, round, and rib), or the secondary trimming of primals or sub-primals (e.g., steaks and roasts). For the purposes of FSIS sampling, bench trim is only from cattle **not** slaughtered on-site at the establishment and that is designated for use in raw ground beef, beef patties, and other non-intact raw beef products.

Non-intact beef products

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 (with or without marinade), and beef that has been reconstructed into formed entrees. Frenching is a method of preparing boneless chops by flattening with a cleaver.

*Note: An **intact** beef product is one in which nothing has penetrated into the muscle beyond the normal cut-up processes, such as primal cuts, sub-primal cuts, steaks, roasts, boned out chucks, etc.*

Raw ground beef products

Raw ground beef products subject to FSIS sampling for *E. coli* O157:H7 meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)). They include:

- ground or chopped beef or veal;
- hamburger;
- beef or veal patties;

Raw Beef Product Sampling

- beef or veal patty mix; and
- ground beef or veal product with added seasonings.

Note: A raw ground beef product formulated with any amount of advanced meat recovery (AMR) product is considered “ground beef”. However, raw product comprised **only** of beef from AMR systems is **not** sampled as a raw ground beef product; instead, it is considered a raw ground beef component or raw beef patty component and sampled under the MT 54 sampling project.

Raw ground beef components other than beef manufacturing trimmings

Raw ground beef components other than beef manufacturing trimmings subject to FSIS sampling for *E. coli* O157:H7 are intact or non-intact beef products intended for manufacturing into ground beef products identified in §319.15(a), (b), or (c). Such products include raw beef esophagus (weasand) meat, head meat, cheek meat, beef from AMR systems, and lean finely textured beef (LFTB).

Note: A beef AMR system is a mechanical process separating skeletal muscle tissue from bones of cattle other than skulls or vertebral column bones of cattle \geq 30 months of age that meets the requirements in 9 CFR 318.24. Establishments may label the resulting product from beef AMR systems as “beef”.

Raw beef patty components

Raw beef patty components subject to FSIS sampling for *E. coli* O157:H7 include **all** raw ground beef components other than beef trim listed above, as well as partially defatted chopped beef (PDCB), partially defatted beef fatty tissue (PDBFT) and heart meat.

Note: LFTB, PDCB and PDBFT are low temperature rendered products. The lean is removed from fat or very fat trimmings using heat or in the case of beef fatty tissue a centrifugation, drum drying process.

Recall

A recall is a plant’s voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). “Recall” does not include a market withdrawal or a stock recovery.

Product that is adulterated and has left the establishment’s control may be subject to a recall. The Recall Management Staff (RMS) is notified immediately if product has left

Raw Beef Product Sampling

the establishment's control. The DO notifies the RMS (see FSIS Directive 8080.1, "Recall of Meat and Poultry Products"). RMS coordinates all recall activities including issuing a press release and having effectiveness checks performed. The press release has the product name, lot number and the supplier. The recall would involve at least the sampled lot, but the scope of the recall could be expanded depending upon a review by the RMS of all production factors and establishment's control measures in place within the operation to limit potential contamination exposure. All recalls of meat and poultry products are voluntary. Raw beef products produced on the shift represented by the positive sample could be subject to voluntary recall. If the raw beef product, e.g., rework, was used as an ingredient in other raw product formulations, those secondary products could 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 evaluates the situation and proceeds on a case-by-case basis.

Sample

A sample for raw products is a collection of product, such as ground beef, beef trimmings, bench trim, and AMR product that represents a larger amount of product (e.g., the sampled lot).

Sampled lot

The sampled lot is the amount of product represented by the sample tested for *E. coli* O157:H7. The establishment defines the sampled lot. "Cleanup-to-cleanup" may be a part of the procedures that the establishment has in place to distinguish one portion of production from another portion of production. "Cleanup-to-cleanup" may be an effective means of preventing *E. coli* O157:H7 cross contamination between raw beef products during production. However, "cleanup-to-cleanup" without other supporting documentation **may not** be adequate to distinguish one portion of production from another (i.e., "cleanup-to-cleanup" is not a stand-alone reason for distinguishing between segments of production because *E. coli* O157:H7 is source material contaminant).

Factors or conditions that may determine the sample lot include an establishment's:

- Use of a scientific, statistically based sampling program for *E. coli* O157:H7 to distinguish between segments of product;
- Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production;

Raw Beef Product Sampling

- Use of processing interventions that limit or control *E. coli* O157:H7 contamination;
- Use of beef manufacturing trimmings and raw beef components or rework carried over from one production period to another production period; and
- Production of bench trim, i.e., small pieces of beef trimmings from raw intact steaks and roasts.

Note: The sampled lot may be limited to the container(s) of beef trimmings (bench trim) and not the primal cuts or intact steaks and roasts because such products would not be adulterated if positive for *E. coli* O157:H7. However, if an establishment produces bench trim from steaks or roasts that are non-intact or are to be made non-intact (e.g., they have been or will be needle tenderized), a finding that the bench trim is positive for *E. coli* O157:H7 would be evidence that the steaks or roasts are also positive and thus adulterated. The establishment may be able to distinguish the steaks or roasts from the bench trim. For example, if the establishment applies an antimicrobial treatment to the steaks or roasts before tenderization, but not to the bench trim, the establishment may be able to support that the positive applies only to the bench trim.

If multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered adulterated.

Sample unit

A sample unit is an individual package, or container, or portion of product (e.g., 4 inch X 2 inch X 1/8 inch tissue slice). It may take several sample units to make up one sample, depending upon the amount needed for the analysis. The amount of sample to be collected is identified in FSIS Directive 10,010.1. Some samples (composite samples) are made up of more than one sample unit.

Sampling Procedure and Sampling Project Numbers

FSIS verification activities include collecting and testing raw products for microbial hazards. For example, FSIS conducts routine analyses on raw ground beef products, and beef manufacturing trimmings, bench trim, raw ground beef components and beef patty components intended for use in raw ground beef products for *E. coli* O157:H7.

Raw Beef Product Sampling

Follow-up analyses will be conducted when FSIS or another Federal or State entity finds these products positive for *E. coli* O157:H7.

Samples are collected and submitted to FSIS Field Service laboratories whenever the Inspector-in-Charge (IIC) receives sample requests from the Pathogen Reduction and Enforcement Program (PREP). The directed sample requests for microbial analyses are on FSIS Requested Sample Programs Form, 10,210-3. Samples collected and submitted for *E. coli* O157:H7 testing must be documented in the Performance Based Inspection System (PBIS). Since a directed sample request is **not** a scheduled procedure in PBIS, procedure 05B02 is recorded as **unscheduled** on the Procedure Schedule the day the sample is mailed to the lab.

The raw beef products listed on the previous page fall into the 03B and 03C HACCP process categories and have a specific sampling program/project code. The sampling project codes for *E. coli* O157:H7 testing are:

- MT05 – Routine Testing of Raw Ground Beef at Retail;
- MT06 – Follow-up Sampling of Raw Ground Beef in Response to a Positive Result in Retail Raw Ground Beef Product;
- MT08 – Routine Testing of Imported Raw Ground Beef;
- MT43 – Routine Testing of Raw Ground Beef in Federal Establishments;
- MT44 – Follow-up Sampling of Raw Ground Beef Product in Response to a MT43 Positive Result in Raw Ground Beef Product at Federal Establishments;
- MT44T – Any Follow-up Raw Ground Beef or Raw Ground Beef Component Sampling Outside of Projects MT44 and MT52 Collected by In-plant Personnel at Federally Inspected Establishments including:
 - Components at the grinder,
 - Response to a recall based on State epidemiological data,
 - Current production from an establishment linked to an outbreak (separate from Outbreak samples that go to Outbreak Section Eastern Laboratory (OSEL) as part of an investigation), and
 - Extra raw ground beef samples at an establishment following numerous trim samples.
- MT50 – Routine Testing of Domestic Raw Beef Manufacturing Trimmings Derived from Cattle Slaughtered at the Establishment;

Raw Beef Product Sampling

- MT51 – Routine Testing of Imported Beef Manufacturing Trimmings and Components;
- MT52 – Testing of Beef Manufacturing Trimmings or Other Components From Originating Slaughter Suppliers, Based on an MT43 Positive Result, at Federal Establishments;
- MT53 – Follow-up Testing of Positives from 1) Routine Testing of Beef Manufacturing Trimmings (MT50); 2) Routine Testing of Other Components (MT54); or 3) Positive Follow-up Testing at Suppliers (Positive MT52 Samples);
- MT54 – Routine Testing of Domestic Components Other than Trim at Federal Establishments; and
- MT55 – Routine Testing of Beef Manufacturing Trimmings Derived from Cattle Not Slaughtered at the Establishment.

General Instructions for All *E. coli* O157:H7 Sampling Projects

Samples are collected and submitted to the FSIS laboratory when you receive FSIS Form 10,230-3, Requested Sample Programs, from PREP. Whenever you receive a sample request form, determine if you have the required sampling supplies on hand. Don't wait until the day you are to collect the sample to find out you don't have the required sampling items. The three FSIS Field Service Laboratories are responsible for providing the sampling supplies. If you need sampling supplies, send an e-mail request through Outlook. You need to order the supplies at least 72 hours before you intend to collect a sample. E-mail the FSIS laboratory which is identified in Block 9 of the sampling request form. Use one of the following e-mail addresses:

Sampling Supplies-EasternLab@fsis.usda.gov

Sampling Supplies-MidwesternLab@fsis.usda.gov

Sampling Supplies-WesternLab@fsis.usda.gov

Include the following information:

- Exact supplies needed, e.g., N60 sampling method
- Establishment's street address (no P.O. Boxes)
- Establishment's phone number

Note: For **follow-up samples** include the project number (MT44 for multiple follow-up ground beef product samples; MT53 or MT52 for multiple follow-up sampling of beef manufacturing trimming and other raw ground beef or raw patty component samples) in your e-mail.

Raw Beef Product Sampling

4. COLLECT TISSUES/SAMPLES ON		
Day of:	Week of:	Within 30 days of: July 10 , 2009

In Block 4 of FSIS Form 10,210-3 there is a pre-printed **time frame**. The pre-printed date in Block 4 tells you when to collect a sample (e.g., “Within 30 days of July 10, 2009”, means the sample must be collected between July 11th and August 9th). By 30 days **after** (not before) the date printed in the block, you should have collected a sample. **All** samples not collected within the designated time frame on the sample request form (e.g., “Within 30 days” after the date printed in the box) are discarded at the labs. Do not send in a sample after the 30 days unless you are directed to do so. If the plant will not produce the targeted raw beef product during the 30-day window, you **must** send the form back to the laboratory listed in block 9 with an explanation of why no sample was sent in block 33. FSIS needs to account for all sample request forms that were sent to the field.

<p>33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE</p> <p>(72) <input checked="" type="checkbox"/> REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date.)</p> <p>(60) <input type="checkbox"/> PLANT DOES NOT SLAUGHTER SPECIES/CLASS OR PRODUCE THE REQUESTED PRODUCTS (If checked, plant will be removed from this sampling program.)</p> <p>(57) <input type="checkbox"/> NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE</p> <p>(53) <input type="checkbox"/> OTHER (Explain)</p>
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You need to make yourself aware of any establishment sampling and testing programs for *E. coli* O157:H7. No establishment that produces raw ground beef products or beef manufacturing trimmings and raw ground beef and beef patty components **intended to be used in non-intact product** is exempt from FSIS verification testing for *E. coli* O157:H7 even when the establishment has its own robust (rigorous) testing program for *E. coli* O157:H7. Therefore, you are to collect samples even when the plant analyzes samples representing 100% of its raw beef products intended for grinding.

All samples are collected after the establishment has applied all antimicrobial interventions to the production lot, except for any microbiological testing intervention. If the establishment intends to test the product for *E. coli* O157:H7 before completing the pre-shipment review, you **do not** wait for the establishment to receive the test results before collecting and sending a sample to the FSIS laboratory. However, if the HACCP plan has a CCP for freezing product, freezing may occur in the process after the establishment’s microbiological testing. Under these circumstances, you are to wait until the product passes the freezing CCP before collecting a sample.

Raw Beef Product Sampling

All samples are selected **randomly** from the type of raw beef product requested. You must randomly select a day, shift, and time within the 30-day window **after** the sample collection date indicated in Block 4 of FSIS Form 10,210-3. In order for the sample to be representative of a lot, every attempt must be made to avoid taking a sample that is biased (i.e., nonrandom). There should be an equal chance that sampling will occur during all shifts that the plant operates. You're not required to randomly select the lot, but you do have to randomly select the sample from that lot. One of the best ways to ensure an unbiased sample is to randomly select a **time** to collect the sample. You can use a random number table or generator to determine the day and time. Record the shift from which you collected the sample in block 28 of Form 10,210-3.

Samples must be collected in a sanitary manner. You want to assure that the sample is not contaminated with extraneous microorganisms from the environment, hands, clothing, sample containers and sampling devices. Remember to wash and sanitize your hands when collecting samples in their final packaged form. When it is not possible to collect the sample in final packaged form, follow the instructions for aseptic sample collection (e.g., putting on the sterile gloves) in FSIS Directive 10,010.1. You **must** put the samples collected from product packaged in institutional or bulk containers (e.g., combo bins, non-consumer size boxes or plastic bags) in the **sterile** Whirlpak® bags. Answer the questions in block 28. The FSIS laboratory will discard any sample which does not appear to be in a finished packaged form if it is placed in any bag other than a sterile Whirlpak® bag, e.g., a zip-lock bag!

Note: If the establishment changes the intended use of the product (e.g., diverts all of the product represented by the sample to cooking either at the establishment or at another establishment) after you collected the sample proceed with submitting the sample to the FSIS laboratory for analysis.

You must safeguard the security of the samples when preparing, storing, packaging, and mailing the sample to the FSIS laboratory. Samples are to be sent to the laboratory the same day they are collected, or as soon as the overnight courier service is available. If the sample must be held overnight, you are to keep it under refrigeration in a **secure** location. **Do not** freeze the sample unless for some reason you are unable to ship the sample so that it arrives at the FSIS laboratory within 48 hours, then you are to freeze the sample. If the establishment has a CCP for freezing, the sample you collect is frozen and must be kept frozen. **Note:** The only time a frozen sample is collected is when the plant has a CCP for freezing.

On the day Federal Express picks up the sample, you enter an **unscheduled procedure 05B02** on the Performance Based Inspection System (PBIS) procedure schedule using the result code "a" for performed. You need to verify that the PBIS Profile Extension Product Volume information is accurate and up-to-date regarding the plant's raw beef product production volume. If you believe that additional sampling may

Raw Beef Product Sampling

be needed, contact the District Office (DO) through supervisory channels. DO personnel determine if more sampling is appropriate.

Alternative Lot Definitions

You may permit an establishment to reduce its lot size to one combo bin or other unit (e.g., box) on the day that you collect a sample when the establishment:

- Samples its beef manufacturing trimmings or large pieces of bench trim using the N60 sampling procedure, other raw ground beef components, or raw ground beef products under its own testing program;
- Has a validated intervention for *E. coli* O157:H7 at a CCP in the HACCP plan that covers the raw beef product or requires an intervention for *E. coli* O157:H7 at a CCP for that raw beef product's source materials; and
- Samples and tests every production lot for *E. coli* O157:H7 and generally collects its samples of beef manufacturing trimmings, bench trim, other raw ground beef components, or raw ground beef products across multiple combo bins or other sample units.

If an establishment meets the criteria above and reduces its lot size to a single combo bin or sample unit when you sample the raw beef product, then collect samples from the single combo bin or sample unit following applicable instructions outlined in this handout and FSIS Directive 10,010.1. If the establishment does not meet criteria above, you collect the sample consistent with other applicable instructions in this in this handout and FSIS Directive 10,010.1.

Steps in Sampling

The FSIS laboratory is completely dependent on you to properly collect, prepare, and ship the sample. The FSIS Form 10,210-3 that accompanies each sample must be completely and accurately filled out. Your role in the process is vital. The information entered on the form becomes part of a legal document. If mistakes are made during the collection of the sample or on the form, the lab will discard the sample.

There are 5 steps in product sampling.

1. Determine which product to sample
2. Notify plant management

Raw Beef Product Sampling

3. Collect the sample
4. Pack and mail the sample and form
5. React to the results

Step 1: Determine which Product to Sample

When FSIS Form 10,210-3, Requested Sample Programs (see Attachment 3), is sent to the IIC, certain blocks will be pre-printed with information specific to the sample to be collected. For instance, the raw beef product/category (e.g., raw ground or comminuted beef or veal products, including ground beef, hamburger, beef patties, beef patty mix, etc.) is specified on the request form. The sampling project code such as MT43, MT50, MT54 or MT55 is indicated in block 14 of the request form. For instance:

- Routine sampling of raw ground beef products is conducted under project code MT43,
- Routine sampling of beef manufacturing trimmings derived from cattle slaughtered at the plant is conducted under project code MT50,
- Routine sampling of raw ground beef components (including raw beef patty components) other than beef manufacturing trimmings is conducted under project code MT54, and
- Routine testing of beef manufacturing trimmings derived from cattle not slaughtered at the plant (bench trim) is conducted under project code MT55

To assist you in determining which product to sample, you will need to know the plant's processes and how product is labeled. Before collecting a sample, review the FSIS directives covering that sample type or program. The directed sample request may have additional instructions printed in block 18 of the form.

Beef Manufacturing Trimmings that are Sampled from Cattle Slaughtered at the Establishment

You only collect samples of beef manufacturing trimmings that the establishment intends for use in raw ground beef and other raw ground beef products that were **produced from cattle slaughtered at the establishment** under the MT50 sampling project.

To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where the establishment records and HACCP documents are unclear about the product's intended use, the trimmings will be considered for use in raw ground beef products and other non-intact raw beef products.

Raw Beef Product Sampling

If the establishment commingles the beef trimmings with beef product processed at other establishments, you collect the sample before the establishment commingles the product.

Do not collect samples of beef manufacturing trimmings from production lots that are going to be further processed into ready-to-eat products or from lots of commingled beef manufacturing trimmings produced at **different** establishments.

Low-temperature rendered (LTR) products, including partially defatted chopped beef (PDCB), lean finely textured beef (LFTB), and product known as boneless lean beef tissue (BLBT) are produced from beef manufacturing trimmings and can be used as a component in raw ground beef and beef patty products. When these products are injected with gaseous ammonia, it rapidly raises the pH. Scientific studies support that this procedure serves as an antimicrobial intervention that reduces *E. coli* O157:H7 in beef manufacturing trimmings to an undetectable level.

If the establishment produces ammoniated low-temperature rendered product, **do not** sample this product or beef trimmings intended for use in ammoniated low-temperature rendered product under the routine sampling program for beef manufacturing trimmings (MT50) if the establishment:

- has one or more CCPs validated for the production of ammoniated low-temperature rendered product in its raw ground HACCP plan; and
- clearly segregates beef manufacturing trimmings destined for the ammoniated process from the beef manufacturing trimmings that will not undergo the ammoniated process because the beef manufacturing trimmings that do not receive this intervention are subject to FSIS sampling and testing for *E. coli* O157:H7 under the MT50 sampling program.

Note: Ammoniated LTR product is subject to follow-up verification sampling (under project code MT52) when it was used as a component in a raw ground beef product that was sampled by FSIS under project code MT43 or MT44, or by another Federal or State entity and tested positive for *E. coli* O157:H7.

Bench Trim or Beef Manufacturing Trimmings that are Sampled from Cattle NOT Slaughtered on-site at the Establishment

Generally, the same type of beef trimmings are sampled under the MT55 sampling program as under the MT50 sampling program with exception that samples of beef trimmings the establishment intends for use in raw ground beef or other raw ground beef products are collected from cattle **not slaughtered** at the establishment. However, unlike the MT50 sampling program, if the establishment commingles beef

Raw Beef Product Sampling

trimmings from cattle it slaughtered with bench trim derived from cattle slaughtered at another establishment, those commingled beef trimmings **are** subject to sampling under the MT55 sampling program.

To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where the establishment records and HACCP documents are unclear about the product's intended use, the beef trimmings will be considered for use in raw ground beef products and other non-intact raw beef products.

Do not collect samples of bench trim from production lots that are going to be given a full lethality treatment, e.g., further processed into **ready-to-eat (cooked) products** at the establishment or at another official establishment.

Raw Ground Beef Components and Beef Patty Components OTHER than Beef Manufacturing Trimmings that are Sampled

You only collect samples of raw ground beef **components** or raw beef patty **components** other than beef manufacturing trimmings that are intended for use in raw ground beef and other raw non-intact beef products **that were produced from cattle slaughtered at the establishment.**

To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where such documents are unclear about the intended use or consumer, or the plant lacks control measures to ensure that the product is used as intended, handle the product as if it were for use in a ground beef product or other raw non-intact raw beef product. Also, if the plant **has not** identified the intended use or consumers of the finished product, there is noncompliance with 417.2(a)(2).

When you receive a sampling request Form 10,210-3 with the MT54 sampling project code in block 14, you choose among the products produced at the slaughter establishment by following the priority list below. For example, if the establishment produces product from AMR systems (#1 on the priority list) on the day of collection, you are to take a sample of it; if not, you are to collect low temperature rendered lean finely textured beef (#2 on the priority list) if it is available, and move down the list until there is an available product.

1. Product from AMR (Advanced Meat Recovery) Systems
2. Low Temperature Rendered LFTB (lean finely textured beef)
3. Partially Defatted Beef Fatty Tissue (PDBFT)
4. Partially Defatted Chopped Beef (PDCB)
5. Weasand Meat

Raw Beef Product Sampling

6. Head Meat
7. Cheek Meat
8. Heart Meat

When you receive subsequent sample request forms with the project code MT54 in block 14, you start at the top of the list and continue down the list choosing the next item on the priority list that is produced by the establishment on day the sample is collected. You select a different component than previously collected, when possible.

If the establishment commingles components with beef product processed at other establishments, you need to collect the sample before the establishment commingles the product.

Do not collect samples of components from production lots that are going to be further processed into **ready-to-eat products**. The LTR products, (e.g., LFTB, PDBFT and PDCB) are often added to the formulation of ready-to-eat products.

Raw Ground Beef Products that are Sampled

The products that are included in “raw ground beef” are raw (chopped or ground) products made from various raw cuts and/or parts of cattle carcasses (beef or veal). Such products are ground beef, hamburger, beef or veal patties, and beef or veal patty mix that meet the standards of identity for ground or chopped beef identified in §319.15(a), (b), or (c). Sampled products may **contain** raw ground beef and beef patty components such as beef derived from AMR systems, LFTB, or PDCB. Do not sample the ground beef product if the plant only portions it, e.g., removes it from institutional size or bulk containers and packages it into consumer ready packages.

When you receive subsequent sample request forms with project code MT43 in block 14, unless a specific product (e.g., beef patties) is requested on the form, you should, if possible, collect a sample from a different product than you submitted with the previous request form when an establishment produces multiple ground beef products.

You **are** to collect samples from products that contain a mixture of ground beef and non-beef species (e.g., beef and pork patty mix), **unless** the product is labeled in a manner to show that beef is not the predominant meat or poultry component. For example, “Beef Patty Mix, ground pork added” (ingredients: beef, water, pork, corn syrup and seasonings) would be subject to sampling because beef is the predominant species in the product.

Ground beef products intended to be further processed into **ready-to-eat products**, or products made with ground beef but subject to a different standard of identity than in §319.15(a)-(c), such as meatballs, meatloaf, beef sausage (§319.140), and fabricated

Raw Beef Product Sampling

steaks (§319.15(d) **are not** subject to *E. coli* O157H:7 sampling. Ground buffalo or bison is also **not** a raw ground beef product subject to this FSIS verification sampling program.

Primals and Sub-primals that are Sampled

Establishments may produce primals or sub-primals (primals that are further processed into consumer-ready steaks and roast products) that are used in both intact and non-intact product (e.g., tenderized steaks and ground beef products). The establishment may have no way of consistently knowing the final use or user of the product. Therefore, the establishment that produces primals or sub-primals may not be able to identify whether the final end product will be intact (steaks) or non-intact product (ground beef).

Typically, primals and sub-primals are not adulterated if contaminated with *E. coli* O157:H7 because contamination is on the surface of intact products and contamination would be eliminated when they are cooked by the consumer. If a slaughter establishment supplies primals or sub-primals that are used in the production of a ground beef product or boned into beef manufacturing trimmings that FSIS or another Federal or State entity finds positive for *E. coli* O157:H7, FSIS will collect a sample from the source materials used in the production lot that was positive for *E. coli* O157:H7 at that establishment as part of its follow-up verification testing program (project code MT52--See the **Follow-up Sampling at Supplying Establishments** section on page 39).

Step 2: Notify Plant Management

Plant management must be notified before a sample of its raw beef product is taken. Prior notification gives management the option of holding the product represented by the sample pending test results. You need to give the plant enough advanced notice so the sampled lot may be held but not enough time for the plant to alter the production process. Always identify the reason why you are taking the sample (e.g., routine FSIS verification testing, follow-up sampling in response to an *E. coli* O157:H7 positive, a trace-back sample, or follow-up sampling in response to an *E. coli* O157:H7 outbreak) when you notify the plant. **Recommend** that plant management hold the sampled lot of product. Inform plant management that it is responsible for supporting its basis for defining what product is represented by the sample (i.e., the sampled lot). Since the plant may opt to hold the lot, it needs sufficient time to make the necessary arrangements to do so.

The purpose of FSIS sampling is to verify the plant is producing unadulterated product, not to interfere with the plant's operations. **You need to be knowledgeable concerning the plant's production practices.** Give plant management 1 day's notice

Raw Beef Product Sampling

before you collect a sample if that's enough time for the plant to hold the sampled lot or less than 1 day's notice if it does not cause a hardship to the plant. However, after becoming familiar with the plant's process, you may realize that 1 day's notice before collecting a sample is not adequate time for the plant to hold all of the product represented by the sample. You may provide 2 day's notice, if necessary. If the establishment requests more than a couple days' notice prior to collection of the sample, you are to consider the request based on establishment product and process flow. In some cases, based on your consideration, you may agree that more than 2 day's notice is necessary. The District Office or the Policy Development Division (PDD) can be contacted for guidance. You should discuss the notification and time frames with plant management **prior** to any sample requests being received in order to have an agreed upon notification protocol in place when a sample must be collected.

In the case of raw ground beef product, you should give plant management the handout (included with sampling supplies from the lab) stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial results of analyses. This handout can be discussed at a weekly plant meeting with plant management so they are aware of the procedure and protocol you will follow. Inform the plant that if the product represented by the verification sample is not voluntarily held, it is subject to voluntary recall, retention, or seizure if the sample is positive for *E. coli* O157:H7.

Step 3: Collect the Sample

Collecting Beef Manufacturing Trimmings, 2-Piece Chucks, Primals and Sub-primals, and Bench Trim

Follow the general sampling instructions outlined in this handout, e.g., randomly collect a sample (day, shift and time for routine sampling) using aseptic technique from one production lot after all of the plant's interventions except for a microbiological testing intervention within the 30-day sampling window. The N60 method is used for sampling various raw beef cuts intended for use in raw ground beef products.

The N60 method is used for sampling:

- Beef manufacturing trimmings,
- 2-piece chucks,
- Primal/sub-primal cuts (e.g., rounds, briskets, etc.) when the establishment (or another establishment) intends to grind the entire cut into ground beef, and
- Raw beef products when the **intended use is unclear** (includes primals or sub-primals in which the plant is unable to identify whether the final end product will be intact (steaks and roasts) or non-intact product (ground beef products)).

Raw Beef Product Sampling

Before sampling, be sure you have the proper supplies. A plastic caddy, sharp boning knife, hook, sterile gloves and sterile sampling bag are needed for the N60 sampling procedure. It is critical that the knife used for sampling be kept sharp and properly steeled for collecting samples. Also available from the FSIS laboratories, are disposable sampling surfaces (for locations where samples are not collected and cut in the combo bin or where an easily sanitized surface in the production area is not available), cut resistant mesh gloves, and sanitizable clips which can be used to clip the wire at the top of the sampling bag to either the top of the combo bin or the edge of the sampling caddy during collection. The new Whirlpak® sampling bags have a gusseted bottom (flat bottom) which allows the bags to stand without a rack or stand to hold them up. This allows you some assurance that the bag will be anchored in place while samples are cut and that the sampling bag will remain standing while sample pieces are placed in the bag.

You are to sanitize the caddy, knife, and hook before collecting the samples by using the establishment's sanitizing solution according to label instructions. If the establishment uses hot water only, then use hot water to sanitize sampling equipment. Use sterile gloves and handle all sanitized surfaces so that they do not become contaminated.

Collect samples by using the N60 method of sample collection (as described below).

- If a specific production is composed of greater than 5 containers of beef manufacturing trimmings, 2-piece chucks, or primal or sub-primal cuts, randomly select 5 containers for sampling; and
- If the specific production is composed of 5 or less containers, use the table below for sampling.

Number of Sample Pieces to Collect Per Container	
<i># of containers in each specific production</i>	<i># of sample pieces to select from each container</i>
5	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

Note: If the establishment has its own *E. coli* O157:H7 testing program and meets the alternative lot definition criteria on page 12, the sample pieces may come from one container, e.g., combo bin or box.

Raw Beef Product Sampling

Aseptically collect the appropriate number of pieces of beef trim, 2-piece chucks, or primal or sub-primal cuts based on the number of containers that represent one specific production period. Use the sanitized hook to reposition and anchor a piece of meat at the top of the container. For larger pieces of meat, a curved boning knife and short boning hook may work better than the standard meat inspection hook and straight boning knife.

Cut off a slice of the surface that is approximately 4 inches long by 2 inch wide and 1/8 inch thick from each of the 60 pieces of meat. The priority is to collect samples from pieces of product taken from the original surface of the beef carcass. **You must make every effort to ensure that at least 60 thinly (approximately 1/8 inch thick) excised external surface tissue samples are included in the sample.**

Weigh the sample to ensure approximately 2 pounds of product are collected and place the sample slices in the sterile Whirlpak® sample bag. Do not use any other bag, e.g., a zip-lock bag.

Check the product temperature of the top pieces of beef from the containers that were randomly selected (do not take the temperature of the actual sample slices). Record the warmest temperature reading taken in Block 21 of the sample request form. If the product is warmer than 40°F, place the bag containing the sample under refrigeration in a secure location to chill it before shipping. Do not freeze the sample unless freezing is a CCP in the HACCP plan.

If the plant produces **large pieces of bench trim** derived from primals and sub-primals, you are to sample product using the N60 sampling procedure described above when project code MT55 is pre-printed in Block 14 of form 10,210-3. If the plant produces bench trim derived from primals and sub-primals such as steaks, roasts or other cuts designated for non-intact use that are too small to be sampled using the N60 sampling procedure, you are to collect enough pieces to equal 2 pounds of product for sampling.

Note: If a plant produces both large pieces of bench trim derived from primals and sub-primals and small pieces of bench trim derived from trimming steaks, roasts and other cuts, you are to sample only the product that can be sampled using the N60 sampling procedure. If the plant commingles both types of trim, you are to collect samples from the product that lends itself to N60 sampling procedure described above. (Refer to FSIS Notice 51-09 for sampling bench trim).

Collecting Raw Ground Beef and Beef Patty Components other than Beef Manufacturing Trimmings

Follow the general sampling instructions outlined in this handout, e.g., randomly collect a sample (day, shift, and time for routine sampling) using aseptic technique from one

Raw Beef Product Sampling

production lot after all of the plant's interventions except for a microbiological testing intervention within the 30-day sampling window.

For AMR products and LTR products select a sample consisting of no less than 1 lb but no more than 2 lb of product from a specific production lot. For other raw ground beef components and beef patty components such as cheek meat, heart meat, and weasand meat collect one piece, or enough pieces, of the beef component to equal no less than 1 lb but no more than 2 lb of product from a specific production lot. If the component is very large, follow the N60 sample collection method.

Note: Place samples taken aseptically from bulk packaged raw ground beef components (e.g., in combo bins or large weight boxes) in a sterile Whirlpak® bag provided by the laboratory not a zip-lock bag.

If the N60 method is used to collect a component, check the product temperature of the top pieces meat from the containers that were randomly selected. Record the warmest temperature reading taken in Block 21 of the sample request form. If the product is warmer than 40°F, place the bag containing the sample under refrigeration in a secure location to chill it before shipping.

Collecting Raw Ground Beef Products

Follow the general sampling instructions outlined in this handout, e.g., randomly collect a sample (day, shift, and time for routine sampling) using aseptic technique from one production lot after all of the plant's interventions, except for a microbiological testing intervention within the 30-day window.

You are to collect a 1 lb sample of ground beef product from the current day's production in final packaged form (whenever possible). If ground beef product in final packages is not available for sampling (e.g., if the ground product final package is too large) or for any reason you are unable to collect a 1 lb package of finished product, you are to collect the 1 pound sample aseptically and using sterile gloves and the sterile Whirlpak® bags. When an establishment produces multiple raw ground beef products, the IIC should oversee sampling procedures to ensure that a different product within the requested product type is sampled each time a sample request form is received.

You may receive an FSIS Form 10,210-3 from PREP requesting the collection a raw ground beef product sample for *E. coli* O157:H7 testing of under the MT43 sampling program at the following monthly rates:

- Up to 4 times within a calendar month for establishments that produce greater than 250,000 lbs of ground beef product per day from the estimated production volumes recorded in block 28 of FSIS Form 10,210-3

Raw Beef Product Sampling

- Up to 3 times within a calendar month for establishments that produce between 50,000 to 250,000 lbs of ground beef product per day from the estimated production volumes recorded in block 28 of FSIS Form 10,210-3
- Up to 2 times within a calendar month for establishments that produce between 1,000 to 50,000 lbs of ground beef product per day from the estimated production volumes recorded in block 28 of FSIS Form 10,210-3
- Generally, no more than once within a calendar month for establishments that produce less than 1,000 lbs of ground beef product per day from the estimated production volumes recorded in block 28 of FSIS Form 10,210-3. FSIS will ensure that these establishments are sampled at least once per quarter.

When more than 1 sample is scheduled to be collected during a month, you are to randomly select a day, shift, and time to collect a maximum of 2 samples after the sample collection date indicated in Block 4 of Form 10,210-3, but not before that date. You can collect two samples per day as long as each sample corresponds to a microbiologically independent and individually identifiable lot of product. However, when the establishment cannot continue to operate under the 2 sample per day frequency (e.g., because the establishment cannot fill orders and hold all sampled product) or because your workload cannot accommodate this sampling frequency, you can only collect a single sample. **You must collect at least one sample per FSIS Form 10,210-3 whenever a sample request form is received and product is available during the month.**

Note: If an establishment requests that IPP collect more than 2 samples per day, IPP are to instruct the establishment:

- to make a request to the Risk and Innovations Management Division (RIMD), Office of Policy and Program Development via <http://askfsis.custhelp.com> for review.
- to type “sampling” in the subject line in askFSIS.
- that the question in askFSIS should include a description of the control program that the establishment has in place that ensures microbiological independence between lots.

RIMD will review the request and consider the establishment's FSIS testing history, System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) history, and FSIS's resources. RIMD will provide a response to the establishment as to whether the establishment qualifies to have up to 4 samples taken per day by the IPP.

An establishment with a sound basis for defining lots and sub-lots of raw ground beef product and has production schedules that define the specific raw ground beef

Raw Beef Product Sampling

components used at specific times, may request that you collect the sample at the start of operations rather than at the randomly chosen time during the day. When the establishment requests the use of this **alternative sampling method**, you are to determine if the establishment:

- has treated the source materials for the ground beef product that you intend to sample differently from other source materials used for grinding, e.g., has applied antimicrobial interventions it does not normally use on the source materials of the ground beef product you intend to sample.
- has ground the source materials distinctly different (e.g., different suppliers, different types of source materials) from those source materials it typically grinds on the day you intend to collect the sample.

If the establishment **has not** made any changes to how the source materials are treated and how it ground them and the plant has documentation showing that a specific lot of product is scheduled to be ground at the random time you selected when you received the FSIS Form 10,210-3, you are to allow the establishment to grind that lot of product at the beginning of operations on the day that you randomly selected for sampling. At the weekly meeting, you are to discuss the alternative parameters that allow a sample to be taken at the beginning of production.

IPP must understand the establishment's lotting and sub-lotting practices and the establishment's standard practices for scheduling, or "staging," product the establishment grinds on production days because they **must** verify that the establishment has a sound method of lotting and sub-lotting source materials. IPP are to use the questions in Chapter 2, III. C.—Verifying Establishment Lotting and Sub-lotting— in FSIS Directive 10,010.1, to assist them in determining the establishment lotting and sub-lotting practices. The responses to these questions will determine if an establishment meets the **alternative parameters** that allow a sample to be taken at the beginning of production.

As outlined in FSIS Notice 08-09, FSIS does not collect *Salmonella* sets in establishments that produce less than 1000 pounds of raw ground beef per day. Although these low volume establishments will still not be scheduled as part of the *Salmonella* verification testing program, FSIS will request that raw ground beef samples be submitted for testing for *Salmonella*, including serotyping, as well as *E. coli* O157:H7. Form 10,210-3 with project code MT43 pre-printed in block 14 and Form 10,210-3 with project code MT43S in block 14 are mailed separately and represent 2 different sampling programs. IPP receive sample requests forms under the MT43 sampling program more frequently than under the MT43S sampling program. When you receive a sampling form with project code MT43S, hold the form until you receive a sampling form with project code MT43. When you have both forms, collect and submit **one** 1 lb

Raw Beef Product Sampling

raw ground beef sample and both sample forms (MT43 and MT43S project codes) to the laboratory following the sampling directions in this handout and FSIS Directive 10,010.1. The sample will be tested for both *Salmonella* and *E. coli* O157:H7.

If the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded (see Attachment 2 for discard reasons). If the plant has freezing as a CCP in its HACCP plan, Office of Public Health Science (OPHS) may provide additional guidance on a case-by-case basis.

Collecting Samples in Establishments that Slaughter, Produce Manufacturing Trimmings and/or Other Raw Ground Beef Components and Grind Beef

Some establishments may produce raw beef products that are subject to different routine verification sampling programs, e.g., MT43, MT50, MT54 and MT55. Therefore, you may receive **multiple** routine sample requests (MT50 or MT55 and MT43 or MT54) during the same 30-day sampling window. You are to complete **all** sample requests by selecting samples from independent production lots, **unless** you are only able to collect one sample (e.g., because the establishment produces 1,000 pounds or less of product on a daily basis, or only on an intermittent basis). In this situation, you prioritize by sampling the beef manufacturing trimmings under the MT50 and MT55 sampling programs using the N60 collection method.

Some slaughter establishments may grind all the beef trimmings and other raw ground beef or beef patty components they produce and not ship any beef trim or other components. In this situation, IPP are to sample the trim under the MT50 sampling program or the other components under the MT54 sampling program when they receive sampling requests with these codes.

Step 4: Packing and Mailing the Sample

If the paperwork is missing, not complete, or if it is for the wrong type of raw beef product, the lab **will** discard the sample. Be sure the identification on the sample and the paperwork match, otherwise the sample will be discarded.

All sample forms received **without** a collection date are discarded.

Microbiological pathogen samples submitted on FSIS Form 10,210-3 must have Part II, blocks 19, 20, 21, 22, and 28-32 completed. Otherwise the lab discards them.

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD <input type="checkbox"/> YES <input type="checkbox"/> NO
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Raw Beef Product Sampling

Note: Block 21 doesn't apply to samples collected in the **final packaged form** such as raw ground beef and/or veal product samples.

28. REMARKS

Note: Block 28 has additional information and questions you need to answer. Check the box that best describes the raw beef component sampled. Provide the production volume information requested, record the shift from which the sample was collected and any other requested information.

29. COLLECTOR'S SIGNATURE	30. NAME OF COLLECTOR (Print)	31. BADGE NO.	32. TELEPHONE NO. AT EST.

Note: The badge number is for the positive identification necessary for a traceable chain of custody. For example, if there are two Sam Smiths in FSIS, it is important to identify which Sam Smith sent the sample. Using your badge number does not violate your privacy, but it does supply the necessary positive identification for legal purposes.

One or more individually identified samples may be submitted in a shipping container. Follow the instructions in FSIS Directive 7355.1, "Use of Sample Seals for Program Samples and Other Applications." You may need to include additional cooling packages in the shipping container to keep the sample or samples cool during transportation. To submit multiple samples, you may request larger boxes from the laboratory identified in Block 9 of FSIS Form 10,210-3 by sending an e-mail message to their e-mail addresses on page 9 of this handout. If you include more than one sample in the shipping container, include one of the identifiers (bar code) for the other sample on the Container Seal, 7355-2A. This lets the lab know that there are multiple samples in the box. The labs will discard them if it is not clear which sample goes with which sample form.

Double-check and compare the address on the expanded billable stamp to make sure it is going to the lab indicated in block 9 of the sample form. The lab will discard the sample if you mail it to the wrong lab.

The shipping containers you receive should have the top and bottom sealed by the lab with tamper-evident tape. You will **not** receive any tamper-evident tape to use. If the tape is cut or missing, **do not** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of

Raw Beef Product Sampling

origin for processing; complete the seal by writing “seal broken” in the “Form No.” blank).

Pack the sample in this order.

1. Gel pack
2. Coolboard
3. Sample with paperwork (all in a zip-lock bag)
4. Foam plug
5. Close the shipper with seal (7355-2A – Container Seal)

To ensure the product is maintained at refrigeration temperature, place the sample in a pre-chilled shipping container with a frozen gel pack, even if the sample was previously refrigerated or frozen. The piece of cardboard called the coolboard goes on top of the gel pack to separate the gel pack from the sample. Put a small bar code sticker from Form 7355-2 at the top center of the sample form (i.e., paperwork) and put the form or forms (MT43 and MT43S projects) in a plastic bag or sleeve. Put another small bar code sticker on the bagged sample. Put the sample and paperwork into the larger zip-lock bag and affix the Identification Label (7355-2B) to the bag. Note that the 7355-2B is a **label** rather than a seal and must simply be affixed. There is no need to fold over and seal the bag with the label. The zip-lock bag, containing the bagged sample and the paperwork, is put into the shipper. Filler material is **not allowed** in the shipping container. This means that no newspaper, paper towels, etc., can be inside the shipping container to take up any empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. Put any extra unused bar codes into the box so that the lab can account for them, or put them on the Container Seal where they won't cover any written or printed information. Alternatively, if you keep a record of the sample, you can affix the extra bar code to your record. Close up the box and seal it.

For sample integrity, a Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

Raw beef product samples are mailed to the laboratory on the first available day the contract carrier picks up after collecting the sample. **Do not wait** until the establishment completes the pre-shipment review before submitting the samples to the laboratory for *E. coli* O157:H7 testing. If the establishment intends to test the product for *E. coli* O157:H7 before conducting the pre-shipment review, **do not wait** for the establishment to receive test results before submitting the sample to the laboratory. Make sure the correct date is in block 20 on FSIS Form 10,210-3.

Samples are mailed so they arrive at the FSIS lab the next day. Samples should not be held over the weekend if it is avoidable (not more than three days). However, if you hold the sample over the weekend (Friday to Monday), you must freeze it. The current

Raw Beef Product Sampling

contract carrier will **deliver** on Saturdays, but not **pick-up** on a Saturday. With the newer expanded billable stamps, there is no need to designate Saturday delivery.

Double-check that the lab address in block 9 of the FSIS Form 10,210-3 is the same as on the expanded billable stamp. If these are different, your sample will be discarded. If the lab listed in block 9 is different from the one on the expanded billable stamp, e-mail the lab listed in block 9 and request an expanded billable stamp from that lab. You should determine if you have expanded billable stamp for the correct lab when you **first** get your sample request, **not** when you are about to mail the sample.

Check the expiration date on the expanded billable stamp. Do not use it if it is expired.

On the expanded billable stamp, enter the establishment number, shipping date (day sample box picked up by carrier) and the establishment's phone number.

Example 1: You receive a sample request from PREP for project code MT43. You read the information on the 10,210-3 and the related directives. You note the time frame in Block 4 of the form. You make sure you have the proper sampling supplies and billable stamp for the lab and randomly select the day, shift, and time to collect the sample. On the appropriate date, you notify plant management that you will be collecting a sample today and provide the reason for taking the sample.

You ask what products are being produced that meet the product type requested. The production manager tells you that today they are producing bulk raw ground beef in 20-lb twist-tie bags, raw hamburger in 2-lb tray packs, raw beef patties packed 12 to a vacuum sealed bag, and raw beef patty mix in 40-lb boxes. In the recent past, you had sent in samples of the beef patties and the bulk ground beef, which were negative for *E. coli* O157:H7. To ensure you are sampling the various products, this time you select the hamburger. You inform the production manager that you'll sample the hamburger.

At the time you go out to collect the sample off the packaging line, you notify plant management. A QC person accompanies you out to the line. You wash and sanitize your hands and then pick up a package off the line. The QC person asks why you selected that package. You tell her it was random based on time.

You realize that you won't be able to mail the sample until tomorrow morning, so you refrigerate the sample according to the directions in FSIS Directive 10,010.1. You put it in the retain cage in the cooler and secure it with a government lock. The following morning, you pack and send the sample to the FSIS lab listed on the 10,210-3 sample request form. You enter an unscheduled procedure 05B02 on the procedure schedule.

Step 5: Results

Access LEARN (Laboratory Electronic Application for Results Notification) to track your sample receipt and results. LEARN is a computer application that notifies FSIS personnel of the receipt and status of samples sent to FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard, and the results of the analyses when they are completed. More information is contained in FSIS Directive 10,200.1.

You check LEARN the day after you submitted the sample to the FSIS laboratory. If you click on the correct sample in LEARN, at the bottom of the screen there should be a discard reason/description if the sample was discarded. This is below the normal area on the screen where results are found. If the sample was discarded, notify the establishment. This is especially important when the plant is holding product. The product no longer needs to be held if the sample was discarded.

The first lab analysis is accomplished within two days of sample receipt. It is a screening test that identifies the possible presence of *E. coli* O157:H7. If the screening test is negative, *E. coli* O157:H7 is not present (or below detectable levels) in the sample tested. The negative results are posted in the LEARN system. FSIS resumes normal sampling at that establishment.

Every FSIS verification sample that the laboratory confirms positive for *E. coli* O157:H7 goes through three stages of analysis. If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7 and additional testing is necessary to confirm the result. The laboratory reports the sample result in LEARN as a "Potential Positive". In the next stage, based on further analyses that reveal more evidence to suggest that *E. coli* O157:H7 may be present in the product, LEARN reports the sample result as "Presumptive Positive". Upon further analysis and conclusive evidence that *E. coli* O157:H7 is present in the sample, the result is reported in LEARN as "Confirmed Positive". The confirmatory testing is usually accomplished within 3 to 4 days of the sample receipt at the FSIS laboratory, but can sometimes take longer.

Presumptive positive and positive sample results are e-mailed to plants that have an e-mail address in the PBIS plant profile. Negative results are not e-mailed to the plant. **Even if the establishment receives sample result notifications by e-mail, it is still your responsibility to notify the establishment when sample results are posted on LEARN.**

Note: Positive *Salmonella* results from raw ground beef samples submitted to the laboratory under project code MT43S will not have any immediate regulatory consequences. Therefore, upon receiving negative *E. coli* O157:H7 results from the same sample (MT43), you are to notify the plant that it may release any affected

Raw Beef Product Sampling

product on hold. If you receive the *Salmonella* results before the *E. coli* O157:H7 results, you should wait to notify the plant until you receive the *E. coli* O157:H7 results.

The Office of Data Integration and Food Protection (ODIFP) and OPHS will analyze the *Salmonella* sample results from raw ground beef produced in low volume establishments and the information provided Block 28 of the sample request form.

Workshop I

1. When would a ground beef sample be sent to the lab for an *E. coli* O157:H7 directed sample?
 - a. the day before the “use by” date
 - b. just prior to packaging
 - c. as soon as the contract carrier is available after the sample is collected
 - d. as soon as the lot is assembled

2. Plant management is notified that you are taking a sample
 - a. when you receive the analysis result (either from LEARN or the DO).
 - b. if the plant has a good working relationship with FSIS.
 - c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
 - d. because of the Freedom of Information Act (FOIA).

Scenario

1. You received FSIS Form 10,210-3 requesting a raw ground beef or veal sample under the MT43 project code. This is the first time you have received this type of sample request.

As a critical thinker, what do you do next?

The instructions tell you to randomly select and aseptically collect an unfrozen one pound sample prior to freezing. The plant receives beef trimmings and chubs of ground beef. The chubs may be added to the beef trimmings and ground, or they may be shipped without any further processing. The ground beef and beef trimmings are ground into ground beef, ground beef patties, raw beef and pork

Raw Beef Product Sampling

sausage, and cooked meatloaf. The plant has one grinder and does a complete cleaning and sanitizing of the equipment prior to the start of operations each day.

What product could you sample for the *E. coli* O157:H7 under this project?

When would you notify plant management that you will take a sample?

The plant manager asks you to tell him specifically the time when you will collect the sample so he can stop production after the sample is taken.

How do you respond?

What should you do after you collect and submit the sample?

FSIS Actions after a Positive FSIS or another Federal or State Entity Sample Result

Requesting Supplier Information when there is an FSIS Presumptive Positive Sample Result

The lab notifies the DO using BITES (Biological Information Transfer E-mail System) prior to posting the information in LEARN if the sample is presumptive positive for *E. coli* O157:H7. Because the laboratory confirms most "Presumptive Positives", the contact person in the DO where the establishment is located alerts the plant if the sample is "Presumptive Positive." This ensures that the plant receives that important message when you are not available. The DO contact will also inform the plant that if the results are confirmed positive, FSIS will collect information regarding specific suppliers of the source materials used in the production of the raw beef product that tested positive (confirmed).

Raw Beef Product Sampling

Supplier Information that is collected:

- Name of the establishment (could be the same establishment that produced the positive raw beef product)
- Point of contact (name, title, e-mail address, and fax number)
- Phone number
- Supplier lot number
- Production date
- Name of supplied material and any additional information to clearly identify the source material

If the source materials are imported from a foreign establishment, additional information will be need to be gathered by the establishment (country of origin, foreign establishment number, shipping mark, I-house, and bar-coding or other information to aid in identifying the product as outlined in FSIS Directive 10,010.1).

At the time the plant is informed that the sample is presumptive positive, it should start gathering the supplier information along with distribution information.

Collecting Supplier Information when there is a Confirmed Positive Sample Result

When an FSIS laboratory or another Federal (e.g., Agricultural Marketing Service-AMS) or State entity confirms a sample is positive, you collect the required supplier information from the plant and e-mail it to the DO contact designated to receive this message. You need to:

- Ensure that the source materials used in the raw beef product are specifically identified (e.g., beef trimmings, bench trim, sub-primal cuts, beef hearts, veal trimming, head meat or cheek meat),
- Include the supplying establishment's name and number if the supplying establishment is the same establishment that produced the raw beef product that was positive,
- Make a note of any information the plant is unable to provide, and
- Copy your Frontline Supervisor (FLS).

The DO accesses the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), and opens a case file for the incident. The DO enters all the supplier information you provided into STEPS. The DO is also responsible for determining whether any of the supplying establishments were also **originating supplying slaughter establishments** that produced the source materials that were used in the raw beef product that tested positive for *E. coli* O157:H7. Follow-up samples are only collected from originating supplying slaughter establishments. With respect to supplying establishments that **are not** originating supplying slaughter establishments, the DO is to inform the IIC to collect

Raw Beef Product Sampling

supplier information on the source materials that went into the lot represented by the positive sample and forward the information to the DO.

Enforcement Actions Based on FSIS and Establishment Test Results

You need to determine if the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products. If the raw beef product sample you submitted is positive for *E. coli* O157:H7 and the plant tested the **same** product, check the plant's test results to determine whether it also found the sampled product positive for *E. coli* O157:H7. If the plant held the product or maintained control of the product (e.g., the plant moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS **AND** the establishment found the product positive for *E. coli* O157:H7, you **do not** issue a noncompliance record (NR). Verify that the establishment performs the appropriate corrective actions.

Issue an NR when FSIS finds product positive for *E. coli* O157:H7, but the plant does not, under the appropriate 03 ISP code using the "verification" noncompliance classification indicator and cite §417.4(a) and §301.2 as the relevant regulations. As soon as possible after the establishment has implemented its corrective action, perform the HACCP 02 procedure for the specific production that tested positive. Determine whether or not the plant implements corrective actions that meet the requirements described in §417.3. Verify whether the establishment held or shipped the affected product. In addition, if the plant has its own testing program, review its records to determine if the plant has found multiple *E. coli* O157:H7 positive results which would be evidence of a systemic problem. In processing establishments, verify the implementation of the SSOP by following the instructions in FSIS Directive 5000.4. If the establishment delays disposition of the positive product, you are to work with your FLS to determine how to work with the establishment to ensure proper and timely disposal of the product.

Plants are expected to ship only wholesome unadulterated product. The establishment is responsible for determining what product it holds and what it determines to be "affected product". (FSIS Directive 8080.1 contains more information related to affected product or "scope".) If the plant does not control its product, then take a regulatory control action (retain product if it is available or take a withholding action per §500.3(a)(1) if the plant shipped the adulterated product into commerce). If any affected product has left the plant and it is no longer under the plant's control, notify RMS through the DO. A recall may be recommended. (Documentation and enforcement will be covered in more detail in a later module.)

Raw Beef Product Sampling

Plant management must account for all affected products by identifying them and their location. The plant must take **corrective actions** that meet one of the following requirements.

- 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan, or
- 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan, or if it is addressed in prerequisite programs, or
- 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the SSOP.

The establishment may need to conduct a reassessment of its HACCP plan or reevaluate its SSOP or prerequisite programs to meet these requirements. In addition, the plant should reassess (§417.4(a)(3)) because something in the process has changed.

Issue an NR if the plant fails to take the appropriate corrective actions.

If product disposition is to occur off-site, verify that the plant maintains appropriate control of the product as explained in the next section.

Off-Site Disposition of E. coli O157:H7 Positive Product

Raw beef products confirmed positive for *E. coli* O157:H7 may be moved off-site for proper disposition, under appropriate controls. Product may be transferred to another official establishment for further processing to destroy the pathogen. Plants may opt to dispose of the product through rendering or disposal in a landfill. Plants may also divert product that is presumptive positive, rather than wait for a confirmation. Presumptive positive product must be controlled just like confirmed positive product. Plants may use their own controls (e.g., company seals) or move the product under FSIS control (e.g., USDA seals or FSIS Form 7350-1, "Request and Notice of Shipment of MPI Sealed Meat/Poultry"). When the product is destined for a landfill or rendering operation, it moves under company controls, because FSIS representatives are not at those locations to remove USDA seals or follow up with FSIS Form 7350-1.

When the establishment moves presumptive positive or positive product off-site for disposition, verify the plant that produced the positive product maintains appropriate control of the product at **all times**, including while it is in transit to the off-site location where the product will either be processed to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

When you perform the HACCP 01 or 02 procedure, verify that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;

Raw Beef Product Sampling

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

Note: If an establishment ships adulterated product to a renderer or landfill operation, you are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314.3).

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

Note: An instructional “For Cooking Only” statement on the container label is not a sufficient control.

- Maintained records showing that every lot of product implicated by the positive test result received appropriate disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

Note: Records of receipt at an official establishment, landfill operation, or renderer **are not** adequate to show that the product received appropriate disposition. Documentation (a record) from the official establishment, landfill operation, or renderer must show that the positive product was further processed to destroy *E. coli* O157:H7 or the specific product was destroyed. For example, this record may be a record of receipt and control pending the product receiving a lethality treatment. The record should include information necessary to identify the product, the number of pounds of raw beef product received (landfill check weights), and the number of pounds of such product rendered or destroyed.

- Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

You cannot complete the HACCP 02 procedure for the specific production until the plant completes the corrective action and documentation requirements (417.3(a) or 417.3(b) and 416.15), which includes receiving documentation from the official establishment or landfill operation or renderer that demonstrates proper disposition/disposal of every lot implicated by the positive result and conducts pre-shipment review of the corrective actions.

Note: If the product is shipped to another official establishment for disposition (e.g., cooking), IPP at that establishment are to verify that the receiving establishment

Raw Beef Product Sampling

adequately addresses the pathogen in the product as part of their ongoing HACCP 01 and 02 verification duties.

Issue an NR if you find noncompliance while verifying the plant's off-site product disposition corrective actions. Document the noncompliance under 9 CFR 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan or 9 CFR 416.15 and 417.3(b) if *E. coli* O157:H7 is addressed in the Sanitation SOPs or 9 CFR 417.3(b) if *E. coli* O157:H7 is addressed in a prerequisite program. You should contact the DO, through supervisory channels, if the determination is made, or if questions arise about whether the establishment committed the prohibited act of selling or transporting adulterated articles in commerce (no controls) that have not been inspected and passed.

Verification Activities at a Plant Receiving E. coli O157:H7 Positive Product

If you are the inspection program employee at the plant that receives raw ground beef products, beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components that tested positive for *E. coli* O157:H7, you have certain verification functions to perform to ensure the establishment adequately addresses the pathogen in the product.

When you perform the HACCP 01 or 02 procedures for such products, verify that the plant

- documents receipt of presumptive or confirmed positive product (as per §417.5),
- maintains control of the product, and
- addresses the receipt *E. coli* O157:H7 in its hazard analysis, flow chart, and HACCP plan (includes an adequate lethality treatment to destroy the pathogen).

You are to verify that the establishment has supporting documentation validating the effectiveness of the lethality treatment, i.e., it is sufficient to reduce *E. coli* O157:H7 to undetectable levels, during the HACCP 01 procedure. You are not required to be present at the establishment to verify the disposition of the raw beef product that is positive or presumptive positive for *E. coli* O157:H7. You can verify that the product received proper disposition through records review.

Note: FSIS does not require establishments to re-test product for *E. coli* O157:H7 after the establishment subjects the product to a lethality treatment adequate to destroy the pathogen.

Document all noncompliance as per FSIS Directive 5000.1.

FSIS Verification Activities at Supplying Establishments when a Raw Beef Product at an Official Establishment or Retail Facility Tests Positive for E. coli O157:H7

When raw beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments, including the originating supplying slaughter establishment that produced the source materials (e.g., primals, sub-primals, beef manufacturing trimmings, bench trim, or raw ground beef or beef patty components) that were used to produce the positive product. The DO will contact the IIC at **each** of the supplying plants, including the originating supplying slaughter plants. If you are at the **supplying plant**, remind the plant that the notification is to ensure that the supplier knows that it **could be** the source of positive product. The IIC at the supplying establishment will ensure that a HACCP 02 procedure is performed to verify that the supplier met all the HACCP regulatory requirements (e.g., monitoring, verification, recordkeeping, corrective actions, and reassessment) at all CCPs in the HACCP plan for source material production lots sent to the plant or retail facility where the positive was found. If the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products, IPP are to review establishment records to determine if it has found multiple positive results which would indicate there is a systemic problem. IPP are to verify the plant's control of its sanitary dressing procedures during procedure 06D01 per FSIS Directive 6410.1.

Multiple Follow-Up Sampling After an E. coli O157:H7 Positive Sample Result

Each time that an FSIS routine sample or another Federal or State entity's sample of raw ground beef product, beef manufacturing trimmings, bench trim, or ground beef or raw beef patty components tests positive for *E. coli* O157:H7, IPP will receive 16 follow-up sample request forms, 10,210-3, to sample product from the establishment that produced the positive raw beef product. IPP will also receive 16 follow-up sample request forms to sample product from the establishment when FSIS follow-up samples of beef trimmings or ground beef or raw beef patty components test positive for *E. coli* O157:H7 **OR** when an originating slaughter establishment is the **sole supplier** or a **repeat** supplier of the source materials implicated in positive sample result. The sample request forms are automatically generated through PREP and sent to the establishment.

Note: If the IIC does not receive sampling forms within 14 days of the positive sample result, he or she is to contact the SamplingForms-Headquarters@fsis.usda.gov mailbox and request the forms for follow-up sampling of a positive.

For low volume establishments, (establishments that produce less than 1000 pounds per day of the product to be sampled), **8** samples need to be collected instead of 16 samples. The remaining 8 sample request forms need to be returned to the laboratory in

Raw Beef Product Sampling

the shipping container with the last follow-up sample submission. The type of sample requested will be based on the type of raw beef product implicated in the positive test result. Each of the 16 sample request forms will have the sampling project code pre-printed in Block 14 to identify the type of raw beef product to sample. For instance:

- Sample raw ground beef product under the MT44 project code after a routine MT43 project code (ground beef product) positive result;
- Sample beef manufacturing trimmings, bench trim, OR other raw ground beef or raw beef patty components under the MT53 project code after a
 - routine MT50 project code positive result (beef trim derived from cattle slaughtered at the plant); OR
 - routine MT54 project code positive result (raw ground beef/beef patty component); OR
 - routine MT55 project code positive result (beef trim derived from cattle NOT slaughtered at the plant) ; or
- Sample ground beef products under the MT53 project code after a follow-up MT44 project code positive result (ground beef product); or
- Sample beef manufacturing trimmings or ground beef/beef patty components under the MT53 project code after a follow-up MT52 project code positive result (source material from the originating supplying slaughter plants); or
- Sample source materials (beef manufactured trimmings, primals or sub-primals bench trim, or ground beef/beef patty components) under the MT52 project code when the originating supplying slaughter plant is the **sole supplier** identified in STEPS or as a supplier of source materials for product found to be positive 120 days prior to the date of the current raw beef product positive result, i.e., **a repeat supplier** of source material that has been implicated in a positive result.

Sampling from production lots produced after the positive result starts as soon as possible following receipt of the 16 follow-up sample request forms. You **DO NOT** wait for the establishment to complete the corrective actions taken in response to the positive result before conducting follow-up sampling. As soon as the plant resumes normal production of the product(s) to be sampled, start your sample collection of either 8 or 16 samples at the following daily and weekly frequencies.

- Sample a maximum of 2 follow-up samples per shift per day from different lots (up to 4 samples per day for a 2-shift plant). Follow this procedure unless the establishment can not continue to operate under that sampling frequency (e.g., cannot fill orders or hold all sampled product) or your workload will not

Raw Beef Product Sampling

accommodate that sampling frequency. If either of these concerns arises, discuss it with FSIS supervision immediately.

- At a minimum collect 3 samples per week unless the establishment can not continue to operate under that sampling frequency or your workload will not accommodate that sampling frequency. If either of these concerns arises, discuss it with FSIS supervision immediately.

If the establishment is not currently producing the type of raw ground beef component requested, you are to collect a sample of another component that is available. You are to sample beef manufacturing trimmings if the establishment is producing them. If the establishment is also not producing beef manufacturing trimmings, then you are to collect a sample of another type of raw ground beef or beef patty component (e.g., head meat, heart meat, product from advanced meat recovery (AMR) systems) that the establishment intends to use in the production of raw ground beef products.

You only collect follow-up samples of beef manufacturing trimmings, bench trim, or raw ground beef components or beef patty components that the establishment intends for use in raw ground beef or other raw ground beef products. Randomly select the time to collect the sample of raw ground beef product, beef manufacturing trimmings, or raw ground beef or beef patty component from the establishment's current production. Follow the sample collection instructions (e.g., 1 lb of raw ground beef product, the N60 sampling procedure for beef manufacturing trimmings, bench trim, and 2-piece chucks, and no less than 1 lb but no more than 2 lb of product needed for AMR product, low temperature rendered products, and other raw beef components). Follow the instructions for notifying plant management before taking the sample in FSIS Directive 10,010.1 and as previously covered in this handout. Document each follow-up sample collected in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code 05B02.

Pack the sample and complete the sample request form as outlined in this handout. You may submit more than one sample per shipping container if each sample is individually identified and the shipping container is large enough to hold more than one sample. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample. Return any unused sample request forms in the box with the last follow-up sample.

While you are collecting follow-up samples for *E. coli* O157:H7 testing, you may receive a **routine verification sample request form** for a raw beef product to be tested for *E. coli* O157:H7. In this situation, continue to collect follow-up samples and make **follow-up sampling the priority**, rather than routine sampling. If your workload and the establishment's production practices allow it, collect the sample for routine testing within the allotted 30-day window. **Do not** collect a follow-up sample and a routine verification

Raw Beef Product Sampling

sample from the same product lot. If you are unable to collect the routine sample, you should check box 53 (Other) in Block 33 of Form 10,210-3 and state that you did not collect the routine sample because of follow-up sampling.

While you are collecting follow-up samples for *E. coli* O157:H7 testing under one sampling project code, you may receive follow-up sample request forms for another project code or the same (repetitive) follow-up sampling project code. For example, you may be in the process of collecting the 16 follow-up samples under project code MT52 when the 3rd sample of this set tests positive. As a result of this positive sample result, you will receive 16 follow-up samples for project code MT53. You are to collect the rest of the 16 follow-up samples from the MT52 project code as well as the 16 follow-up samples for the MT53 project code.

Generally, FSIS will continue to collect follow-up samples until the FSIS laboratory finds no positive sample results in a set of 16 or 8 follow-up samples.

Follow-up Sampling at Supplying Establishments

Analysis of *E. coli* O157:H7 sample data collected by FSIS indicates that a plant that has had a positive sample is likely to receive a second positive within 120 days of receiving the first positive result. In response to this finding, FSIS has implemented a follow-up sample testing protocol for establishments that supply raw beef products to establishments that have had product test positive for *E. coli* O157:H7.

On a monthly or bi-monthly basis (during the high prevalence season April to October), the Policy Analysis Division (PAD), OPPD will review data from STEPS to schedule follow-up sampling of suppliers. PAD informs the “Sampling Forms – Headquarters” mailbox of the source materials IPP are to sample at supplying establishments based on information in the STEPS database. PAD also determines whether IPP are to collect **a single** follow-up sample or **multiple** follow-up samples from the information in the STEPS database. For instance, PAD determines if an originating slaughter establishment was the only supplier. If multiple originating slaughter establishments supplied source materials for the raw beef product, PAD determines if any of those originating slaughter establishments have been identified in STEPS as a supplier of source materials for product that tested positive for O157:H7 within approximately 4 months (or 120 days) of the current raw beef product positive result. PAD requests 16 follow-up sample request forms if the originating slaughter establishment is the only supplier or if an originating slaughter establishment is a repeat supplier for **each** source material (e.g., beef trimmings, bench trim, AMR product, 2-piece chucks, sub-primal cuts, etc.) used in the positive raw beef product. However, when a supplier is not the sole supplier or a repeat supplier in STEPS, PAD requests a **single follow-up** sample from the supplier for **each** source material used in the positive raw beef product.

Raw Beef Product Sampling

Based on information from PAD, the DO informs IPP of which type source materials the establishment supplied to the beef boning, cut-up, or grinder facility, so that IPP can sample that raw beef source material from the establishment's current production. If the originating supplying slaughter establishments produced more than one source material used by the boning, cut-up or grinding establishment, PAD will generate sample request forms for each type of source material. The sample request form, FSIS Form 10,210-3, has project code MT52 pre-printed in Block 14.

When AMS notifies FSIS of a positive *E. coli* O157:H7 result for raw ground beef product sample collected under the AMS commodity purchase program, PAD determines the originating supplying slaughter establishments. PAD informs the DO that AMS found a positive sample. PAD requests 8 follow-up sample forms for the type of ground beef product AMS found positive, regardless of establishment production volume, in response to the AMS positive result. In addition, if a sole supplier or repeat supplier in STEPS supplied source materials for the ground beef product that AMS found positive, PAD requests 8 follow-up sample forms for the supplier of the raw beef source material regardless of the supplier's production volume.

In combination slaughter/processing establishments, if FSIS or another Federal or State entity finds a raw ground beef product positive, and the establishment produced the source materials used to produce raw ground beef product that tested positive, PAD generates 16 MT52 sampling program request forms. IPP are to collect either 8 or 16 samples, based on establishment production volume, of the type of source materials used in the positive raw ground beef product. IPP **are not** to collect follow-up samples of the ground beef product. In this situation, PAD notifies the DO to instruct the IIC to mail the forms for multiple follow-up samples of raw ground product (MT44) back to the laboratory via the United States postal service.

If ammoniated LTR product was used as a component in raw ground beef products that tested positive for *E. coli* O157:H7 when sampled by FSIS or another Federal or State entity, PAD generates 16 or 8 sample request forms, or one sample request form. IPP are to collect a sample of ammoniated beef trim at the establishment that produced the ammoniated low-temperature-rendered product, even if that establishment is not an originating supplying slaughter establishment.

If a sample collected under the MT52 sampling program tests positive, PAD generates multiple follow-up sample requests under the MT53 sampling program.

Upon receipt of the MT52 follow-up sample request form, FSIS Form 10,210-3, you randomly collect the of sample source materials (beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components) indicated on the request form from the establishment's current production. Follow the sample collection instructions (e.g., the N60 sampling procedure for beef trim, 2-piece chucks, and

Raw Beef Product Sampling

primals/sub-primals, and no less than 1 but no more than 2 lb of AMR product, low temperature rendered products, and other raw ground beef components) and the instructions for notifying plant management before taking the sample previously covered in this handout. Document the follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code 05B02.

Follow-up Sampling of Ammoniated Low Temperature Rendered Products after an *E. coli* O157:H7 Positive Sample Result

Ammoniated LTR product is subject to the MT52 follow-up verification sampling program when it is used as a component in raw ground beef products that are sampled by FSIS under MT43 or MT44 sampling programs or by another Federal or State entity and are positive for *E. coli* O157:H7. You are to randomly collect a sample consisting of 1 lb but not more than 2 pounds of the ammoniated low-temperature-rendered product from a specific production lot.

If the establishment that produced the ammoniated LTR product is not an originating supplying slaughter establishment, e.g., a combination slaughter processing plant, sample request forms with project code MT52 in Block 14 are not generated for the slaughter establishments that produced the source materials used in the ammoniated LTR, unless the sample of ammoniated LTR product that you submit to the FSIS laboratory lab is positive. When the ammoniated LTR product submitted to the lab under the MT52 project code tests positive for *E. coli* O157:H7, you collect supplier information from the establishment that produced the ammoniated low-temperature rendered product and e-mail it to the DO. The DO will enter the supplying establishments into STEPS. Sample request forms with project code MT52 in Block 14 are generated for the slaughter establishments that produced the source materials used in the positive ammoniated LTR product.

Document the follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code 05B02. Pack the sample and complete sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

Follow-Up Sampling at the Originating Supplying Slaughter Establishments for Intact Raw Beef Products not Intended For Use in Raw Ground Beef Products

When an establishment used intact product, (e.g., primals or sub-primals such as steaks and roasts) as source materials in a raw ground beef product that FSIS finds positive for *E. coli* O157:H7, you are to **select a carcass** at the originating supplying slaughter establishment for follow-up sampling under project code MT52 rather than the raw ground beef component, e.g., beef trimmings, AMR product, head meat, etc., from the carcass if the originating slaughter plant can demonstrate:

Raw Beef Product Sampling

- Through HACCP production records and purchase specifications the intact beef product used as a raw ground beef component **was not intended** for grinding or non- intact product, and the plant had informed purchasers of this intent, and
- That the intact product was derived from beef carcasses in a manner to minimize commingling with other raw beef cuts and product was packaged separately and not commingled with other beef cuts prior to packaging (e.g., bone-in loins or boneless rounds were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other beef cuts). You must be able to verify that the product was handled as stated above through records review or direct observation.

The two conditions are meant to show that the supplying plant intended the product for use in intact product, e.g., steaks and roasts. If both conditions **are not** met, you are to continue to sample the beef trimmings or primals or sub-primals that were used to produce the positive raw ground beef products using the **N60 sampling procedures**. If both of these conditions **are** met, you aseptically collect enough tissue slices from the external surface off the carcass to equal 2 pounds. The slices are to be very thin (approximately 1/8 inch thick). Follow the instructions for sampling large components on pages 18-20, e.g., sanitize the caddy, knife, and hook before collecting the samples and use sterile gloves and sterile Whirlpak® bags. Cut the slices from:

- the surface of the **same part of the carcass** (e.g., chuck, loin, round, etc.) that the establishment used in producing the positive raw ground beef product sample, when possible.
- the carcass while the carcass is hanging in the cooler before fabrication, when possible.

Note: If it is not possible to do either of these things, contact the Risk and Innovations Management Division (RIMD) through askFSIS at <http://askfsis.custhelp.com/>. RIMD personnel are to cc the appropriate district personnel on their reply.

Document the follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code 05B02. Pack the sample and complete the sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

If the follow-up sample result for the carcass is positive for *E. coli* O157:H7, then only the sampled carcass is implicated because *E. coli* O157:H7 contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. The establishment will need to take

Raw Beef Product Sampling

corrective actions for that carcass. The plant may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (e.g., by cooking or irradiation). Head and cheek meat from that carcass which was removed from the skull during the slaughter process is not implicated by the positive result. You should verify the plant's control of its sanitary dressing procedures during procedure 06D01 per FSIS Directive 6410.1.

FSIS Actions after a Positive *E. coli* O157:H7 Follow-Up Sample Result

Access LEARN to track your follow-up sample receipt and results. Respond to discarded samples, negative results, presumptive positive results, and confirmed positive results as previously described in your handout. The actions FSIS takes in response to *E. coli* O157:H7 positive FSIS follow-up samples are the same actions FSIS takes for an *E. coli* O157:H7 positive FSIS routine verification sample.

When an FSIS generated follow-up sample is found positive for *E. coli* O157:H7 an establishment's sample for the same lot is also positive, you should not issue an NR provided that the plant held the product represented by sample (or maintained control of the product) pending its own test results. You need to verify that the plant takes corrective actions that meet the requirements in §417.3.

When an FSIS generated follow-up sample is found positive and the plant either did not test the product lot or did not find the pathogen, you will issue an NR under the appropriate 03 ISP code using the "verification" noncompliance classification indicator and citing §417.4 and §301.2 as the relevant regulations. As soon as possible after the establishment has implemented its corrective actions, perform the HACCP 02 procedure for the specific production that tested positive. Determine whether or not the plant implements corrective actions that meet the requirements described in §417.3.

If disposition of the positive product is to occur off-site, verify that the plant has met all corrective action requirements, e.g., maintained control of product during transportation, has records identifying who received the product and showing proper disposition or disposal, and has conducted a pre-shipment review after receiving the disposition or disposal records as described in the **Off-Site Product Disposition** section on pages 33 and 34 of this handout. If you find noncompliance, document it in accordance with Directive 5000.1. Notify the DO through supervisory channels when the plant has not properly moved the positive product off-site.

DO and EIAO Responses to Positive Results

The District Office (DO) will schedule a Food Safety Assessment (FSA) at an establishment within 30 days after being notified that FSIS or another Federal Agency

Raw Beef Product Sampling

or State entity has found a raw beef product positive for *E. coli* O157:H7. The follow-up sampling results will provide objective data that an EIAO will use in formulating an Agency position when conducting the FSA. In addition, the DO is to schedule an EIAO to conduct an FSA at establishments identified in STEPS as sole suppliers of positive *E. coli* O157:H7 ground beef product and establishments in the STEPS database more than once in the past 120 days identified as a multiple supplier except if the establishment applied a full lethality treatment to the implicated source material.

The DO and EIAOs will consider the results of follow-up sampling and take the appropriate enforcement actions (e.g., issue an NOIE, withhold or suspend inspection, reinstate a suspension), if warranted. Below are factors the DO and EIAOs consider when making a determination about whether to stop collecting follow-up samples and to take a suspension or withholding action:

- the establishment is failing to implement proposed corrective actions;
- the establishment's corrective actions that the establishment is implementing are ineffective;
- the establishment has recurring sanitary dressing noncompliances that render its corrective actions ineffective (see FSIS Directive 6410.1); or
- the establishment does not have support for decisions made in its HACCP plan or hazard analysis (see FSIS Directive 5000.1).

Plant-Generated Sampling

Some plants may have their own sampling programs for *E. coli* O157:H7. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes produce safe, wholesome unadulterated product. These sampling programs may or may not be included in the plants' SSOP or HACCP plans. Even though these programs may not be included as part of the SSOP or HACCP system, plants are still required to share records and analyses results with you.

FSIS has taken the 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 they are moving the product, but the product is still under the establishment's control. FSIS is providing establishments the flexibility to move their product before pre-shipment review when the establishment is conducting testing for *E. coli* O157:H7 and maintains control of the product (e.g., through company seals or FSIS control).

Raw Beef Product Sampling

Based on the regulatory requirements of 9 CFR 417.2(a)(1)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of any testing that the establishment performs that may have an impact on the establishment's hazard analysis are subject to FSIS review and must be available to IPP upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, **on at least a weekly basis**, you must review the results of any testing and of any monitoring activities the plant performed that may have an impact on the hazard analysis. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite programs, contact the Policy Development Division (PDD) or raise the concern through supervisory channels. When records show that the establishment tests beef trim and raw ground beef components for *E. coli* O157:H7, but **never** finds any positives, you are to contact the DO. In addition, when establishment records show **multiple** positive results for *E. coli* O157:H7 in its own testing that may be evidence of a systemic problem, you are to contact the DO. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test results reveal about food safety and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

An establishment may sample raw beef products for *E. coli* O157:H7 when they are received and hold the production lot pending the sample result. If the product is presumptive positive or positive for *E. coli* O157:H7, the plant considers the product to be adulterated, does not accept the production lot, and returns the lot to the supplying establishment using FSIS Form 8140-1, "Notice of Receipt of Adulterated or Misbranded Product" under appropriate controls (e.g., company seals or FSIS seals). After the establishment notifies you that it has rejected the production lot, collect the supplier information. You need to notify the DO (9 CFR 320.7) and include the supplier information in your e-mail. The DO is to notify the IIC at the supplying establishment that rejected product is being returned and have IPP at the establishment conduct a HACCP 02 procedure on the affected lot of product.

Note: The Agency recognizes that it is probable that, despite the ongoing processing interventions for controlling *E. coli* O157:H7, some establishment samples of beef manufacturing trimmings and raw ground beef and beef patty components may test positive for *E. coli* O157:H7. These positives may be random events caused by normal process variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions. Establishment verification testing should occur at a frequency to help determine the difference between acceptable process variation and assignable cause variation in the testing results associated with beef manufacturing trimmings and raw ground beef and beef patty components. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

Raw Beef Product Sampling

If review of the establishment's *E. coli* O157:H7 sampling program reveals it is only performing screening tests and not further analyzing "potential positive" test results to determine whether *E. coli* O157:H7 is isolated from the product, e.g., presumptive positive or confirmed positive, you are to verify that the establishment appropriately addresses the product as if the product is positive for *E. coli* O157:H7. The establishment cannot perform a second screening test for *E. coli* O157:H7 on the product and find it negative. Performing additional screening tests does not negate the original positive screening test. A screening test is not a conclusive (specific) test for the pathogen.

The plant is not obligated to notify FSIS when it receives a presumptive positive or a positive sample result, but it must take corrective actions that meet the requirements of §417.3 each time a presumptive positive or a positive result is obtained. The plant must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

When you are aware that there was a presumptive positive or positive result you must:

- Conduct a HACCP 01 or 02 procedure to verify the plant's corrective actions (§417.3(a) or (b)), and
- Issue an NR **only** if the plant fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

Note: *The HACCP 02 procedure cannot be completed until pre-shipment review is completed, which includes the plant's review of disposition documentation.*

Some plants may opt to divert the product to another official establishment for cooking when they receive a **presumptive positive** in their testing program, or to a landfill or renderer for disposal. However, the plant is still obligated to meet **all** parts of §417.3. It is still required to have proper control of the product while it is in transit for disposition. It also must maintain documentation of appropriate disposition.

When product that is **presumptive positive or confirmed positive** for *E. coli* O157:H7 is transported to another official establishment, renderer, or landfill operation for appropriate disposition, the plant sending the product must:

- maintain records identifying the official establishment, renderer, or landfill operation that receives the presumptive positive or positive product,

NOTE: *If the product is analyzed while in transit, the plant must maintain records identifying the official establishment to which the product is being sent.*

Raw Beef Product Sampling

- maintain control of product (company controls or FSIS controls),
- maintain records that indicate product received proper disposition, and
- complete pre-shipment review only after it has all disposition records for that particular product.

If you are aware that presumptive positive or positive product is in transit, verify the controls. If you find noncompliance with the plant's handling of presumptive or confirmed positive product, contact the District Office.

Example 2

A plant has its own testing program for *E. coli* O157:H7 for its raw hamburger patties. The plant has not included it as a verification activity in its HACCP plan. In the last test, the result was positive. The plant always holds product pending results. The plant does not need to inform you of its positive result, but the plant must implement corrective actions that meet the requirements of 9 CFR 417.3. You must verify that the plant took the necessary corrective actions to meet these requirements. You should become aware of the positive from your regular review (at least weekly) of the plant's sampling results or from reviewing corrective action records or observing corrective actions the plant takes.

Example 3

A plant has its own testing program for *E. coli* O157:H7 in its beef trim. The testing is part of the verification of the overall HACCP plan. The plant analyzes the samples while the product is in transit, but still under the plant's control. When the result is received, the plant completes the pre-shipment review. The product is **not** in commerce, but in transit. The last test result was positive. The plant must implement corrective actions that meet the requirements of 9 CFR 417.3. Again, you must verify that the plant meets **all** four requirements described in 417.3.

Whether the plant brings the product back to the establishment for disposition, or it diverts it for further processing at another official establishment or to a landfill or renderer, the plant must demonstrate control of the adulterated product until that product receives proper disposition. The establishment must provide documents evidencing proper disposition.

Example 4

The establishment has a finished product sampling program as part of its verification of the HACCP plan for raw ground beef product. Its last sample was presumptive positive.

The plant diverted the product to cooking at its own in-plant cooking operation. It identified all affected product and cooked it separately from its other products. The company used a HACCP plan that had been designed specifically for product known to contain *E. coli* O157:H7 and which contains a CCP for lethality that was validated to eliminate *E. coli* O157:H7. Records demonstrating the positive product received proper disposition are available.

The plant identified the source of the presumptive positive *E. coli* O157:H7 contamination as coming from a new supplier. Plant management required the supplier to demonstrate that validated antimicrobial interventions are implemented in its process, sample and test its product for *E. coli* O157:H7 and provide a Certificate of Analysis (COA) with each shipment before purchasing any other products from that supplier. The plant includes this certification as a HACCP verification.

Instructional or Disclaimer Statements

Although instructional and disclaimer statements do not affect the samples you collect, you may encounter them while performing your verification duties.

Establishments that Label the Product

An ***instructional statement*** concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure the pathogen is eliminated or reduced to undetectable levels. Examples of such statements are “for full lethality treatment” (any process that eliminates or reduces *E. coli* O157:H7 to undetectable levels) or “for cooking only” (application of heat to a product at a sufficient temperature and for a sufficient period of time to eliminate or reduce the pathogen to undetectable levels). A “full lethality treatment” may be cooking or another process that eliminates *E. coli* O157:H7, such as fermentation or salt curing.

Note: A statement of limited use “for further processing” without further qualification is **not** an instructional statement.

A ***disclaimer statement*** concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were **NOT** used in producing the product. An example of such a statement is “product has not been tested for *E. coli* O157:H7”. 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

Raw Beef Product Sampling

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 (§417.6). In other words, *E. coli* O157:H7 must be addressed in the HACCP plan if disclaimer statements are used.

Note: A statement that the establishment does not intend to use the product in ground product or other non-intact product **is not** an instructional or disclaimer statement (e.g., not intended for grinding or not intended for raw ground beef).

Instructional and disclaimer statements **are not** required. They can only be used on product for use at other official establishments (not for use on retail product). The Labeling Policy and Delivery Division (LPDD) must approve the use of such statements. When LPDD approves the use of instructional statements, LPDD specifies that such statements can only be used on products destined for official establishments that ensure the product receives an adequate lethality treatment. If an establishment places an instructional statement on its label, IPP are to verify that the product is being sent to an official establishment.

When LPDD approves the use of disclaimer statements, LPDD specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plans. When an establishment submits a disclaimer label to LPDD for approval, LPDD is to review it with the assumption that the establishment has a validated intervention for *E. coli* O157:H7. LPDD need not review any additional documentation to support the statement. This review, however, in no way is an approval of the hazard analysis for the product.

Note: Establishments' use of instructional or disclaimer statements is entirely optional.

When you conduct an 04B04 procedure, verify the plant has received sketch approval from LPDD for any instructional or disclaimer statements. The plant is required to maintain these approvals in its labeling records. Issue an NR (reference §317.4(a)) if the plant did not receive sketch approval or does not maintain that sketch approval in its labeling records. FSIS will likely not request that establishments recall product that it has shipped with unapproved labels because use of such product will not result in adverse health consequences. However, FSIS may rescind approval for such labels.

Note: Labeling may be generically approved if LPDD previously approved it as sketch labeling and the final labeling was prepared without modification or with only certain modifications (9 CFR 317.5(9)(i)(xxiv)). Therefore, if the establishment has received sketch approval for labeling bearing instructional or disclaimer statements on one particular raw ground beef product, raw ground beef component, or raw beef patty component, the regulations allow the establishment to use the labeling on any other raw

Raw Beef Product Sampling

ground beef products, raw ground beef components, or raw beef patty components, as long as the establishment makes no modifications or only certain allowed modifications to the labeling.

When you conduct a HACCP 01 or 02 procedure, verify that establishments meet the HACCP regulatory requirements for the production of such products. You are to verify that:

- the instructional or disclaimer statement is not serving as a control or CCP to address *E. coli* O157:H7,
- the instructional or disclaimer statement is not justifying the plant's determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in the production of these products,
- the use of any instructional statements is reflected in the plant's decision-making documentation or hazard analysis, and
- the plant's HACCP plan for products bearing disclaimer statements includes validated intervention for *E. coli* O157:H7 (in a CCP),
- the plant's hazard analysis shows how the plant is ensuring that the product will go for cooking only or for another full lethality treatment only when the statement "for cooking only" or "for full lethality treatment" is used, and
- the plant has controls in place to ensure that the product goes only to plants that cook it when the statement "for cooking only" is used.

When you find that the plant's use of instructional statements or use of disclaimer statements does not meet the requirements, document noncompliance as per FSIS Directive 5000.1. Cite 417.5(a)(1) and/or 417.5(a)(2) and use the recordkeeping noncompliance classification indicator on the NR.

Note: If a plant labeled product with an instructional or disclaimer statement and does not send the product to a second plant that further processes the product to destroy the pathogen, you are to document the noncompliance on an NR because the product would be misbranded. Plants can only place these statements on product for use at other official establishments where the establishment will treat the product in a way to address *E. coli* O157:H7. If the product was not sent to an official establishment for further processing to destroy the pathogen, the product would be misbranded because the labeling did not disclose the material fact that the product may contain *E. coli* O157:H7 and, therefore, may be injurious to the health of consumers.

Establishments Receiving Product with Instructional or Disclaimer Statements

If you are assigned to a plant that receives product with instructional or disclaimer statements, when you perform a HACCP 01 or 02 procedure, verify that

Raw Beef Product Sampling

- positive product bearing instructional or disclaimer statements that enters the plant has moved in commerce under appropriate controls,

Note: An instructional or disclaimer statement **is not** a control for movement of positive product.

- the plant's HACCP plan addresses the use of product with disclaimer statements as if it may be contaminated with *E. coli* O157:H7, and
- the plant follows any instructional statements on the incoming product, e.g., product labeled "for cooking only" was cooked to a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level.

When you find that the plant does not meet the requirements for receiving products with instructional statements or disclaimer statements, document noncompliance as per FSIS Directive 5000.1. Cite 417.5(a)(1) and/or 417.5(a)(2) and use the recordkeeping noncompliance classification indicator on the NR.

Retain products processed with incoming product that bear instructional or disclaimer statements if the plant didn't follow the instructional statement, or if its hazard analysis or decision-making documents don't address the use of product with disclaimer statements as if it were contaminated with *E. coli* O157:H7. Retain product if the process is not adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels, or if the product is not intended for further processing that would destroy the pathogen. In addition to issuing an NR, notify the DO through supervisory channels of the conditions observed concerning the use of instructional or disclaimer statements. The DO may send an EIAO to the plant to conduct a comprehensive food safety assessment or implement an enforcement action.

Summary

Currently, the microbiological hazard of *E. coli* O157:H7 is of most concern in raw beef/veal products, so FSIS is focusing on analyses for that microorganism in these products.

Procedure 05B02 is devoted to directed sampling for food safety concerns. When an FSIS sample for a raw beef product is confirmed positive for *E. coli* O157:H7, and the plant has not found the same product to be positive, issue an NR for HACCP noncompliance, verify the plant's corrective actions, check appropriate decision-making documents, collect supplier information, assist as needed in any recall, and conduct an O2 procedure on the specific production that tested positive. You cannot complete the O2 procedure until the establishment has taken corrective actions and the product has

Raw Beef Product Sampling

received proper disposition (including completing a pre-shipment review). If the establishment maintained control of the product and sampled it, and both the establishment's and FSIS's samples were found positive for *E. coli* 0157:H7, you are NOT to issue a Noncompliance Record. You must verify that the establishment's corrective actions meet the requirements in §417.3.

If you find regulatory noncompliance, e.g., the plant fails to take corrective action in accordance with §417.3, while performing the 02 procedure, document it on an NR (as per FSIS Directive 5000.1). If you find that the plant moved positive product without the necessary controls, or if you find that the plant does not have records documenting proper disposition of the positive product moved off-site, contact your DO through supervisory channels.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Scenarios

1. The establishment where you are assigned slaughters and fabricates beef. It samples its own beef trimmings as a prerequisite program. On Thursday afternoon, you remembered that, according to FSIS Directive 5000.2, you are to review such records on at least a weekly basis. You go to the office where the records for the prerequisite program are kept and review the sampling results. You notice that on Monday morning, the beef trim tested from the previous Wednesday was confirmed positive for *E. coli* O157:H7. What are your responsibilities in this scenario?

2. Last week, you submitted a sample of the plant's raw ground beef patties to the FSIS lab. Three days ago you notified the plant that the sample was presumptive positive. Today, when you arrived at the plant, the plant manager told you that he'd been informed by the District Office that the sample was confirmed positive. What are your responsibilities in this scenario?

ATTACHMENT 1**Resources**

Currently, there are several directives associated with microbial sampling of raw products that fall into the 03B, 03C, and 03J process categories. This list is current as of 6/17/04. You should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ⇒ All Public Folders ⇒ Agency Issuances ⇒ Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the “What’s New” page.

FSIS Directive Number	Directive Title
5000.1	Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations
5000.2	Review of Establishment Data by Inspection Program Personnel
7355.1	Use of Sample Seals for Laboratory Samples and Other Applications
7700.1	Irradiation of Meat and Poultry Products
8080.1	Recall of Meat and Poultry Products
10,010.1	Microbiological Testing Program for <i>Escherichia coli</i> O157:H7 in Raw Ground Beef
10,200.1	Accessing Laboratory Sample Information via LEARN
10,210.1	Unified Sampling Form
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses
10,600.1	Sample Shipment Procedures

“Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7” are at http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp

ATTACHMENT 2

Discard Reasons

Only those reasons that may apply to raw samples are listed here. The codes are not given in this table since they are used for tracking purposes. Your frontline supervisor has access to this information and monitors the number of discarded samples. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

No Sample Received with Form
Collected Outside Scheduled Time Frame
Temperature Too High
Tissue/Sample Spoiled/Rancid
Container Damaged
Wrong Tissue/Sample for Requested Analysis <i>(Residue samples)</i>
Insufficient Tissue or Sample
Delayed Shipment <i>(FedEx doesn't get sample to the lab in 24 hour time frame)</i>
Shipped on Friday w/o Saturday Delivery label
Original Form Not Submitted w/Sample
Target Tissue Not Received <i>(Residue samples)</i>
No Form Received with Sample
Original Form Altered by Sample Submitter
Laboratory Problem*
No Gel Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
Sent to Wrong Lab
Sample ID # on Bag does not match ID # on Form
Security Seal Missing or Not Intact
No Accredited Lab Tests Performed
Headquarters/ PDD/DO Discard
Sampling Instructions Not Followed

Raw Beef Product Sampling

ATTACHMENT 3

<i>Internal lab code here</i>	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE REQUESTED SAMPLE PROGRAMS <input type="checkbox"/> FOOD CHEMISTRY <input type="checkbox"/> MICROBIOLOGY <input type="checkbox"/> RESIDUE	<i>Barcode here</i>
		1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS							
2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/DISTRICT	6. STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Within 30 days of:			
8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est., Retail Store)				9. NAME & ADDRESS OF RECEIVING LABORATORY			
10. SLAUGHTER CLASS CODE		11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED			
14. PROJECT NO.		15. COUNTRY OF ORIGIN		16. COUNTRY COPY	17. FOREIGN EST. NO.		
18. ADDITIONAL INSTRUCTIONS							

PART II. COLLECT SAMPLE INFORMATION (To be completed by sample collector)					
19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE		22. PRODUCT HELD <input type="checkbox"/> YES <input type="checkbox"/> NO	
23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS <input type="checkbox"/> NORMAL (06) <input type="checkbox"/> INCREASED (07) <input type="checkbox"/> SPECIAL (53) <input type="checkbox"/> HOLD (24)			
26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE				27. ANIMAL ID (Tag No.)	
28. REMARKS					
29. COLLECTOR'S SIGNATURE		30. NAME OF COLLECTOR (Print)	31. BADGE NO.	32. TELEPHONE NO. AT EST.	

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE	
(72) <input type="checkbox"/>	REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)
(60) <input type="checkbox"/>	PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS (If checked, plant will be removed from this sampling program)
(57) <input type="checkbox"/>	NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE
(53) <input type="checkbox"/>	OTHER (Explain)

PART III. LABORATORY RECEIPT INFORMATION		
34. SAMPLE PACKAGING <input type="checkbox"/> 3034 Intact Package <input type="checkbox"/> 3035 Non-intact Package		35. SAMPLE RECEIPT DATE
36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERATURE
39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)