TABLE OF CONTENTS

FSIS DIRECTIVE	10,010.1, Revision 2	7/31/09

VERIFICATION ACTIVITIES FOR *Escherichia coli* O157:H7 IN RAW BEEF PRODUCTS

CHAPTER I – GENERAL

I. PURPOSE

A. The Food Safety and Inspection Service (FSIS) is reissuing this directive to incorporate in one document the instructions that the Agency has issued in multiple notices regarding *Escherichia coli* (*E. coli*) O157:H7. The directive includes instruction to inspection program personnel (IPP) and import inspection personnel for sampling raw beef products for FSIS verification testing for *E. coli* O157:H7. In addition, it outlines actions FSIS will take when samples of raw ground beef, raw ground beef components, or raw beef patty components test positive for *E. coli* O157:H7. Finally, it includes instructions for other verification activities concerning *E. coli* O157:H7.

NOTE: Directive 8010.1, appendix 1, provides directions to compliance investigators for conducting sampling for *E. coli* O157:H7 as part of the in-commerce surveillance activities at retail stores.

B. Key Changes

FSIS has revised this directive to include instructions for:

- Routine verification sampling of beef manufacturing trimmings and other raw ground beef and raw beef patty components for E. coli O157:H7 at the slaughter establishments that produced those components

- 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

- Submitting samples to the laboratory without waiting for the establishment to complete pre-shipment review

- Factors to consider to determine whether to take an enforcement action when FSIS finds samples positive for E. coli O157:H7

- Collecting 8 follow-up samples when the Agricultural Marketing Service (AMS) finds product positive for E. coli O157:H7

- Verifying that establishments producing mechanically tenderized or injected raw or heat-treated beef products have considered E. coli O157:H7 in their hazard analyses for these products

- Verifying the adequacy of Critical Control Points (CCPs) or prerequisite programs that address E. coli O157:H7

- Reviewing establishment records for E. coli O157:H7 testing of trim when the establishment has never identified a positive result

- Increased sampling based on rates in FSIS new sampling algorithm

- Routinely verifying that adulterated product is denatured before it is shipped to a landfill operation or renderer

- Policy Analysis Division (PAD) in the Office of Policy and Program Development (OPPD) responsibilities

- Collecting a sample of ground product at the start of operations when product is scheduled to be ground later during the day, provided the establishment meets certain criteria

- Collecting follow-up samples of beef manufacturing trimmings, rather than ground product, at combination slaughter/processing establishments in response to an FSIS (or other State or Federal entity) positive result in the ground product

- Performing a HACCP 02 procedure at the originating supplying slaughter establishment when notified by the District Office (DO) through the use of FSIS Form 8140-1 (9 CFR 320.7)

- Sampling product for E. coli O157:H7 that may contain a mixture of ground beef and non-beef species

- Actions FSIS will take when slaughter suppliers that produce primals or subprimals are identified in System Tracking E. coli O157:H7 – Positive Suppliers (STEPS) because they supplied primals or subprimals that were used to produce raw ground beef product that FSIS found positive for E. coli O157:H7.

II. CANCELLATIONS

FSIS Directive 10,010.1, dated 3/31/04, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components

FSIS Notice 44-09, dated 6/1/09, Changes in Sampling Frequency for *E. coli* O157:H7 Testing in Raw Ground Beef

FSIS Notice 05-09, dated 1/7/2009, Measures to Address *E. coli* O157:H7 at Establishments that Receive, Grind, or Otherwise Process Raw Beef Products
FSIS Notice 105-08, dated 12/31/08, New Sampling Code for *Escherichia coli* O157:H7 Testing in Raw Ground Beef
FSIS Notice 85-08, dated 11/20/08 Routine Sampling and Testing of Raw Ground Beef Components Other Than Trim and Imported Raw Ground Beef Components For *Escherichia coli* (*E. coli*) O157:H7
FSIS Notice 79-08, dated 10/30/08, Multiple Follow-Up Sampling After FSIS Positive *Escherichia coli* (*E. coli*) O157:H7 Results
FSIS Notice 77-08, dated 10/30/08, Instructions for Verification Sampling Programs for *E. coli* O157:H7 in Raw Beef Products
FSIS Notice 23-09, dated 4/1/09, Routine Sampling of Beef Manufacturing Trimmings Intended for Use in Raw Ground Beef
FSIS Notice 22-09, dated 4/1/09, Follow-up Sampling of Certain Raw Ground Beef Products after an FSIS Verification Sample Tests Positive for *E. coli* O157:H7

III. REASONS FOR REISSUANCE

FSIS is reissuing this directive in its entirety to incorporate new procedures and to incorporate all changes in Agency policy for *E. coli* O157:H7 previously issued through FSIS notices.

IV. REFERENCES

Federal Meat Inspection Act
9 CFR 318.2, 325.10, 416, 417, and 500
FSIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel
FSIS Directive 5000.4, Performing the Review Portion of 01B02 in Raw and Ready-to-Eat Processing Operations
FSIS Directive 6410.1, Verifying Sanitary Dressing Procedures in Slaughter Operations of Cattle of Any Age
FSIS Directive 7355.1, Use of Sample Seals for Program Samples
FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 8410.1, Detention and Seizure
FSIS Directive 10,000.1, Policy On Use of Results From Non-FSIS Laboratories
FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN
FSIS Directive 10,210.1, Unified Sampling Form
FSIS Directive 12,600.1, Voluntary Reimbursable Inspection Services, Revision 1, Amendment 2

V. BACKGROUND

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. FSIS will continue its sampling and testing for

E. coli O157:H7 in raw ground beef products, raw ground beef components, and raw ground beef patty components.

FSIS has made changes to its testing program to increase the likelihood that the Agency will detect the pathogen. For example, in 2007 and 2008, FSIS implemented routine sampling of beef manufacturing trimmings and other raw ground beef components (including raw beef patty components) for *E. coli* O157:H7. FSIS traces positive samples of raw ground beef back to the establishment that slaughtered the cattle used to produce the source materials. Also, FSIS submits samples to the FSIS laboratory without waiting for the establishment to complete pre-shipment review. FSIS collects 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.

Non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended for use in non-intact products also are 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) are an example of an intact raw beef product that is intended to be used for non-intact product. Raw ground beef and patty components other than beef manufacturing trimmings include raw esophagus (weasand) meat, head meat, cheek meat, beef from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat. Official establishments may further process raw beef products contaminated with *E. coli* O157:H7 using a procedure validated to destroy the pathogen.

VI. TERMINOLOGY

A. Raw Ground Beef Products: FSIS samples raw beef food products that 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)). In addition, FSIS will begin sampling product that contains a mixture of ground beef and non-beef species, unless the establishment labels the product in a manner to show that beef is not the predominant species in the product.

1. Raw ground beef products include:

    a. raw ground or chopped beef;

    b. hamburger;

    c. ground or chopped veal;

NOTE: For purposes of this directive, when the directive references beef, veal is included.

d. veal or beef patties;

e. veal or beef patty mix; and

f. ground veal or beef product with added seasonings.

NOTE: A raw ground beef product formulated with any amount of beef product derived from Advanced Meat Recovery (AMR) systems is considered "ground beef." Raw product comprised only of beef from AMR systems is not sampled as a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component (see VI, B., 3. of this section for a description of AMR systems).

B. Raw Ground Beef and Patty Components

1. Beef Manufacturing Trimmings are:

Two 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 subprimal 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 beef parts of boneless beef that establishments frequently use as components of raw ground beef.

2. Raw Ground Beef Components, Including Raw Beef Patty Components, Other Than Beef Manufacturing Trimmings are:

Raw esophagus (weasand) meat, head meat, cheek meat, beef from AMR systems (see definition 3. below), low temperature rendered (see definition 4. below) LFTB, partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat.

3. A beef AMR system is a mechanical process separating skeletal muscle tissue from bones of livestock other than skulls or vertebral column bones of cattle $\geq$ 30 months of age, in accordance with 9 CFR 318.24.

NOTE: Establishments may label the resulting product from beef AMR systems as beef.

4. Low Temperature Rendering:

a. removal of lean from fat or very fat trimmings using heat; or

b. a centrifugation, drum drying process for boneless beef fatty tissue.

NOTE: Establishments may label the resulting product as "Lean Beef Trimmings,

Finely Textured," "Lean Beef Blocks, Derived from Beef Trimmings," or "Lean Beef Chips, Derived from Beef Trimmings."

C. Products Not Subject To FSIS Sampling

Fabricated steaks and finely sliced beef (9 CFR 319.15(d)) do not meet the standard of identity for ground or chopped beef product and, therefore, would not be subject to *E. coli* O157:H7 sampling. Raw beef sausage products are not subject to FSIS' *E. coli* O157:H7 sampling and testing. Ground buffalo or bison is also not a raw ground beef product subject to this FSIS verification sampling.

D. The Sampled Lot

1. The sampled lot is the product represented by the sample tested for *E. coli* O157:H7 (see Chapter II I. A.) The establishment is responsible for defining the sampled lot.

2. FSIS does not recognize "Clean-up to clean-up" alone as a supportable basis of distinguishing one portion of production from another portion of production.

3. Factors or conditions that may determine the sampled lot include:

a. any scientific, statistically based sampling programs for *E. coli* O157:H7 that the establishment uses to distinguish between segments of production;

b. 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. The following may lead to the cross-contamination between raw beef components during production:

i. improper sanitary dressing procedures;

ii. insanitary product contact surfaces on equipment such as machinery and employee hand tools;

iii. improper employee hygiene;

c. processing interventions that limit or control *E. coli* O157:H7 contamination; and

d. beef manufacturing trimmings and raw beef components or rework carried over from one production period to another.

4. 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 to be adulterated.

NOTE: If positive product is in commerce, FSIS generally determines the amount of product that should be recalled based on various factors, such as the control measures in place within the operation to limit potential contamination exposure. FSIS also considers the amount of carryover or rework from other production lots and any other factors that may link other production lots to the sampled product. The Recall Committee is responsible for evaluating all production factors and control measures and then determines the scope of the affected product subject to recall.

5. FSIS may sample product from a single carcass for *E. coli* O157:H7 testing under Ch. III, X. Establishments may also sample carcasses. A single beef carcass may represent an "independent" lot if the establishment maintains sanitary dressing procedures and other controls necessary to prevent cross-contamination among carcasses, equipment, personnel, facilities, carryover, and rework. For example, establishments would need to ensure that personnel do not handle carcasses or meat from carcasses in a manner that will allow cross–contamination.

E. Potential, Presumptive, And Confirmed Positives

1. A Potential Positive is a sample that causes a positive reaction with the screen test.

2. A Presumptive Positive is a sample that has typical colonies, observed on Rainbow Agar, and reacts specifically with O157 antiserum.

3. A Confirmed Positive is a biochemically-identified *E. coli* isolate that is serologically or genetically determined to be O157 and that meets at least one of the following criteria:

a. positive for Shiga toxin (ST) production

b. positive for the Shiga toxin gene (stx)

c. genetically determined to be "H7"

Typically, FSIS's *E. coli* O157:H7 confirmation test results become available four to five days after FSIS collects and ships the sample to the FSIS Field Services Laboratories.

F. Sampling Project Numbers For *E. coli* O157:H7 Testing

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)
- Extra raw ground beef samples at an establishment following numerous trim samples

MT50 – Routine Testing of Domestic Raw Beef Manufacturing Trimmings

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

CHAPTER II – IPP RESPONSIBILITIES FOR COLLECTING AND SUBMITTING SAMPLES

This chapter provides sampling instructions for off-line inspection personnel (GS-8, 9, 10, and Public health Veterinarians (PHVs)) for collecting samples of raw ground beef, beef manufacturing trimmings, and raw ground beef components for *E. coli* O157:H7 sampling programs.

I. GENERAL SAMPLING INSTRUCTIONS

A. Instructions For All *E. coli* O157:H7 Sampling Programs

1. When the Pathogen Reduction and Enforcement Program (PREP) schedules IPP to take samples at an establishment, PREP will send the Inspector-in-Charge (IIC) FSIS Form 10,210-3, Requested Sample Programs.

2. IPP are to notify official establishment management before collecting samples. IPP are to notify establishment management of the reason they are taking the sample (e.g., routine FSIS verification testing, follow-up sampling in response to an *E. coli* O157:H7 positive, trace back sampling, or follow-up sampling in response to an *E*. *coli* O157:H7 outbreak).

3. IPP are to provide enough time for the establishment to hold the sampled lot but not enough time to alter the process. To provide establishments enough time to hold the entire sampled lot, IPP are to:

a. be knowledgeable concerning the establishment's production practices;

b. be familiar enough with the process to realize that, in some cases, notifying the establishment one day before collecting the sample may not be adequate time to allow the establishment to hold all product represented by the sample;

c. provide 1 day's notice if such advance notice is sufficient for the establishment to hold the sampled lot. IPP may also provide 2 days notice if necessary. If less than one day's advance notice would not cause a hardship for the establishment, IPP may provide less than one day's notice before FSIS collects a sample for *E. coli* O157:H7 testing;

d. consider establishment requests for more than 2 days' notice before collecting the sample based on the establishment's product and process flow. In some cases, based on this consideration, IPP may agree that more than 2 days' notice is necessary. For example, if an establishment makes case-ready product and requests that the inspector give it notice two days before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, then the inspector is to accommodate this request; and

e. inform the establishment that it is responsible for supporting its

basis for defining the product represented by the sample [i.e., the sampled lot (see Ch. I, VI., D.)].

4. IPP are to request sampling supplies when needed. IPP are to request supplies via e-mail at least 72 hours before sampling is to begin. IPP are to e-mail the laboratory identified in block 9 of the sample request form (FSIS Form 10,210-3) by using one of the following e-mail addresses:

Sampling Supplies - Eastern Lab

Sampling Supplies - Midwestern Lab

Sampling Supplies - Western Lab

5. IPP are to include the following information in the supply request e-mail:

a. the exact supplies needed;

b. establishment address (not a P.O. Box); and

c. establishment phone number.

6. IPP are to randomly select a day, shift, and time within the sample window after the sample collection date indicated in Block 4 of FSIS Form 10,210-3, Requested Sample Programs. IPP are to collect samples from all shifts the establishment operates. There should be an equal chance that sampling will occur during any particular shift. IPP are to record the shift from which they collected the sample in block 28 of Form 10,210-3;

7. IPP are only to collect a frozen sample if the establishment has a CCP for freezing in its HACCP plan.

NOTE: If the HACCP plan has a CCP for freezing, then IPP are to collect the sample after product represented by the sample has passed all establishment interventions except microbiological testing, including the CCP for freezing the product. If the establishment has a CCP for freezing, freezing may occur in the process after microbiological testing. In these circumstances, IPP are to wait until the product passes the freezing CCP before collecting a sample. IPP are to ship the samples to the laboratory as soon as possible;

8. IPP are to collect the sample after the establishment has completed production of a lot (as defined by the establishment) and applied all interventions except any microbiological testing intervention. If the establishment intends to test the product for *E. coli* O157:H7 before completing pre-shipment review, IPP are not to wait for the establishment to receive the test results. Rather, IPP are to collect the sample and prepare it for shipment to the laboratory for the first available FedEx pick-up;

9. IPP are not to sample product that the establishment intends for use

in intact product, or ready-to-eat products, provided the establishment's hazard analysis and flow chart show that the product is intended for one of these uses and identify establishment controls that ensure that the product is used as intended. IPP are to verify that there are measures in place to ensure that the product is used as intended. Such controls may include letters to receiving establishments;

10. In cases where the establishment records and HACCP documents are unclear about the product's intended use, IPP are to consider the product as intended for use in raw ground beef products or other non-intact raw beef product;

11. If the establishment decides to change the intended use of the product (e.g., to cook all the product represented by the sample or send the product to another establishment to cook the product after FSIS has collected the sample), IPP are to proceed with submitting the sample to the FSIS laboratory for analysis;

12. IPP are to collect a sample even if an establishment analyzes samples representing 100% of its raw beef products intended for grinding, and the establishment communicates that information to IPP;

13. IPP are to use sterile whirlpak bags, when collecting samples not in finished packaged form under the raw *E. coli* O157:H7 project numbers. IPP are to answer the questions in Block 28. The laboratory will discard any samples in bags other than the sterile whirlpak bags;

14. IPP are to refrigerate the samples held overnight. IPP are not to freeze the sample. If IPP are not able to ship the sample so that it arrives at the laboratory within 48 hours, then IPP are to freeze the sample. As indicated in 7. above, if the establishment has a CCP for freezing, IPP are to keep the frozen sample frozen;

NOTE: Freezing and thawing the product may increase the growth of pathogens in the product.

15. If the raw beef product requested for sampling is unavailable during the 30-day window, IPP are to complete Block 33 and mail the FSIS Form 10,210-3 to the laboratory listed in block 9 on the form;

16. IPP are to safeguard the security of samples when preparing, storing, packaging, and submitting samples for testing (see FSIS Directive 7355.1). IPP are to ship the sample via overnight FedEx courier the same day as they collect the sample, or as soon as overnight courier service is available. IPP are not to ship a sample on Saturday or the day before a Federal holiday;

17. IPP are to make themselves aware of the establishment's sampling and testing programs for *E. coli* O157:H7.

18. IPP are to check Laboratory Electronic Application for Results Notification (LEARN) in accordance with FSIS Directive 10,200.1 to obtain test

results and provide LEARN results to establishment management, even if the establishment receives e-mail notifications. The Biological Information Transfer and E-mail System (BITES) messages will report FSIS presumptive positive and confirmed positive test results to the (DO);

19. IPP are to document collecting and submitting samples under *E. coli* O157:H7 sampling programs and follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code 05B02 as "A-performed" on the day FedEx picks up the sample;

20. Reminder, IPP are to verify that the PBIS Profile Extension Product Volume information is accurate and up-to-date regarding raw beef product production; and

21. If IPP determine that additional sampling is useful, they are to contact the DO. If DO personnel determine that the sampling is appropriate, they are to contact the Risk and Innovations Management Division (RIMD), OPPD, at (202) 205-0210. RIMD is to consult other offices within FSIS, including the Office of Public Health Science. RIMD is to provide IPP, through the DO, with an appropriate amount of samples to collect.

B. Sampling Instructions In Establishments That Slaughter, Produce Trim, and Grind

1. It is possible that establishments produce ground product, beef manufacturing trimmings, and other raw ground beef or beef patty components. Therefore, IPP may receive sample requests for MT43, MT50, and MT54 samples during the same sampling window. If possible, IPP are to fulfill all sample requests by selecting samples from three independent production lots. If IPP are only able to collect one sample (e.g., because the establishment produces 1,000 pounds of product or less on a daily basis, or only on an intermittent basis), they are to sample beef manufacturing trimmings under the MT50 sampling program.

2. Some slaughter establishments may produce beef manufacturing trimmings, other raw ground beef components, or patty components and grind that product. They may not ship the 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.

II. ALTERNATIVE LOT DEFINITIONS

A. IPP may permit an establishment that samples beef manufacturing trimmings, other raw ground beef components, or raw ground beef products under its own testing program to reduce its lot size to one combo bin or other unit (e.g., box) on the day that FSIS conducts sampling if IPP find that the establishment:

1. has a validated intervention for *E. coli* O157:H7 at a CCP in the HACCP plan that covers the product or requires an intervention for *E. coli* O157:H7 at a CCP for that product's source materials; and

2. samples and tests every production lot for *E. coli* O157:H7 and generally collects its samples of beef manufacturing trimmings, other raw ground beef components, or raw ground beef products across multiple combo bins or other sample units.

B. If an establishment meets these criteria and reduces its lot size to a single combo bin or sample unit when FSIS samples the product, IPP are to collect samples from the single combo bin or sample unit following applicable instructions in this directive. If the establishment does not meet the criteria, IPP are to collect the sample consistent with other applicable instructions in this directive**.**

III. INFORMATION FOR COLLECTING SAMPLES OF GROUND BEEF PRODUCTS

See Attachment 1 for a corresponding flow chart.

NOTE: IPP are to collect samples from product that contains a mixture of ground beef and non-beef species, unless the establishment labels the product in a manner to show that ground beef is not the predominant species in the product.

A. Collecting A Ground Beef Sample

1. IPP are to collect samples from establishments that grind product or form patties. If the establishment only portions the product, IPP are not to sample it for *E. coli* O157:H7.

2. IPP are to collect a 1-pound sample from the current day's production following the instructions in Ch. II, I. Whenever possible, IPP are to take samples that are in their final packages. If ground product in final packages is not available for sampling (e.g., if the ground product final package is too large) or for any reason IPP are not able to collect a 1-pound package of finished product, IPP are to collect the 1-pound sample aseptically (see Ch. II, V) and use the sterile whirlpak bags.

3. IPP may receive FSIS Form 10,210-3 for *E. coli* O157:H7 sampling and testing of raw ground beef products (MT43) at the following monthly rates:

a. up to 4 times within a calendar month (See block 4 of FSIS form 10,210-3) for establishments with ground beef product production volumes of greater than 250,000 lbs/day, as estimated and recorded in block 28 of FSIS Form 10,210-3 each time a sample is collected;

b. up to 3 times within a calendar month (See block 4 of FSIS form 10,210-3) for establishments with ground beef product production volumes of

50,000 to 250,000 lbs/day, as estimated and recorded in block 28 of FSIS Form 10,210-3 each time a sample is collected;

c. up to 2 times within a calendar month (See block 4 of FSIS form 10,210-3) for establishments with ground beef product production volumes of 1,000 to 50,000 lbs/day, as estimated and recorded in block 28 of FSIS Form 10,210-3 each time a sample is collected;

d. generally, no more than once within a calendar month (See block 4 of FSIS form 10,210-3) for establishments with ground beef product production volumes of less than 1,000 lbs/day, as estimated and recorded in block 28 of FSIS Form 10,210-3 each time a sample is collected. However, FSIS will ensure that at these establishments at least one sample is collected quarterly.

4. When more than 1 sample is scheduled to be collected during a month, IPP are to randomly select a day, shift, and time to collect a maximum of 2 samples.

a. IPP are to collect verification samples within the month starting from the sample collection date indicated in block 4 of the form, but not before this date.

b. IPP may collect 2 samples per day as long as each sample corresponds to a microbiologically independent and individually identifiable lot of product.

i. However, IPP are not to collect 2 samples per day if the establishment cannot continue to operate under that sampling frequency (e.g., because the establishment cannot fill orders and hold all sampled product) or because the IPP's workload cannot accommodate that sampling frequency. Under these circumstances, IPP should collect a single sample.

ii. 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 RIMD, OPPD via http://askfsis.custhelp.com for review. IPP are to instruct the establishment to type "sampling" in the subject line in askFSIS. IPP are also to tell the establishment 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 also take into consideration 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. If IPP have questions about RIMD's response they may contact RIMD through askFSIS or at 1-800-233-3935 by pressing 1 and then 4.

c. In all cases, IPP are to collect at least 1 sample per FSIS Form 10,210-3 whenever a sample request form is received and product is produced and available during the month.

5. IPP may find that an establishment may have written procedures to grind a minimum batch of product that represents the entire lot in a smaller grinder. To ensure that the sample is representative of the lot, establishments with these written procedures need to have supporting documentation that describes how the minimum batch is representative of the entire lot (e.g., includes an appropriate proportion of all types of trim used to produce the lot). As a general guide, the minimum batch should not be less than 50 pounds. If the establishment's written procedures and grinding practices meet these criteria, IPP are to sample this minimum batch of product after randomly selecting the day, shift, and time and notifying the establishment as set out in Ch. II, I., A., 2.

6. IPP may submit one or more individually identified samples per box and are to follow FSIS Directive 7355.1, "Use of Sample Seals for Program Samples and Other Applications." If necessary, they are to include additional cooling packages in the box to keep the sample or samples cool during transportation. To submit multiple samples, IPP 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 for sampling supplies.

B. Alternative Parameters For Sampling A Lot At The Start Of Production

1. In an establishment that has a sound basis for defining lots and sub-lots of raw ground beef product (See Ch. II, III, C) and has production schedules that define the specific components used at specific times, IPP may collect samples following the parameters below. When the establishment requests the use of this alternative procedure and IPP determine that the establishment meets the criteria below:

a. IPP are to randomly select a production date and time within the time frame indicated on the FSIS Form 10,210-3, Requested Sample Programs.

b. IPP may select a time of production for sampling that is after the beginning of operations. If the establishment has documentation showing that a specific lot of product is scheduled to be ground at the selected production time, IPP are to allow the establishment to grind that lot of product at the beginning of operations on the day that IPP selected for sampling.

c. IPP are to verify that the establishment is not treating the source materials of ground product that FSIS samples differently from other source materials used for grinding.

i. For example, IPP are to verify that the establishment is not using interventions it does not normally use on the product FSIS will sample.

ii. Similarly, on the production day that they have selected for sampling, IPP are to verify that the establishment is not grinding source materials distinctly different (e.g., different suppliers on different types of source materials) from those it typically grinds.

d. IPP are to discuss with establishment management at the weekly meeting the procedures in this section. IPP are to 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.

C. Verifying Establishment Lotting And Sub-lotting

IPP are to use the questions in this section to assist them in determining establishment lotting and sub-lotting practices. IPP are to use the responses to these questions to determine if an establishment meets the criteria for this procedure. For example, if an establishment always rotates its lots so that IPP are only collecting samples from one of the establishment's suppliers, and the establishment receives product from more than one supplier, then IPP are not to collect the sample under the alternative parameters. If IPP have questions regarding the information the establishment provides based on the questions in this section, contact PDD at (800) 233-3935 or through AskFSIS.

1. Are establishments lotting or sub-lotting raw ground beef product based on source materials? If yes,

a. Does the establishment consider raw ground beef product produced from source materials from different suppliers to be different lots or sub-lots of product?

b. Does the establishment ensure that source materials from different suppliers are ground separately?

c. Does the establishment consider raw ground beef product from different combos from the same supplier to be separate lots or sub-lots of product? If so, on what basis?

2. If an establishment produces the trim used in its own grinding operation, does the establishment have a method for lotting or sub-lotting raw ground beef product that is based on source materials? IPP are to verify that the establishment's decisionmaking documents supporting decisions for the trim it produces, such as lotting for that trim, are equivalent to decisionmaking documents supporting decisions regarding trim from an outside source.

3. If the same carcasses are used as source materials to fill all the combos, does the establishment differentiate among combos? If so, on what basis?

4. Is the establishment lotting or sub-lotting raw ground beef product based on establishment testing? If yes,

a. What is the frequency of establishment testing?

b. What is the method of testing?

c. What is the sensitivity of the method of testing? What is the reliability of the test? For example, suppose 10 samples were collected. In

reality, all 10 samples contained *E. coli* O157:H7 but the test came back positive for only 8 samples. The test showed false negative tests for 2 samples. The test is only 80% sensitive.

d. What is the volume of product tested relative to the volume of product produced? Is the establishment testing a representative sample of the product?

e. Based on its testing, what is the establishment's level of confidence that it will detect *E. coli* O157:H7, if it were present? What is the *E. coli* O157:H7 prevalence level that would achieve this confidence?

f. Does the establishment increase its testing during the *E. coli* O157:H7 high prevalence season?

g. Does the establishment increase its testing in response to its own *E. coli* O157:H7 positive finding (or a positive finding in a screening test for *E. coli* O157:H7)?

IV. IPP RESPONSIBILITIES FOR COLLECTING SAMPLES OF BEEF MANUFACTURING TRIMMINGS AND OTHER RAW GROUND BEEF COMPONENTS OTHER THAN TRIM INTENDED FOR USE IN RAW GROUND BEEF PRODUCTS

See Attachments 2 and 3 for corresponding flow charts.

A. General Sampling Instructions

IPP are to:

1. follow the instructions in Chapter II, I;

2. sample only raw ground beef components produced from cattle slaughtered at the establishment. If the establishment commingles such product with beef product processed at other establishments, IPP are to collect the sample before the establishment commingles the product;

NOTE: Fat is not a component that FSIS routinely samples; however, if fat is implicated as a source for product that FSIS found positive the Agency may elect to sample the fat under follow-up sampling.

3. randomly collect samples from one specific production lot;

4. sanitize the caddy, knife, hook, or tongs before collecting the samples by using the establishment's sanitizing solution according to label instructions. If establishments use hot water only, then IPP also are to use hot water to sanitize sampling equipment; and

5. use sterile gloves and handle all sanitized surfaces so that they do not become contaminated.

B. Sample Collection Procedures For Beef Manufacturing Trimmings

IPP are to collect samples of beef trimmings when the slaughter establishment produces beef trimmings destined for use in raw ground beef or other non-intact product, or when the intended use of the product is unclear. IPP are to consider all 2-pc chucks as intended for non-intact product. If the establishment (or another establishment) intends to grind the entire primal/subprimal cuts into ground beef, IPP are to collect samples using the N60 sampling method and submit the product under the MT50 sampling number. IPP are to complete the appropriate boxes on the MT50 sample forms and mail all MT50 sample forms to the laboratories with or without a sample at the end of the 30-day window. IPP are to:

1. select samples by using the N60 method of sample collection (as described below) and collect 60 individual pieces of raw beef manufacturing trimmings:

NOTE: IPP are to make every effort to ensure that at least 60 thinly excised external surface tissue samples are included in the sample.

a. if an establishment's production lot is greater than 5 containers of beef manufacturing trimmings, IPP are to select randomly 5 containers for sampling; and

b. if the establishment's production lot is 5 or less containers, IPP are to use the chart below for sampling;

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

2. aseptically collect the appropriate number of pieces of beef manufacturing trimmings based on the number of containers that represent one specific production period. IPP are to use the sanitized hook or tong to lift a piece of meat off the top of the container. IPP are to collect 60 pieces for each sample.

3. cut off a slice that is approximately a 4-inch length by 2- inch width and 1/8-inch thickness from each of the 60 pieces. IPP are to cut off as much of the beef manufacturing trimmings' outer surface as possible. The outer surface may be fat. If this is the case, sample the meat surface closest to the outer surface. The priority is to collect samples from pieces of product taken from the original surface of the beef carcass;

4. collect and bag the sample slices in the sterile whirlpak sample bag;

5. check the product temperature of the top pieces of meat from randomly selected containers of beef manufacturing trimmings. IPP are not to take the temperature of the actual sample slices. IPP are to record the temperature on the sample request form in block 21 (record only one temperature). If the sample pieces came from more than one container, IPP are to record the temperature of the warmest container in block 21 (record only one temperature) of the sample request form. If the product is warmer than 40° F, IPP place the bag containing the sample in a cooler to chill before shipping, maintain sample security (Ch. II, I., A., 16). Freezing the sample may alter the results of the analysis (See Ch. II, I, 7. and 14.);

6. completely fill out the sample request form. IPP are to ensure that the product temperature is recorded in block 21, and the requested information in block 28 is complete.

NOTE: If PAD, OPPD, or the DO become aware that a company owns both a slaughter establishment and a sister processing establishment to which the slaughter establishment sends all carcasses for fabrication, and the second establishment does not fabricate carcasses from any other source, PAD or the DO is to notify Office of the Chief Information Officer (OCIO) with a "cc" to the Frontline Supervisor (FLS) and IPP through the sampling forms mailbox SamplingForms-Headquarters@fsis.usda.gov, so that IPP can sample the fabrication facility.

C. Selecting Components Other than Beef Manufacturing Trimmings

1. When IPP receive a sampling request form (FSIS Form 10,210-3) with the MT54 sampling project number in block 14, they are to 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 (first on the priority list below) on the day of collection, IPP are to take a sample of it; if not, they are to collect product from Low Temperature Rendered Beef (LTRB) (second on the priority list) if it is available, and move down the list until there is an available product.

The priority list is:

a. Product from AMR Systems

b. Low Temperature Rendered LTRB

c. Partially Defatted Beef Fatty Tissue

d. Partially Defatted Chopped Beef (PDCB)

e. Weasand Meat

f. Head Meat

g. Cheek Meat

h. Heart Meat

2. When IPP receive subsequent sample request forms with the project number MT54 in block 14, they are to continue on to the next product on the priority list that the establishment produces on the day that they are collecting a sample. They are to select a different component than previously collected when possible.

NOTE: FSIS developed the priority list from the National Advisory Committee on Microbiological Criteria for Food (NACMCF) Response to USDA/FSIS Request for Guidance on Baseline Study Design and Evaluations for Raw Ground Beef Components found at http://www.fsis.usda.gov/OPHS/NACMCF/2003/gb_base.pdf. In the future, FSIS may establish additional project numbers to capture detailed information in connection with this sampling.

3. If an establishment saves the raw beef core samples taken for fat analysis in a fat analyzer from raw boneless beef trimmings, IPP are to sample this product the same way as AMR if the intended use is in raw ground beef. Establishments may produce this product under an existing HACCP plan or have a separate HACCP plan for this product (9 CFR 417.2(b)(2)).

D. Collecting The Sample of Components Other than Trimmings

1. For all such components, IPP are to follow the instructions in Chapter II, I.

2. AMR product and LTRB product

To sample AMR or Low Temperature Rendered (LTR) products, IPP are to select randomly a sample consisting of no less than 1 pound but not more than 2 pounds of product from a specific production lot.

3. Other Raw Beef Components

To sample other raw beef components (e.g., heart meat), IPP are to collect randomly one piece, or enough pieces, of the beef components to equal no less than 1 pound but not more than 2 pounds of product from a specific production lot. If the component is very large, IPP are to cut slices in the manner as described in Ch. II, IV.

E. Description of Ammoniated Product

Establishments produce LTR products (including partially defatted chopped beef, LFTB, and product known as boneless lean beef tissue (BLBT)) from beef trimmings and may use them as components in raw ground beef and beef patty products. This product can also undergo a step that involves injecting gaseous

ammonia into the product to raise the pH rapidly. Scientific studies support that this step serves as an antimicrobial intervention that reduces *E. coli* O157:H7 to an undetectable level in beef manufacturing trimmings.

F. Sampling Ammoniated LTR Products Under The Beef Manufacturing Trimmings (MT50) Verification Sampling Program

1. If the establishment produces ammoniated LTR product, IPP are not to sample this product or trimmings intended for use in ammoniated LTR product under the routine sampling program for beef manufacturing trimmings (MT50) if the establishment:

a. has one or more CCPs validated for the production of ammoniated LTR product in its raw ground HACCP plan; and

b. clearly segregates beef manufacturing trimmings destined for the ammoniated process from the beef manufacturing trimmings that will not undergo the ammoniated process. Other beef manufacturing trimmings that do not receive an intervention are subject to FSIS sampling and testing for *E. coli* O157:H7.

2. If a slaughter establishment produces beef manufacturing trimmings that it does not ammoniate or intend to use in ammoniated LTR product, the trimmings are subject to the MT50 sampling verification program (routine sampling of trim).

3. Ammoniated LTR product is subject to the follow-up verification sampling program (MT52 sample number) when it is used as a component in raw ground beef products that tested positive for *E. coli* O157:H7 when sampled by FSIS under MT43 or MT44 sampling programs (see Ch. III, VI) or by another Federal or State entity. PAD identifies and schedules the sampling of this product.

G. Establishments Producing Primals and Subprimals

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

Typically, primals and subprimals are not adulterated if contaminated with *E. coli* O157:H7 because they are intact products for which cooking by the consumer results in a safe product. If slaughter suppliers that produce primals or subprimals are identified in STEPS because they supplied primals or subprimals that were used in the production of ground beef product that FSIS or another Federal or State entity found positive for *E. coli* O157:H7, FSIS would sample at the supplier of the source materials used in the production lot that was positive for *E. coli* O157:H7.

The DO is to inform the supplier establishment in writing, through STEPS or another written method (e.g., mail) that a particular type of product produced by the supplier establishment tested positive for *E. coli* O157:H7 in a production lot produced by another establishment or at a retail facility. In this situation, FSIS may sample subsequent production of primals or subprimals (Ch. II, I; and IV) at the supplier as part of its follow-up verification testing procedure.

V. ASEPTIC SAMPLING TECHNIQUES

A. Preparing For Sampling

1. Extraneous organisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological analysis are necessary; therefore, use of aseptic sampling techniques and of clean, sanitized equipment is of utmost importance.

2. If an area is designated for preparing and gathering sampling supplies, IPP should use it. IPP may choose to use a stainless steel, wheeled cart, if available, when carrying out the actual sample collection procedure. IPP may choose to use a small tote or caddy to carry items to the sampling location.

3. IPP are to wear sterile gloves while collecting samples. 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 are not sterile.

B. Putting On The Gloves

IPP are to first wash and sanitize their hands to the mid-forearm. IPP are to dry their hands using disposable paper towels. IPP are to follow the procedure for putting on sterile gloves.

1. IPP are to position the glove package so that the letters L and R are facing them (L=left, R=right)

2. When the package is opened, the gloves are folded, forming a cuff on the sleeve, and lying palm up. IPP are to leave the gloves in the package until they put on the gloves.

3. IPP are to hold one glove open by the inside cuff, insert a hand into the glove, palm-side up, and remove the glove from the package.

4. IPP are to pull the glove completely on with the ungloved hand, touching only the inside cuff, and pull the cuff up without touching the outside surface of the glove with the ungloved hand.

5. IPP are to repeat this procedure with the other glove, with one key exception. IPP are not to handle the second glove inside the cuff because hands

are not sterile. Therefore, IPP are to place the ungloved hand, palm up, into the second glove.

6. IPP are to insert the fingers of the gloved hand into the fold of the second cuff and ease the second cuff onto the hand and handle the second glove from the outside to adjust the cuff on the wrist.

7. Once both gloves are on, IPP can touch the outside of a glove with the other gloved hand to adjust the fit.

NOTE: If at any time IPP are concerned that they may have contaminated a glove, they are to discard it and repeat this procedure for putting on sterile gloves.

CHAPTER III – FSIS ACTIONS AFTER A POSITIVE FSIS OR ANOTHER FEDERAL OR STATE ENTITY SAMPLE RESULT

This chapter provides instructions for off-line inspection personnel (GS-8, 9, 10, and PHVs), EIAOs, and District Office Personnel. This chapter provides instructions for all the steps IPP are to follow after a sample tests positive for *E. coli* O157:H7.

See Attachments 1, 2, and 3 for corresponding flow charts.

I. SUPPLIER INFORMATION FOR A PRESUMPTIVE POSITIVE

Actions FSIS Takes When There Is A FSIS Presumptive *E. coli* O157:H7 Positive For A Raw Ground Beef Product Sample

Every FSIS verification sample that the laboratory confirms positive for *E.* coli O157:H7 goes through three stages of analysis. The laboratory reports results of each through LEARN (see Ch. II, I., A., 18). The laboratory initially screens the samples and, as appropriate, reports the "Potential Positives." At the next stage, based on laboratory results, LEARN reports some samples as "Presumptive Positives." In the final stage, some samples are "Confirmed Positive."

1. Because the laboratory confirms most "Presumptive Positives," the contact person in the District where the establishment is located is to inform establishment management immediately that:

a. the sample is "Presumptive Positive;"

b. if the results are confirmed positive, IPP will collect the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

i. the name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment. If the supplying establishment is the same as the establishment that produced the ground beef, IPP are to include the establishment name and number for that establishment as a supplying establishment;

ii. the supplier lot number; and

iii. the production date, name of supplied material, and any additional information to identify clearly the source material used to the management of the supplying establishment. IPP are to identify specifically the type of source materials the establishment used in producing the ground beef (using one of the defined terms in the definition section of this directive)(e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, and head or cheek meat).

2. If the source materials for a confirmed positive are from a foreign

establishment, the District contact person is to inform establishment management immediately that if the results are confirmed positive IPP will collect the following information from the establishment at which the sample was taken:

a. the country of origin;

b. the foreign establishment number;

c. the U.S. import establishment number (stamped on shipping cartons);

d. whether the sampled raw ground beef product was from a sole source or from multiple sources;

e. the description of the imported product (e.g., beef trim or coarse ground product);

f. the date the imported product entered the country (obtained from shipping documents)

g. the health certificate number (found on the health certificate accompanying the imported product);

h. the shipping marks (see information on the shipping mark in the note below);

i. the barcoding, production code, or date or any other information that identifies the product's date of production; and

j. the U.S. grinder establishment that produced the sampled product.

NOTE: Shipping marks are unique alphanumeric characters applied to the shipping cartons in the foreign country. They are important for tracing the product. The mark links product with the foreign health certificate.

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

II. SUPPLIER INFORMATION FOR A CONFIRMED POSITIVE

Information IPP Collect When The Laboratory Confirms A Positive For *E. coli* O157:H7 In A Raw Ground Beef Product Sample And Notification Concerning the Positive Result

1. When an FSIS laboratory or another Federal or State entity confirms a sample is positive, IPP collect the information in Ch. III. I. from the establishment. IPP are to make note of any information that the establishment is unable to provide.

2. IPP forward the information listed above by e-mail to the designated DO contact, with a "cc" to the FLS.

3. The DO is to access the STEPS, open a case file for the incident, and follow STEPS procedures. The DO is to identify all supplying establishments associated with the production of the raw beef products that tested positive for *E. coli* O157:H7.

4. The District Manager or designee:

a. enters into STEPS all supplier information it received from the IIC at the establishment that received the original positive on its ground beef. The DO enters information in STEPS based on an FSIS positive result or an AMS positive result. If another Federal or State positive result led to a recall, the DO is to enter information in STEPS based on these third party results;

b. determines whether any of the supplying establishments were also originating supplying slaughter establishments and notes this information under the remarks section in STEPS. With respect to supplying establishments that are not originating supplying slaughter establishments, the DO is to inform the IIC to collect supplier information on the product that went into the lot represented by the positive sample and forward the information to the DO. (To determine this, the IICs may need to examine establishment records);

NOTE: If the DO enters one or more establishments into STEPS that are not within its District, STEPS will automatically notify the appropriate DO. The DO that receives the notification is to repeat the steps above for establishments within its District and add any additional information into STEPS.

c. directs the IICs at all establishments that supplied product represented by the positive sample, including the originating supplying slaughter establishments that were identified in STEPS, to perform an 02 procedure per Ch. III, VII of this directive.

d. is to forward the supplier information (e.g., shipping marks, foreign establishment number, production code, and country) via e-mail to the Office of International Affairs (OIA), Import Inspection Division (importinspection@fsis.usda.gov), as directed in Ch. XI of this directive, if the supplier is a foreign establishment. OIA is to notify the inspection program officials of the exporting countries of the positive result and to request them to collect and test follow-up samples at the originating slaughter establishment. OIA is to initiate follow-up sampling at the port of entry based on the data provided in STEPS and an analysis of the foreign establishment's compliance history. In addition, OIA is to verify product disposition similar to domestic product (see Ch. III, IV., F).

e. is to work stepwise through the information collected at each establishment to identify the originating supplying slaughter establishments that supplied product. FSIS will only collect follow-up samples from originating supplying slaughter establishments (see Ch. III, VI.). If the grinding establishment used beef manufacturing trimmings or other ground beef or beef patty components from one or more suppliers, it is possible that some of the

supplier establishments are not originating supplying slaughter establishments.

5. If any of the originating supplying slaughter establishments commingle beef manufacturing trimmings or other ground beef or beef patty components processed at other establishments, IPP are to forward the supplier information to the DO. The DO is to enter the information concerning originating slaughter establishments into STEPS.

6. If FSIS verification samples from a retail store test positive for *E. coli* O157:H7, the DO may receive word through STEPS that an establishment in its District was an originating supplying slaughter establishment. The DOs with the originating supplying slaughter establishments in their districts are to notify the IIC at the originating supplying slaughter establishments (as described above), and PAD is to e-mail the Samplingforms – Headquarters mailbox to generate sample request forms for these establishments (see Ch. III, VIII., A., 2.).

III. BASING ENFORCEMENT ACTIONS ON FSIS AND ESTABLISHMENT TEST RESULTS

A. If FSIS finds product to be positive, and the establishment tested the product, IPP are to check establishment *E. coli* O157:H7 test results (see FSIS Directive 5000.2) to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7.

B. If the establishment held the product or maintained control of the product (e.g., the establishment 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, IPP are not to issue a noncompliance record (NR). IPP are to verify that the establishment performs the appropriate corrective actions.

C. Generally, if an FSIS sample tests positive for *E. coli* O157:H7, and the establishment did not find the product positive for *E. coli* O157:H7, IPP are to issue a noncompliance record (NR). However, in the unusual case that the establishment has a written program to divert all product that FSIS samples to cooking, IPP are not to issue an NR. IPP are to verify that such products are diverted per the written program.

D. If FSIS finds product positive for *E. coli* O157:H7, but the establishment does not, as set out in FSIS Directive 5000.1, IPP are to:

1. issue an NR under the appropriate 03 ISP code using the "verification" noncompliance classification indicator (cite 9 CFR 301.2 and 417.4(a) on the NR); and

2. verify whether the establishment held or shipped the affected product. If the establishment has shipped the product and it is not under the establishment's control, IPP are to contact the Recall Management Staff (RMS) through the DO in accordance with Directive 8080.1.

3. as soon as possible after the establishment has implemented its

corrective action, perform a HACCP 02 procedure for the specific production that tested positive for *E. coli* O157:H7 and verify that the establishment implements corrective actions that meet the applicable requirements in 9 CFR 417.3. If the establishment delays disposition of the positive product, IPP are to work with their FLS to determine how to work with the establishment to ensure proper and timely disposal of the product. IPP are to examine whether the establishment found multiple positives for *E. coli* O157:H7 in its own testing, evidencing a potential systemic problem. In processing establishments, IPP are to use Directive 5000.4, Performing the Review Portion of 01B02 (Pre-Operational Sanitation Verification) in Raw And Ready-to-Eat Product Processing Operations, to verify establishment implementation of its Sanitation SOP.

IV. OFF-SITE DISPOSITION OF PRODUCT

See Attachment 3 for a corresponding flow chart.

A. When conducting a HACCP 01 or 02 procedure at an establishment that transports presumptive positive or positive product to another site for appropriate disposition, IPP are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

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

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

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 is not a sufficient control.

4. maintained records showing that presumptive positive or positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

5. completed pre-shipment review for the presumptive positive or positive product only after it has received the records demonstrating lethality or disposal for that particular product.

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

C. If an establishment ships adulterated product to a renderer or landfill operation, IPP are to routinely verify the establishment denatures the product

before the product leaves the establishment (9 CFR 314.3).

D. If IPP find noncompliance with these requirements, they are to document it in accordance with FSIS Directive 5000.1. In situations where the establishment has not properly moved the product, IPP also are to notify the DO through supervisory channels.

E. When performing HACCP 02 procedures, IPP are to verify that the establishment that produced the *E. coli* O157:H7 positive or presumptive positive product maintains records showing that every lot implicated by the test results received appropriate disposition at an official establishment, landfill operation, or renderer. Records of receipt at an official establishment, landfill operation, or renderer are not adequate to show that the product received appropriate disposition. Rather, IPP have to verify that the establishment that produced the positive or presumptive positive product has a record from the establishment, landfill operation, or renderer that received the positive product evidencing that it appropriately further processed or destroyed the specific product represented by the positive sample. This record may be a record of receipt or control pending the product receiving a lethality treatment. The record could include information necessary to identify the product, the number of pounds of raw beef product received, and the number of pounds of such product rendered.

V. VERIFICATION ACTIVITIES AT AN ESTABLISHMENT THAT RECEIVES PRODUCT POSITIVE FOR *E. coli* O157:H7

A. When IPP perform a HACCP 01 or 02 procedure at an establishment that has received product from a lot that is positive for *E. coli* O157:H7, they are to verify that the establishment adequately addresses the pathogen in the product. IPP are to verify that the establishment:

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

2. maintains control of the product; and

3. addresses the receipt *E. coli* O157:H7 in its hazard analysis, flow chart, and HACCP plan, so that the positive product will receive an adequate lethality treatment to destroy the pathogen;

B. IPP do not have to be present to verify proper disposition of raw beef product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7. If IPP are not present when disposition of such product occurs, they are to verify that such product received proper disposition through records review.

C. IPP are to verify that establishments that further process raw beef product that is positive for *E. coli* O157:H7 have HACCP records of a validated lethality treatment sufficient to show that the product received proper disposition.

NOTE: FSIS does not require establishments to test product for *E. coli* O157:H7 if the establishment subjects the product to a lethality treatment adequate to

destroy the pathogen.

D. If IPP find noncompliance with V. A. above, they are to take appropriate action as described in FSIS Directive 5000.1, Chapter IV.

VI. PROCEDURES FOR FOLLOW-UP SAMPLING

Multiple Follow-up Sampling at Establishments That Have Product That Tests Positive For *E. coli* O157:H7

1. If FSIS finds raw ground beef product (MT43), beef manufacturing trimmings (MT50), or other ground beef or raw beef patty components (MT54), to be positive for *E. coli* O157:H7, through PREP, IPP automatically receive 16 follow-up sample forms to sample product from the establishment that produced the positive product. In addition, IPP will automatically receive forms as a result of a positive follow-up test of raw ground products (MT44). 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.

NOTE: If FSIS takes an action to initiate a recall based on State positive sample results (e.g., resulting from Outbreaks) or an AMS positive sample result, RMS creates the case file in STEPS and the DO then enters the supplier information into the STEPS database.

a. At low volume establishments (establishments that produce less than 1,000 pounds per day of product in question), IPP are only to submit 8 samples and mail the remaining 8 follow-up forms with the last sample collected.

b. Multiple follow-up sample forms for raw ground beef product samples will have the MT44 sampling project number in block 14 of FSIS Form 10,210-3, Requested Sample Programs.

c. Multiple follow-up sample forms for beef manufacturing trimmings or other raw ground beef or raw beef patty components will have the MT53 sampling project number in block 14 of the form. As is explained in Ch. III., VIII, of this directive, Follow-up Sampling at Suppliers, IPP also may receive multiple follow-up sample forms with the MT52 sampling project code in block 14 of the form.

2. Upon receipt of the multiple follow-up forms, IPP are to begin collecting samples from lots produced after the FSIS positive product finding, if the establishment resumes production. IPP are not to wait until the establishment completes corrective actions required under 9 CFR 417.3. If the establishment is producing product, IPP are to sample the eligible product produced.

3. IPP are to collect 8 samples for low volume establishments or 16 for all other establishments, at the following daily and weekly frequencies:

a. a maximum of 2 follow-up samples per shift per day from different lots (or up to 4 samples per day at a 2-shift establishment), unless the establishment cannot continue to operate under that sampling frequency (e.g., because the establishment cannot fill orders and hold all sampled product), or the IPP's workload cannot accommodate that sampling frequency; and

b. a minimum of 3 follow-up samples per week, unless the establishment produces the product in question less than three times per week, the establishment cannot continue to operate under that sampling frequency, or the inspection program employee's workload cannot accommodate that sampling frequency.

4. If the establishment is not currently producing the type of component requested, IPP are to collect a sample of another component that is available. IPP are to sample beef manufacturing trimmings if the establishment is producing them. If the establishment is also not producing beef manufacturing trimmings, then IPP 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.

5. If IPP need sampling supplies for follow-up sampling, they are to request them via e-mail at least 72 hours before sampling is to begin. IPP are to e-mail the laboratory identified in block 9 of the FSIS Form 10,210-3 (see Ch. II, I., A., 4. and 5). In addition, IPP are to include the follow-up sampling project number (MT44 for multiple follow-up ground beef product samples; MT53 or MT52 for multiple follow-up beef manufacturing trimming and other raw ground beef or raw patty component samples);

6. IPP may submit one or more individually identified samples per shipping container. If necessary, they are to include additional cooling packages in the shipping container to keep the sample or samples cool during transportation. To submit multiple samples, IPP may request larger boxes from any of the laboratories by sending an e-mail message to one of the e-mail addresses for sampling supplies above.

7. IPP are to return any unused forms to the laboratory. IPP may return unused forms in the box with the last follow-up sample.

8. During the period that IPP are conducting follow-up sampling for *E. coli* O157:H7, they may receive a routine sample request form for testing of product for *E. coli* O157:H7. In this situation, IPP are to continue to collect follow-up samples and are to make follow-up sampling the priority, rather than routine sampling. IPP are to collect the samples for routine testing within the allotted 30 days if they are able to do so based on their workload and the establishment's production practices. IPP are not to collect follow-up samples and routine samples from the same lot. If IPP are not able to collect the routine samples, he or she should select box 53 and state that the IPP did not collect the routine samples because of follow-up sampling.

9. If IPP receive requests to conduct follow-up sampling under more

than one sampling code or receive requests to sample product under the same sample code repetitively, they are to collect all samples. For example, if IPP receive forms to collect 16 follow-up samples under the MT52 project code and the 3rd sample of this set tests positive. IPP then receive 16 follow-up samples for MT53 as a result of this positive sample result, IPP would collect the rest of the 16 follow-up samples from the MT52 project code as well as the 16 follow-up samples from the MT53 project code.

10. As noted in, Ch. III, VIII, 3 and 4, PAD requests 16 MT52 follow-up sample forms for the originating slaughter establishments identified for each component used in the positive raw ground beef product. For follow-up sampling at the supplier, IPP may determine that it is necessary to sample other product, in addition to the components used in the positive raw ground product (e.g., if the establishment stopped applying antimicrobials to certain components or only began applying antimicrobials to the product after the establishment's product was found positive). If IPP determine that sampling of additional products would be useful, they are to contact the DO. If DO personnel determine that the sampling is appropriate, they are to contact the RIMD, OPPD, at (202) 205-0210. RIMD is to consult other offices within FSIS, including the Office of Public Health Science. RIMD is to provide IPP, through the DO, with an appropriate amount of samples to collect.

VII. Verification Activities FSIS Conducts At The Supplying Establishment If FSIS Confirms Raw Ground Beef Product At An Official Establishment Or Retail Facility Positive For *E. coli* O157:H7

The IIC at the supplying establishment is to ensure that the IPP perform a HACCP 02 procedure to verify that the establishment meets the applicable regulatory requirements at all CCPs in the HACCP plan (e.g., monitoring, verification, recordkeeping, corrective actions, and reassessment) for the implicated production lots sent to the establishment or retail facility where FSIS found the positive ground beef. In addition, during the HACCP 02 procedure, the IPP are to examine whether the establishment found multiple positives for *E. coli* O157:H7 in its own testing, evidencing a potential systemic problem. Finally, IPP are to verify sanitary dressing procedures per FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age.

VIII. FOLLOW-UP SAMPLING AT SUPPLIERS

Determining Which Establishments To Sample

1. On a monthly basis, the PAD, OPPD is to review data from STEPS to schedule follow-up sampling of suppliers. During the high prevalence season, PAD is to review the data bi-monthly.

2. PAD informs the "Sampling Forms – Headquarters" mailbox (see in paragraph 8. below) of the components IPP are to sample at supplying establishments based on information in the STEPS database. Based on

information from PAD, the DO is to inform IPP of which type of source materials the establishment supplied to the grinding facility, so that IPP can sample those source materials from the establishment's current production. If the originating supplying slaughter establishments produced more than one type of source material that the bench trim producer used, PAD will generate sample request forms for each type of source material. The DO is to inform IPP to collect samples of the specific type of product (including specific primal or subprimal cuts, if applicable) used in the production. PAD is to determine whether IPP are to collect a single follow-up sample or multiple follow-up samples (based on the criteria in paragraph 4. below) at supplier establishments. If the originating supplying slaughter establishments produced more than one type of component that the grinding establishment used, PAD will generate sample request forms for each type of component;

a. Generally, PAD is not to generate a follow-up sample request at:

i. establishments that only bone or fabricate beef primal or subprimal cuts but do not slaughter, except for ammoniated beef trimmings (see Ch. III, IX); or

ii. "sister" fabrication establishments (see note under Ch. II, IV., B.).

b. PAD is to generate follow-up sample requests for ground product if this is the component or product that the establishment supplied for the grinding establishment.

3. If PAD determines that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had been identified in STEPS within approximately 4 months (or 120 days) of the current raw ground product positive result, PAD is to request 16 MT52 follow-up sample forms for the originating slaughter establishments identified for each component used in the positive raw ground beef product.

4. If a supplier is not a sole supplier or a repeat supplier in STEPS, PAD will request a single follow-up sample from the supplier for each component used in the positive raw ground beef product.

5. When AMS notifies FSIS/Office of Field Operations (OFO) and OPPD Headquarters via e-mail of a positive *E. coli* O157:H7 raw ground beef sample result under the AMS commodity purchase program, PAD is to determine the originating supplying slaughter establishments. PAD is to notify OCIO through the sampling forms Headquarters mailbox and the DO that AMS found the sample positive. IPP are to collect 8 follow-up samples of the type of product AMS found positive, regardless of establishment size in response to an AMS positive result. Also, if a sole supplier or repeat supplier in STEPS supplied source materials for ground product that AMS found positive, IPP are to collect 8 follow-up samples at the supplier regardless of the supplier establishment size.

6. In combination slaughter/processing establishments, if FSIS or another Federal or State entity finds ground product positive, and the

establishment produced the source materials used to produce the ground product, PAD will generate MT52 sample request forms. IPP are to collect either 8 or 16 MT52 samples, based on establishment size, of the type of source materials used in the positive raw ground beef product. IPP are not to collect follow-up samples of ground product. In this situation, PAD is to notify the DO to instruct the IIC to mail the forms for multiple follow-up samples of raw ground product back to the laboratory via the United States postal service.

7. 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 is to generate the sample request that IPP are to use to collect a sample of ammoniated BLBT at the establishment that produced the ammoniated low-temperature-rendered product, even if that establishment is not an originating supplying slaughter establishment.

8. PAD is to request multiple or single MT52 follow-up sample forms by sending an e-mail message, with a cc to the appropriate DO, to the following address:

SamplingForms-Headquarters@fsis.usda.gov

The e-mail request is to contain the following:

a. "Request for Multiple MT52 Follow-up Samples" or "Request for Single MT52 Follow-Up Sample" in the subject line of the e-mail;

b. Information concerning whether the result was an AMS result or other Federal or State entity result, if applicable.

c. the establishment number for each originating supplying slaughter establishment from STEPS;

d. the number of sample request forms needed for each originating supplying slaughter establishment per component used in the positive product;

e. each component to be sampled; and

f. the form number of the positive ground beef product sample listed in the STEPS database.

9. If an MT52 sample tests positive, PAD is to schedule a follow-up MT53 sample request by sending an e-mail message (see 8. above), with a cc to the appropriate DO, to the following address:

SamplingForms-Headquarters@fsis.usda.gov.

IX. FOLLOW-UP SAMPLING OF AMMONIATED LOW-TEMPERATURE-RENDERED PRODUCTS FOR THE MT52 VERIFICATION SAMPLING PROGRAM

A. Ammoniated LTR product is subject to the MT52 verification sampling program when it is used as a component in raw ground beef products that tested positive for *E. coli* O157:H7 when sampled by FSIS under MT43 or MT44 sampling programs.

B. IPP are to sample the ammoniated low-temperature-rendered product by randomly selecting a sample consisting of 1-pound but not more than 2-pounds of product from a specific production lot.

C. If the establishment that produced the ammoniated LTR is not an originating supplying slaughter establishment, PAD is not to request MT52 sampling for the slaughter establishments that produced the source materials used in the ammoniated LTR, except as provided in the following paragraph, IX. D.

D. If the ammoniated LTR product tests positive under the MT52 verification sampling program, IPP are to collect supplier information from the establishment that produced the ammoniated low-temperature rendered product. The DO is to enter the supplying establishments into STEPS. PAD is to generate MT52 sample requests for the slaughter establishments that produced the source materials used in the positive ammoniated LTR product.

X. FOLLOW-UP SAMPLING (MT52) OF INTACT BEEF COMPONENTS THAT ARE NOT INTENDED FOR USE IN RAW GROUND BEEF PRODUCTS

A. If an establishment used intact product as a component in the raw ground beef product that FSIS finds positive for *E. coli* O157:H7, IPP are to select a carcass (rather than the component of the carcass) at the originating supplying slaughter establishment for follow-up sampling under the following conditions:

1. HACCP plan records and purchase specification records for product produced at the originating slaughter establishment show that the intact product supplied by the originating slaughter establishment was not intended for grinding or non-intact product, and that the establishment informed purchasers that the product was not intended for grinding; and

2. the establishment derived intact product from the carcass in a manner to minimize commingling with other product and the establishment packaged the product separately from other product without commingling (e.g., boneless chucks were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other product). IPP can verify that the establishment handled the product this way through records review and direct observation.

B. The conditions in paragraph A are meant to show that the supplying establishment intended the product for use as intact product. If both conditions in paragraph A are met, IPP are to cut enough slices off the surfaces of the carcass to equal 2 pounds (following instructions for sampling large components in Ch. II. IV. B). If both conditions in paragraph A are not met, IPP are to continue to sample the intact components that were used to produce the positive raw ground beef products.

IPP are to:

1. cut slices from the surface of the same part of the carcass that the establishment used in producing the positive raw ground beef product sample, when possible.

2. take the slices from the carcass while the carcass is hanging in the cooler before fabrication. If it is not possible to do either of these things, contact the RIMD through askFSIS at http://askfsis.custhelp.com/. RIMD personnel are to cc the appropriate district personnel on their reply.

C. If the FSIS sample collected as described in B. is positive, 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 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). Because establishments remove the head and cheek meat from the skull during the slaughter process and process it separately from the rest of the carcass, FSIS will not consider head or cheek meat implicated by the positive FSIS result.

XI. DO AND EIAO RESPONSES TO POSITIVE RESULTS

A. Within 30 days after being notified that FSIS or another Federal or State entity has found a raw beef product positive for *E. coli* O157:H7, the DO is to schedule an Enforcement, Investigations, and Analysis Officer (EIAO) to conduct a food safety assessment (FSA) at the establishment at which the positive was found, and is to determine whether the Agency needs to take any additional follow-up actions. 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.

B. If during the FSA the EIAO determines that additional sampling may be useful, he or she is to contact the DO. If DO personnel determine that additional sampling is appropriate, they are to contact the RIMD, OPPD at (800) 233-3935 or through askFSIS. RIMD will consult other offices within FSIS, including OPHS. RIMD is to provide the EIAO, through the DO, with an appropriate amount of samples to collect.

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

1. the establishment is failing to implement proposed corrective actions;

2. the establishment's corrective actions that the establishment is implementing are ineffective;

3. the establishment has recurring sanitary dressing noncompliances that render its corrective actions ineffective (see FSIS Directive 6410.1); or

4. the establishment does not have support for decisions made in its HACCP plan or hazard analysis (see FSIS Directive 5000.1).

CHAPTER IV – IPP RESPONSIBILITIES RELATED TO AN ESTABLISHMENT'S TESTING FOR *E. coli* O157:H7

This chapter provides instructions for off-line inspection personnel (GS-8, 9, 10, and PHVs), EIAOs, and District Office Personnel. This chapter provides directions for verifying an establishment's testing for *E. coli* O157:H7.

A. Establishments Conducting Pre-shipment Review For Product That Is Not At The Producing Establishment

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 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). IPP have access to the results of any testing and monitoring activities that the establishment performs that may have an impact on the establishment's hazard analysis (FSIS Directive 5000.2).

B. IPP Responsibilities When An Establishment Conducts Verification Testing For *E. coli* O157:H7

1. IPP are to review the records associated with any *E. coli* O157:H7 testing conducted by an establishment (see FSIS Directive 5000.2). If IPP find presumptive positive or confirmed positive *E. coli* O157:H7 results in the testing records, they are to verify that the establishment is implementing corrective actions when required. When an establishment tests product, a presumptive positive or positive result alone does not warrant an NR. IPP are only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions in accordance with its HACCP system to meet the requirements in 9 CFR 417.3.

2. If the receiving establishment tested the product and found it positive or presumptive positive for *E. coli* O157:H7, did not accept the product because it is adulterated, and returned the product 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), the IIC is to notify the DO after the establishment notifies the IIC at the establishment that found the positive of the rejected product (9 CFR 320.7). Include the supplier information for the product in the e-mail. The DO is to notify the IIC at the supplying establishment of the rejected product being returned and have the IPP at the establishment conduct a HACCP 02 procedure on the affected lot of product. If the DO enters one or more establishments into STEPS that are not within its District, the DO is to notify the appropriate DO. The DO that receives the notification is to repeat the steps above for establishments within its District.

NOTE: The Agency recognizes that it is probable, despite the ongoing processing interventions for controlling *E. coli* O157:H7, that some establishment samples 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. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

3. If an establishment is only performing screening tests and not following up with a presumptive positive or positive test result to determine whether *E. coli* O157:H7 is isolated from the product, then IPP are to verify that the establishment appropriately addresses the product as if the product is positive. The establishment cannot perform a second screening test for *E. coli* O157:H7 on the product and find it negative. Performances of additional screening tests do not negate the original positive screening test. A screening test is not a conclusive (specific) test for the pathogen.

4. If establishment records show that the establishment transports product that it has found presumptive positive or positive for *E. coli* O157:H7 to another establishment for appropriate disposition, or if establishment records show that the establishment moves product before *E. coli* O157:H7 test results become available, IPP are to follow the steps in Ch. III., IV.

5. If IPP are aware that an establishment has found product presumptive positive or positive for *E. coli* O157:H7, and that the establishment is moving the product for further processing to destroy the pathogen or for destruction, they are to verify that the establishment moves the product using the appropriate controls identified in Ch. III., IV.

6. When performing either the HACCP 01 or 02 procedure, IPP are to verify that establishment employees conducting sampling for *E. coli* O157:H7 do not sample sterile product that could not be contaminated with *E. coli* O157:H7 (e.g., product taken from the interior of a carcass). If IPP observe such sampling, they are to document noncompliance on an NR (see FSIS Directive 5000.1).

7. If establishment records show testing of trim and other raw ground beef components for *E. coli* O157:H7, but the establishment never finds any positives, IPP are to contact the DO. In addition, if establishment records show multiple positives for E. coli O157:H7 in its own testing, evidencing a potential systemic problem, IPP are to contact the DO. The DO is to schedule an EIAO to review the establishment's trim and other raw ground beef components sampling and testing methods for trim for *E. coli* O157:H7.

CHAPTER V – VERIFICATION ACTIVITIES AT ESTABLISHMENTS THAT PRODUCE MECHANICALLY TENDERIZED BEEF PRODUCTS

This chapter provides instructions for off-line inspection personnel (GS-8, 9, 10, and PHVs) to verify activities at establishments that produce mechanically tenderized beef products.

A. Non-intact beef products include ground beef; beef that an establishment has injected with solutions; beef that an establishment has mechanically tenderized by needling, cubing, Frenching, or pounding devices (with or without marinade); and beef that an establishment has reconstructed into formed entrees. If these non-intact raw beef products are contaminated with *E.* coli O157:H7 they are adulterated.

B. In establishments that produce mechanically tenderized beef products, including such products that an establishment injects with marinade (or "enhanced" products), IPP are to verify that the establishment has evidence that it considered the potential hazard of *E. coli* O157:H7. If establishments cannot support the decisions made in its hazard analyses, IPP are to follow the directions in FSIS Directive 5000.1.

CHAPTER VI – MEASURES TO ADDRESS *E. coli* O157:H7 AT ESTABLISHMENTS THAT RECEIVE, GRIND, OR OTHERWISE PROCESS RAW BEEF PRODUCTS

This chapter provides instructions for EIAOs and Consumer Safety Inspectors (CSIs) to verify the measures (e.g., prerequisite programs or CCPs) an establishment has in place to address *E. coli* O157:H7.

I. INADEQUATE MEASURES TO ADDRESS *E. coli* O157:H7

A. An establishment that receives, grinds, or otherwise processes raw beef products cannot conclude that *E. coli* O157:H7 is not reasonably likely to occur in its production process because the product it receives bears the mark of inspection. The mark of inspection is a reflection of a finding made by FSIS personnel that the establishment has followed the validated procedures in its HACCP plan, not that the pathogen has been eliminated or reduced to undetectable levels.

B. If IPP find that an establishment's only conclusion regarding control of the pathogen is a determination that *E. coli* is not reasonably likely to occur in its operation because the product that it receives bears the mark of inspection, they are to correlate with the DO through the FLS to determine whether it is necessary for an EIAO to conduct a FSA, or whether an enforcement action, such as a Notice of Intended Enforcement (NOIE), is warranted because the HACCP plan is inadequate (9 CFR 417.6(a)).

II. MEASURES TO ADDRESS *E. coli* O157:H7

A. There is no one, absolute way in which an establishment is to control or prevent *E. coli* O157:H7. IPP may find in verifying the approach to the pathogen that the establishment is using CCPs in its HACCP plan, its Sanitation SOPs, another prerequisite program, or a combination of these mechanisms, to do so.

B. An establishment receiving, grinding, or otherwise processing raw beef products may address *E. coli* O157:H7 by conducting finished product testing before pre-shipment review. In addition, an establishment may incorporate procedures for washing product when removed from Cryovac bags and trimming the outer surface of the product before producing non-intact product, using antimicrobials or other lethality treatments, or taking some other validated measures.

NOTE: Establishments that elect to use procedures must validate the effectiveness of their written protocol. If a study has shown that the establishment's written protocol is effective to address *E. coli* O157:H7, the establishment needs to demonstrate and document that it is capable of consistently following the written protocol for the specific type of raw beef product it receives and processes.

C. Establishments receiving, grinding, or otherwise processing raw beef products may use their Sanitation SOPs or other prerequisite programs to

prevent *E. coli* O157:H7. The establishment in its hazard analysis is to have supporting and ongoing verification documentation that establishes that the pathogen hazard is not reasonably likely to occur in its operation because of the design and execution of its prerequisite program. Such prerequisite programs may include the use of purchase specifications, but purchase specifications without on-going verification by the receiving establishment are not adequate (see 9 CFR 417.4(a)).

D. Under the HACCP regulations, the receiving establishment is to perform on-going verification activities to verify that its HACCP plan is being effectively implemented (9 CFR 417.4(a)), and maintain documents that support that those activities, and the frequency with which it performs them, are appropriate to accomplish their intended purpose. The on-going verification thus needs to address prerequisite programs, as well as critical control points and other control measures. An establishment is not adequately ensuring that its HACCP plan is functioning effectively if it is not assessing the on-going effectiveness of a prerequisite program on which its hazard analysis rests. Given this fact, a prerequisite program involving an annual letter of guarantee and an annual third part audit would not be adequate because the prerequisite program does not include any provision for meaningful on-going verification. A third party audit once a year does not provide the type of continuing activity that would constitute on-going verification. Establishments may utilize the Internet (e.g., e-mail information or current information available on a Web page) to provide up-to-date information on prerequisite programs. Given the sporadic, low-level occurrence of *E. coli* O157:H7, frequent verification is necessary to provide assurance that the presence of this pathogen is being successfully prevented by the prerequisite program. IPP are to examine an establishment's hazard analysis for justification as to why the frequency with which the establishment conducts on-going verification is appropriate.

E. If the establishment uses purchase specifications in a prerequisite program to support the effectiveness of the program, FSIS expects the establishment to have:

1. a document (e.g., letter of guarantee) from each supplier that provides assurance that the supplier employs CCPs that address *E. coli* O157:H7 and that describes the CCP, the monitoring of the CCP, and the use of any interventions. It is important to know whether the CCP is applied during slaughter (pre-chill) versus post-chill because further processing post-chill may introduce or re-distribute contamination on the product;

2. certificates of analysis (COAs) (i.e., actual test results) and the sampling method used (e.g., N60) by the supplier for product meant for grinding. It is important to know whether the production lot represented by the COA at the receiving establishment covers more than the amount of product represented at the receiving establishment; and

3. records (e.g., the receiving establishment's own testing results, ongoing communication with suppliers, or third party audits) that verify on an on-going basis that the receiving establishment is executing its program to achieve

the first two conditions in E. above in a consistent and effective manner to ensure that it is receiving product in which *E. coli* O157:H7 is not detectable.

F. FSIS has identified three basic types of relationships in which a receiving establishment obtains the information in E. 1. and 2. above.

1. The receiving establishment has a direct relationship with its suppliers under which the receiving establishment is informed of the specific slaughter/dressing and fabrication controls employed by the supplier, including any trimming of external surface tissue and application of antimicrobial treatments demonstrated to meet specified microbial criteria established by the supplier and receiver (e.g., demonstrated by counts of microorganisms indicative of process control),

2. The receiving establishment has a more casual relationship with its suppliers under which the establishment receives documentation that provides information about the supplier's general slaughter/dressing and fabrication practices, but does not assert that the products were processed to meet specified microbial criteria (e.g., counts of microorganisms indicative of process control),

3. The receiving establishment has an indirect relationship where the product received by an establishment is from brokers or importers (see G. below).

G. FSIS is aware that it may be difficult for an establishment receiving product from a broker or importer to meet all the criteria in E. 1. and 2. above. Therefore, if an establishment cannot meet these criteria, it may need to include the additional provisions in its food safety program to ensure that it conducts on-going verification of the safety of the product it receives, such as:

NOTE: There may be cases when the following applies to receiving establishments with direct or casual relationships with other official establishments.

1. If the establishment is unable to get an adequate letter of guarantee from a broker or importer, it should seek direct contact with the producing establishment of the product received by the broker or the importer to determine whether the suppliers have validated interventions and procedures.

2. If the establishment is unable to get a COA for each lot, it may obtain evidence from the broker or importer for each incoming shipment of raw beef materials that the materials were tested, and that the test results were negative for *E. coli* O157:H7. The establishment also may have direct contact with the broker's or importer's suppliers to inquire about the sampling and testing methods the supplier uses.

3. If the establishment is unable to achieve E. 1. and 2. above, the establishment should have put in place other mechanisms, including supporting documentation, for controlling the presence of *E. coli* O157:H7, such as:

a. testing incoming product;

b. treating or washing the product when removed from Cryovac bags and trimming the outer surface before processing non-intact product;

c. testing finished product; or

d. using antimicrobials or other lethality treatments on raw beef product and verifying the effectiveness of those antimicrobials.

III. EIAO VERIFICATION ACTIVITIES

A. When conducting a FSA at an establishment that receives, grinds, or otherwise produces raw beef product, the EIAO is to follow the methodology in FSIS Directive 5100.1 to assess whether the establishment has properly supported the measures it takes to address *E. coli* O157:H7.

B. Because of the variety of ways an establishment can control or prevent this pathogen, the EIAO will need to evaluate how the establishment has validated its HACCP system. The EIAO is to assess, as set out in FSIS Directive 5100.1, Part IV, III., *EIAOs Assessment of Validation*, whether the HACCP system includes some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. The EIAO is to determine whether the validation data demonstrate that the establishment can implement the HACCP plan and make it work to demonstrate that *E. coli* O157:H7 has been eliminated or reduced to a non-detectable level. An important element of validation is the identification or development of data that show that the establishment can apply the process or control to get the anticipated effect under actual in-plant operational conditions.

C. When reviewing any Sanitation SOP or prerequisite program that the establishment employs to prevent *E. coli* O157:H7 in raw beef products, the EIAO is to follow the methodology in FSIS Directive 5100.1, Part III., I., *EIAO Assessment of the Sanitation SOPs,* or Part IV, II., *EIAOs Assessment of Prerequisite Programs*, to determine whether the hazard analysis has the supporting and ongoing documentation to demonstrate that the presence of the pathogen hazard is not likely to occur in the establishment.

D. In addition, the EIAO is to seek answers to the questions below to determine whether the establishment has the appropriate scientific support and decision-making documents associated with the development and use of its prerequisite program as required in 9 CFR 417.5(a)(1), and that the judgment made in its hazard analysis continues to be supported by the evidence from the system in operation.

1. Questions on the relationship the receiver has with its supplier

Does the receiver have a direct, casual, or indirect relationship with its supplier?

NOTE: If the relationship is direct or casual, EIAOs are to consider this first when seeking answers to questions 2 and 3, and if the relationship is indirect, EIAOs are to seek answers to question 5. The EIAO is to consider question 4 in either case.

2. Questions on the documents (e.g., letters of guarantee) from each supplier that describe the supplier's procedures

a. Is there a description of the supplier's system, including a description of the validated CCPs the supplier uses to control the pathogen or other intervention or procedures (such as prerequisite programs) addressing the pathogen?

b. Is there a description of the interventions and other procedures used by the supplier?

3. Questions on COAs (i.e., actual test results) and a description of the sampling method used (e.g., N60)

a. Does the establishment require COAs for each lot of product?

b. Is the establishment receiving COAs and maintaining copies of the records?

c. Does the establishment have documentation from each supplier that identifies the laboratory method and sampling method and frequency it uses to support the COA? If the method is different than the FSIS laboratory method and N60 sampling procedures, does the establishment have a record that explains why the laboratory analysis method and sampling procedures it uses will produce results that the establishment can rely upon?

4. Questions on maintaining written procedures and records (e.g., its own testing, ongoing communication with suppliers, or third party audits)

a. Does the establishment maintain ongoing communication with its suppliers to ensure that what is described in the letter of guarantee, and the test results or statements that accompany each shipment, are accurate? If so, how frequent is such communication, and what is the receiving establishment's justification for the frequency? Is the communication documented, and is the documentation available to the EIAO?

b. Does the establishment contract with a third party to conduct audits of its suppliers to ensure that what is described in the letter of guarantee, and the test results or COA, that accompany each shipment are accurate? If so, how frequently are the third party audits conducted, and what is the receiving establishment's justification for the frequency?

c. Does the grinding establishment test the incoming product? If so, is there documentation supporting the verification frequencies and the adequacy

of the sampling and testing procedures? (See guidance document on *E. coli* O157:H7 testing at: http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf)

5. Questions regarding when the establishment receives raw beef product from brokers or importers

a. Does the establishment have a mechanism in place to contact the producing establishment of the product received by the broker or the importer to verify that the producing establishment regularly takes one or more of the actions outlined in II. G. 2. to ensure the safety of the product? Does the receiving establishment document the communication, and is the documentation available to the EIAO?

b. If the establishment is unable to get a COA for each lot, does it receive a general statement with each incoming shipment of raw beef materials that the materials were tested, and that the test results were negative for *E. coli* O157:H7? Does the establishment maintain direct contact with the broker's or importer's suppliers to inquire about the sampling methods the supplier uses?

c. If the answer is no to a. or b. above, does the establishment have CCPs in its HACCP plan or other procedures (e.g., prerequisite programs) to address *E. coli* O157:H7 in raw beef products? For example:

i. Does the establishment have procedures to test the incoming product? If so, is there documentation supporting the verification frequencies and the adequacy of the sampling and testing procedures?

ii. Does the establishment have procedures where it washes the parts after removing them from Cryovac bags and trims the outer surface before producing non-intact product?

iii. Does the establishment have procedures for finished product testing before pre-shipment review? If so, is there documentation supporting the verification frequencies and the adequacy of the sampling and testing procedures? Or

iv. Does the establishment use antimicrobials or other lethality treatments on raw beef product?

E. EIAOs are to consider all the factors above when writing their FSAs at establishments that produce raw beef as set out in FSIS Directive 5100.1. Negative answers to the questions above do not automatically mean that the establishment's system is inadequate. The EIAO in reviewing an establishment's food safety system is to verify that the establishment can support the determinations made in the hazard analysis and that the system as a whole is producing safe, unadulterated product. Also, in cases where establishments meet some of the criteria discussed in this notice in their prerequisite programs but not all elements, EIAOs are to take into consideration the establishment's use

of validated CCPs to control *E. coli* O157:H7.

IV. CSI VERIFICATION ACTIVITIES

A. If a CSI finds that an establishment that receives, grinds, or otherwise processes raw beef products has a CCP to control *E. coli* O157:H7, he or she is to verify that, as set out in FSIS Directive 5000.1, Chapter II, paragraph III, the establishment has validated that the CCP achieves the anticipated effect. If the CSI has questions regarding how the establishment validated the CCP, he or she is to contact the DO. The DO is to determine whether it is necessary to send an EIAO to the establishment.

B. If a CSI finds that an establishment that receives, grinds, or otherwise processes raw beef products addresses the prevention of *E. coli* O157:H7 in raw beef products through a prerequisite program, he or she is to verify that, as set out in FSIS Directive 5000.1, Chapter II, paragraph IV, the establishment's prerequisite program is being executed as designed. If the CSI has questions regarding how the establishment has designed or is executing a prerequisite program, he or she is to contact the DO. The DO will determine whether it is necessary to send an EIAO to the establishment.

CHAPTER VII – VERIFICATION PROCEDURES INVOLVING INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING *E. coli* O157:H7

This chapter provides instructions for off-line inspection personnel (GS-8, 9, 10, and PHVs), EIAOs, and DO Personnel and their responsibilities in verifying establishments' use of instructional or disclaimer statements concerning *E. coli* O157:H7.

See Attachment 4 and 5 for corresponding flow charts.

A. Instructional or Disclaimer Statements Concerning *E. coli* O157:H7

1. An instructional statement concerning *E. coli* O157:H7 is a statement that addresses how the product is to be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. A statement of limited use "for further processing" without further qualification is not an instructional statement.

2. Examples of instructional statements concerning *E. coli* O157:H7 in raw ground beef components, raw beef patty components, and raw ground beef products may include, "for full lethality treatment," "for cooking only," or "for further processing into RTE products that will receive a full lethality treatment." "Cooking" is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate *E. coli* O157:H7. "Full lethality treatment" may be cooking or another process that eliminates *E. coli* O157:H7, such as fermentation or salt curing.

3. 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 the production of the product. An example of a disclaimer statement concerning *E. coli* O157:H7 is, "product has not been tested for *E. coli* O157:H7."

4. Imported product may not bear either an instructional or a disclaimer statement.

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).

B. Types Of Products That Can Bear These Labeling Statements

1. Establishments can only place these statements on product for use at other official establishments. When the Labeling and Program Delivery Division (LPDD), OPPD approves the use of instructional labeling statements, LPDD specifies that establishments can only use such statements on products destined for official establishments that ensure that these products receive 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.

2. Product labeled with a “for cooking only” statement may undergo further processing after it leaves the cooking establishment. As part of performing a HACCP 01 or 02 procedure, IPP at an establishment that cooks product labeled “for cooking only” are to verify that the product 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.

3. IPP are not to object if an establishment labels beef manufacturing trimmings or ground beef with an instructional statement (e.g., “for cooking only”) if the establishment has not tested the product for *E. coli* O157:H7.

4. When LPDD approves the use of disclaimer labeling statements, LPDD is to specify that the establishment can only use the statement 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.

5. Establishments’ use of instructional or disclaimer statements is optional.

6. Positive product can bear instructional or disclaimer statements. However, IPP are to verify that any such product that comes to an establishment that they inspect enters or has moved in commerce under appropriate controls, as described in Ch. III, IV. An instructional or disclaimer statement is not a control for movement of positive product.

C. IPP Verification Activities At Establishments That Place Instructional Or Disclaimer Statements Concerning *E. coli* O157:H7 On The Labeling Of Raw Ground Beef Products, Raw Ground Beef Components, Or Raw Beef Patty Components

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

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

3. If an establishment includes instructional statements or disclaimer statements on product that does not leave the establishment and is for internal purposes only, then IPP are not to assess whether the establishment is appropriately using such statements, as they would with respect to product going to other official establishments. FSIS does not approve such labels submitted by establishments.

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

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

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

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

d. the establishment's HACCP plan for products on which it places a disclaimer statement includes a validated intervention for *E. coli* O157:H7. A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (9 CFR 417.6).

5. If an establishment is placing the statement "for cooking only" or "for full lethality treatment" on raw ground beef products, raw ground beef components, or raw beef patty components, IPP are to verify that the establishment's hazard analysis shows how the establishment is ensuring that the product will go for cooking only or for other full lethality treatment only.

6. If the establishment places a "for cooking only" statement on the product and ships it to outside establishments, IPP are to verify that the shipping establishment has controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that it does not intend for cooking, IPP are to verify that the establishment has

controls in place to segregate product intended for cooking from product not intended for cooking.

7. If IPP find that the establishment's use of instructional statements does not meet the criteria in paragraph 4. a., b., or c., or that the establishment's use of disclaimer statements does not meet the criteria in paragraph 4. a. or b. or d., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Chapter IV using the HACCP 01 or 02 ISP code and the appropriate regulatory citation (usually, 9 CFR 417.5) and the recordkeeping trend indicator.

8. If an establishment labeled product with an instructional or disclaimer statement and does not send the product to a second establishment that further processes the product to destroy the pathogen, IPP are to document the noncompliance on an NR because the product would be misbranded. Establishments 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.

9. If IPP determine that product with an instructional or disclaimer statement is moving outside the establishment and not proceeding to a facility that will treat the product with an adequate lethality, they are to initiate a regulatory control action (9 CFR 500.2(a)).

D. Verification Activities IPP Conduct At Establishments Receiving Raw Ground Beef Components, Raw Beef Patty Components, Or Raw Ground Beef Products With Instructional Or Disclaimer Statements Concerning *E. coli* O157:H7

1. When performing a HACCP 01 or 02 procedure to verify the HACCP requirements are met for products produced using incoming products with an instructional or disclaimer statement, IPP are to verify that establishments that receive such incoming products:

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

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

2. If IPP find that the establishment has not met the criteria in paragraph 1., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation (usually 9 CFR 417.5(a) with the recordkeeping noncompliance classification indicator).

3. IPP are to retain product produced using such incoming products under the following conditions:

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

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

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

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

E. Verification Activities For Product Sent To Warehouses Or Brokers

1. FSIS does not provide identification service under 9 CFR 350.3 at warehouses that subdivide bulk units into smaller units for beef products that bear a disclaimer statement or instructional statement concerning *E. coli* O157:H7. FSIS does not sketch approve labels with these special claims at ID warehouses.

2. IPP are to verify that if an establishment places an instructional or disclaimer statement on raw beef products and sends such product to a warehouse or broker, the establishment ensures that all of the following conditions will be met:

a. the product will not be broken down into smaller units or repackaged at the warehouse;

b. the warehouse or broker will hold the product under appropriate conditions so that it will not be rendered injurious to health or otherwise rendered adulterated, including ensuring that the product will not be held at temperatures that would allow *E. coli* O157:H7 or other pathogens of public health concern to multiply;

c. the warehouse or broker will ship the product bearing the instructional or disclaimer statement only to an official establishment that has an appropriate production process; and

d. the producing establishment has a means of documenting that a second official establishment ultimately received the product and processed the

product appropriately.

3. IPP are to:

a. contact the DO immediately through their FLS if they observe the breaking bulk or repackaging of product bearing this type of statement at an identification warehouse (see FSIS Directive 12,600.1 VIII).

b. detain the product if so instructed (see FSIS Directive 8410.1)

NOTE: Failure of an identification warehouse to adhere to the provisions of its application for service could result in the District Manager withdrawing that service (see FSIS Directive 12,600.1, Section XI).

CHAPTER VIII – IMPORT SAMPLING

This chapter provides instruction for import inspection personnel and Import Inspection Division (IID) management (Regional Import Field Office (RIFO), Headquarters, and field supervisors) on collecting samples for *E. coli* O157:H7 testing and responding to positive *E. coli* O157:H7 results.

I. DEFINITIONS FOR IMPORT SAMPLING

The Automated Import Information System (AIIS) makes sampling assignments for *E. coli* O157:H7 based on the shipment data entered by import inspection personnel. The three types of import reinspection assigned by the AIIS are normal, increased, and intensified.

A. Normal – AIIS randomly selects a lot for sampling for a country for the process category. Under the normal level of sampling, import inspection personnel do not typically retain the lot pending receipt of the laboratory analysis. When FSIS is to sample a shipment under normal sampling, the importer, broker, or applicant has an opportunity to hold voluntarily only the product represented by the sample until FSIS reports the results.

B. Increased – Sampling level above the normal level. OIA management bases the decision to go to increased sampling on analysis of trends, observations identified through data, audits, or information associated with a foreign country's inspection system or a foreign establishment's product. Import inspection personnel are to check the "Increased country and establishment list" in Outlook (Public Folders\All Public Folders\OIA\IID\Import Folder\Increased Level of Inspection/Special Sampling Instructions) daily to confirm any special sampling or product hold procedures. Under the increased level of sampling, import inspection personnel do not typically retain the lot pending receipt of the laboratory analysis. The importer may place the shipment on voluntary hold. When FSIS is to sample a shipment that is eligible for voluntary hold only, the importer, broker, or applicant has an opportunity to hold voluntarily only the product represented by the sample until FSIS reports the results.

C. Intensified – the level of sampling due to a positive *E. coli* O157:H7 FSIS sampling result. When a foreign establishment is under intensified sampling because of a positive *E. coli* O157:H7 result, import inspection personnel are to hold the entire lot of product from which the import inspection personnel selected the sample until the FSIS laboratory reports negative results.

II. RAW GROUND BEEF PRODUCT SAMPLING CONDUCTED AT IMPORT ESTABLISHMENTS

A. Import inspection personnel generally receive sampling instructions from the AIIS. The AIIS assigns import inspection personnel an *E. coli* O157:H7 Type of Inspection (TOI). OCIO works with OIA to send import inspection personnel FSIS Form 10,210-3, "Requested Sample Programs." The form will provide a sample identification number, establishment name, address, and import

establishment (I-house) number specific to the sample the import inspection personnel are to collect.

B. Import inspection personnel are to:

1. request sample forms from the import inspection mailbox, ImportInspection@fsis.usda.gov, with a cc to the applicable Regional Import Field Office (RIFO) mailbox. Import inspection personnel are to request forms by the end of each month. The e-mail is to include:

a. I-house number;

b. project number for the type of sampling (MT08 or MT51); and

c. the number of forms (place orders in increments of 25). OIA recommends that import inspection personnel keep a 3-month supply of applicable sampling forms at the I-house;

2. request sampling supplies when needed. Import inspection personnel are to request supplies via e-mail at least 72 hours before sampling is to begin. Import inspection personnel are to e-mail the laboratory identified in block 9 of FSIS Form 10,210-3 (see Ch. II, I., A., 4. and 5.). Import inspection personnel are to include the I-house address (not a P.O. Box) instead of the establishment address;

3. notify the import establishment management of the reason the import inspection personnel are collecting a sample for *E. coli* O157:H7 testing (normal FSIS verification testing, increased sampling, or intensified sampling);

NOTE: FSIS will not allow the use of instructional (e.g., "for cooking only") or disclaimer statements on imported product presented at port-of-entry;

4. for normal or increased sampling, notify the importer regarding placing the lot on voluntary hold. If the importer requests that the product be placed on voluntary hold, import inspection personnel are not to stamp containers "U.S. Inspected & Passed" (For Canada, import inspection personnel are not to stamp the paperwork "U.S. Inspected & Passed");

5. verify, only if the product is on voluntary hold, that the import establishment holds the lot on premises until import inspection personnel reinspect the product pending the laboratory result. If the laboratory result is negative, import inspection personnel may stamp the containers and release them into commerce;

6. check AIIS to obtain test results and provide AIIS results to the import establishment management even if the establishment receives e-mail notifications. If results do not post into AIIS within 48 hours, import inspection personnel are to notify OIA Headquarters for correction;

7. verify the disposition of the lot. The lot is not eligible for re-exportation if the laboratory analysis is not in compliance. The import

establishment may dispose of the lot by denaturing, destroying, or further processing. Import inspection personnel are to contact the FSIS RMS staff for products that tested positive for *E. coli* O157:H7 that the import establishment has released into commerce;

8. not re-submit laboratory samples assigned at the Normal level if the laboratories discarded for cause;

9. submit a completed FSIS Form 9770-3, "Discarded Sample Report and Findings" for samples that the FSIS laboratory reports as discards to the RIFO supervisor after completion. Import inspection personnel assigned to the import establishment from which the sample was sent are to complete the form;

10. refuse entry on the sampled lot if held, if the product tests reports as positive. If the lot has not been held, import inspection personnel are to notify their supervisor.

NOTE: When a foreign establishment is under intensified or increased sampling for microbiological or residue testing, shipping lots are not eligible for segregation, and import inspection personnel are to hold the entire shipping lot pending laboratory results. Import inspection personnel are to collect and submit a laboratory sample from only one specific production lot code or date.

III. SAMPLING PROGRAM FOR IMPORTED RAW GROUND BEEF AND VEAL PRODUCTS (MT08)

A. Sample Size

Import inspection personnel are to collect a 1-pound intact sample unit from the assigned lot, unless:

1. the intact packages are less than 1-pound. In this situation, import inspection personnel are to select intact packages to obtain an approximate 1-pound sample. If necessary, import inspection personnel are to select product for sampling from multiple open packages;

2. the immediate container is greater than 1-pound. In this situation, import inspection personnel are to select an entire intact package as the sample if it is practical to ship the entire sample unit to the laboratory;

3. the immediate container is of a size that is not practical to ship to the laboratory as an intact unit. In this situation, import inspection personnel are to open the immediate container and select the sample using the aseptic methods described in Ch. II, V.

NOTE: Import inspection personnel are to order special supplies (e.g., sterile gloves and whirlpak bags) from the laboratories. Import inspection personnel cannot order utensils, knives, or tongs from the laboratory.

B. Preparing Samples

Fresh (Unfrozen) Products

1. Import inspection personnel are not to freeze samples of product that arrives Monday through Friday as fresh and unfrozen. Import inspection personnel are to submit samples of product in the fresh, unfrozen state to the laboratory Monday through Friday.

2. If a shipment arrives on Saturday, Sunday, a holiday, or after the contract carrier has picked up packages at the establishment for the day, import inspection personnel are to refrigerate the sample and ship it to the laboratory on the next work day.

3. Import inspection personnel are to collect samples from one specific production code or date and document the production lot code on FSIS Form 10,210-3.

IV. MT51 SAMPLING PROGRAM FOR IMPORTED RAW GROUND BEEF COMPONENTS AND RAW GROUND PATTY COMPONENTS

A. General Sampling Instructions

1. Import inspection personnel are to collect samples from one specific production code or date and document the production lot code on FSIS Form 10,210-3.

2. When collecting samples, import inspection personnel are to:

a. ensure that equipment used for removal of the sample has been properly cleaned and sanitized; and

b. use gloves and handle all sanitized surfaces in a sanitary manner.

B. Beef Manufacturing Trimmings – Fresh (not frozen)

Follow the directions in Ch. II, IV., B.

C. Beef Manufacturing Trimmings – Frozen

To sample frozen beef manufacturing trimmings, import inspection personnel are to select the number of containers from the lot assigned by the AIIS. The containers are to have the same production code or date. Import inspection personnel are to collect 60 individual pieces from frozen beef manufacturing trimmings as follows:

1. remove from the container or expose the top surface of the randomly selected frozen block of beef trimmings;

2. for each individual block, aseptically remove about 15 grams of

slivered product at each of twelve evenly distributed locations around the periphery of the frozen block. The diagram in Attachment 7 illustrates how import inspection personnel would take an N-12 sample at every 30° point around the entire circumference of the frozen block. Import inspection personnel are to repeat the N-12 sampling for each of the additional blocks, until they have taken 60 15-gram samples. During slivering, import inspection personnel are to sample as much surface area as possible. The method of removal of the N60 samples will be at the discretion of the import establishment (i.e., band saw, chisel, electric saw, knife) and will depend on the preparation (i.e., defrosting, tempering) of the containers for samples, when applicable.

3. when import inspection personnel cannot sample five blocks, they are to remove 60 slivered samples from as many blocks as possible in a similar fashion. For less than five blocks, import inspection personnel are to remove the blocks from the container and sample the bottom or one or more side faces of the block to ensure better that the 60 samples represent different sites on the product.

4. composite the contents of each block into a single whirlpak bag.

D. Advance Meat Recovery (AMR) Product and Low Temperature Rendered Beef (LTR) Products

See Ch. II, IV., D., 2.

F. Other Raw Beef Components

See Ch. II, IV., D., 3

V. SUBMITTING THE SAMPLE AND CHECKING FOR RESULTS

Follow the instructions in Ch. II, I., 16. and 18.

VI. ACTIONS TO TAKE BASED ON RESULTS

A. Negative Results

When a sample tests negative for *E. coli* O157:H7, the sampled lot is not subject to further testing, and import inspection personnel may release it if it is on FSIS Hold, and all other reinspection criteria are acceptable.

B. Presumptive Positive

1. When BITES notifies the Import Inspection Division (IID) management (RIFO, HQ, and supervisor) that a sample is presumptive positive, the supervisor will notify import inspection personnel of this result.

2. Import inspection personnel are to:

a. notify establishment management of the presumptive positive result and determine if the lot is on hold (FSIS or voluntary). If the lot is on hold, import inspection personnel are to report this to their supervisor;

b. provide the supervisor with copies of the health certificate, FSIS form 9540-1, FSIS form 10,210-3, and any other documents pertinent to the lot;

c. if the lot is on voluntary hold, inform import establishment management that import inspection personnel are placing the product on FSIS hold. Import inspection personnel are to request that import establishment management contact the importer of record to inform it of the presumptive positive and that the product is on FSIS hold. Import inspection personnel are to report to their supervisor that the product is on FSIS hold;

d. if the lot is not on hold but is still at the import establishment, import inspection personnel are to retain the product and request import establishment management to contact the importer of record to inform it of the presumptive positive result and the retention of the product. Import inspection personnel are to report to their supervisor that the product is being retained;

e. if the lot is not on hold and has been distributed from the import establishment in to commerce, request import establishment management to:

i. contact the importer of record to inform it of the presumptive positive;

ii. request the importer of record stop further distribution of the product and place the involved product in distribution on voluntary hold; and

iii. request distribution information on the product. Import inspection personnel are to report the distribution information to their supervisor.

f. OIA Headquarters is to notify the inspection program officials of the involved exporting countries as soon as the laboratories report a presumptive positive result in order to identify whether the establishment from the exporting country has any other product from the presumptive positive lot identified in the United States.

C. Positive Results

1. When a normal or increased sample tests positive for *E. coli* O157:H7, import inspection personnel are to:

a. refuse entry on the sampled lot, if held. Import inspection personnel are to follow the refused entry procedures identified in FSIS Directive 9020.1, Meat, Poultry, Egg Products, and Shell Eggs Refused Entry Into The United States (U.S.); and

b. contact their supervisor to initiate a Recall if the shipment or lot was not held. RIFO and IID Headquarters are to follow the IID Recall

Procedures per Directive 8080.1 and section D. below.

2. When an intensified sample tests positive for *E. coli* O157:H7, import inspection personnel are to refuse the lot entry.

3. IID Headquarters is to notify import inspection personnel of any action to take relating to the positive result for the shipment (e.g., notifying establishment management, determining other shipments or production dates of the same lot).

4. OIA Headquarters is to notify the inspection program officials of the involved exporting country as soon as the laboratory reports a positive result in order to identify whether the foreign country has any other production lots from the lot identified exported to the United States. If any lots are identified by the foreign country from the same producer with the same production code, OIA is to:

a. request a recall the product if import inspection personnel passed the product under import reinspection; and

b. refuse entry of the product if import inspection personnel have not passed the product under import reinspection.

5. OIA Headquarters is to issue an alert to import inspection personnel to refuse entry for the same lot of product with the same production codes that the foreign country presents for FSIS import reinspection after the confirmed positive result. IID will verify production lot information on all future lots from the foreign establishment or importer of record that will be assigned intensified reinspection.

D. FSIS Recall and Follow Up Actions

If the product represented by the same production codes or dates that tested positive for *E. coli* O157:H7 moved into commerce from the import establishment then:

1. Import inspection personnel are to send a completed copy of FSIS Form 9540-1 and the foreign health certificate via fax (202) 720-6050 to the IID.

2. OIA Headquarters is to notify the head of the inspection service in the country of origin and the Foreign Agriculture Service (FAS) representative to the country from which the positive product arrived of the confirmed positive *E. coli* O157:H7 sample result. OIA Headquarters is also to inform them whether FSIS will request that the importer of record recall any of the applicable product in commerce. OIA Headquarters is to request that the foreign country conduct a FSA or equivalent procedure for the producing establishment and test follow-up samples from the grinding facility or the originating slaughter establishments that produced the positive product.

Chapter IX – Data Analysis

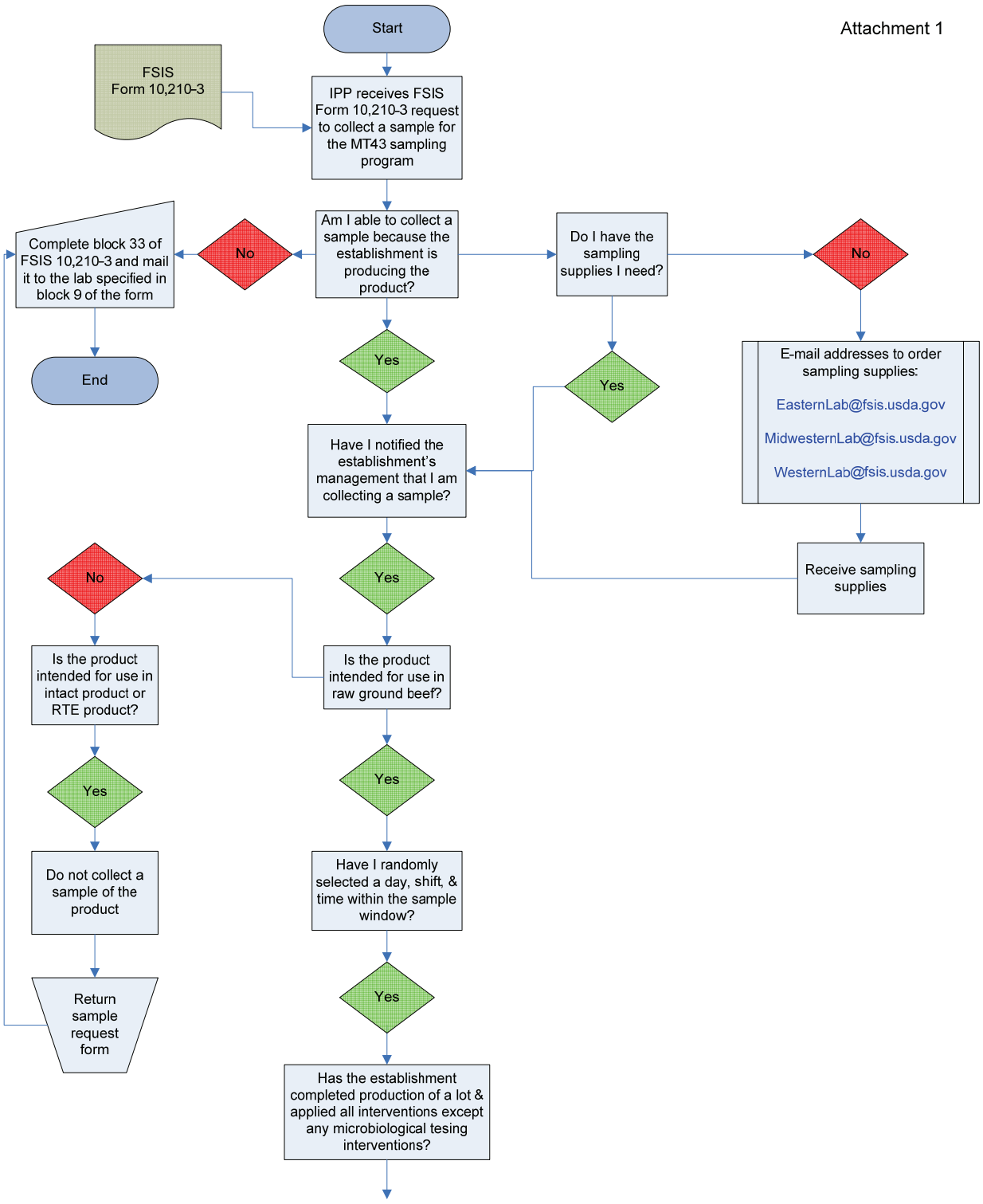
OPHS will report the *E. coli* O157:H7 sample results for raw ground beef products and raw ground beef and patty components. A weekly report, along with an annual summary report will be published on the FSIS Internet. In addition, OPHS will analyze the data to identify trends (e.g., geographical, seasonal and annual trends) in *E. coli* O157:H7 percent positive results and to inform future FSIS policies. OPHS will coordinate and collaborate with Office of Data Integration and Food Protection (ODIFP), OIA, and OPPD. In addition, ODIFP will use the data to calculate a quarterly performance measure of *E. coli* O157:H7 in raw ground beef and ground beef and patty components which will be included in the Agency's quarterly performance report.

Direct all technical questions to the Policy Development Division and all sampling questions to the RIMD at 1-800-233-3935 or submit your question through *askFSIS* at http://askfsis.custhelp.com.

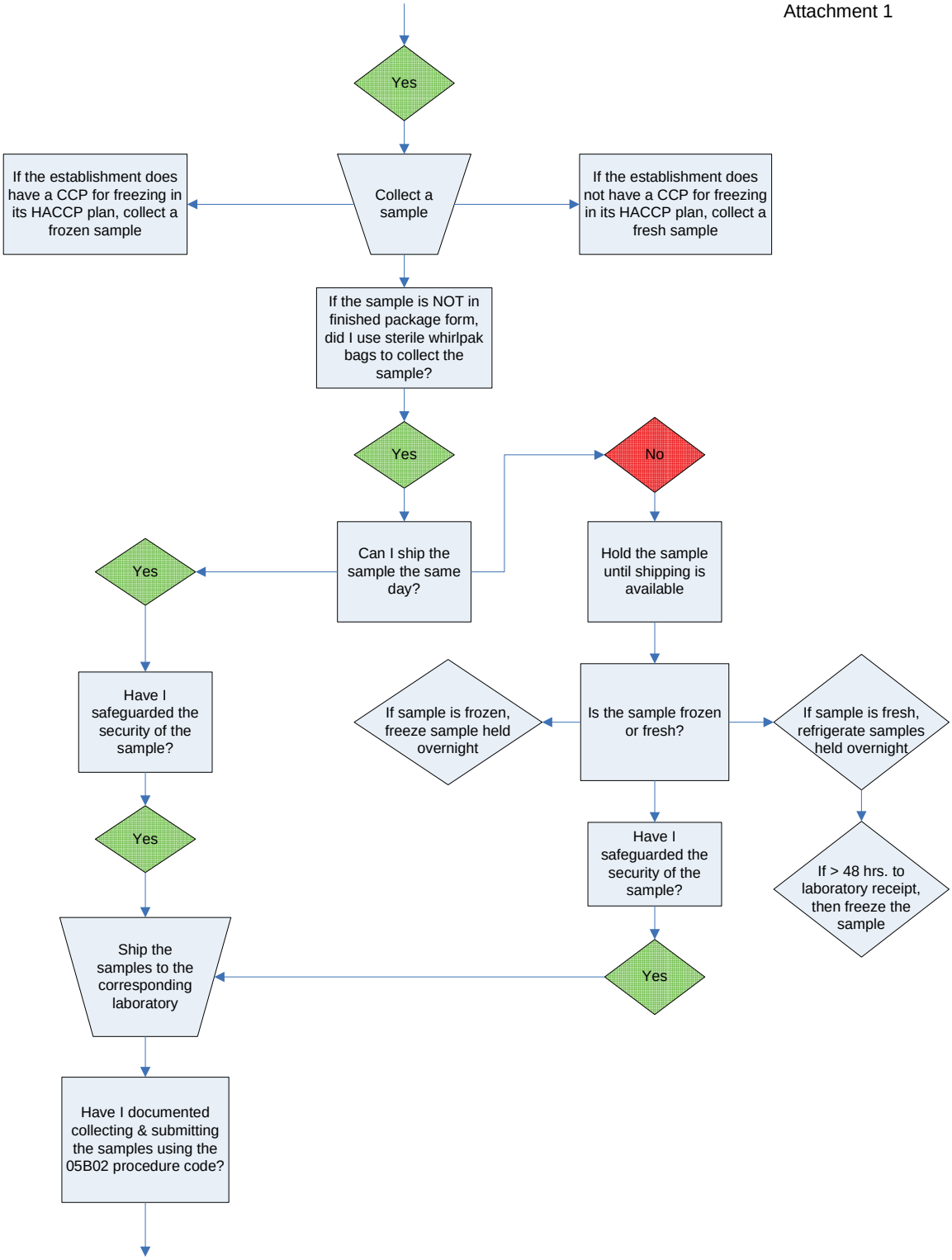
Assistant Administrator
Office of Policy and Program Development

FSIS Sampling and Related Verification Activities – page 1

Attachment 1

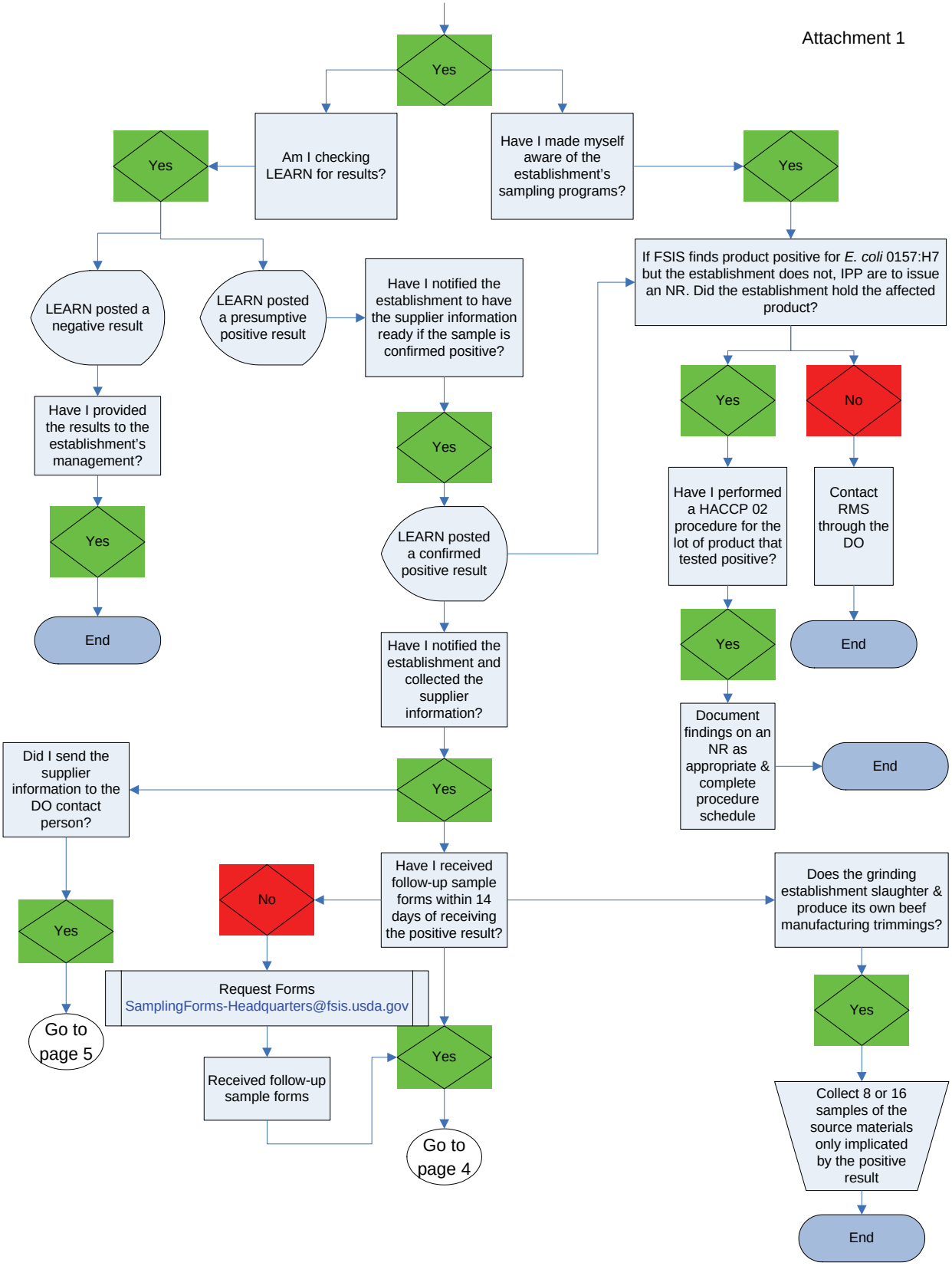


Attachment 1



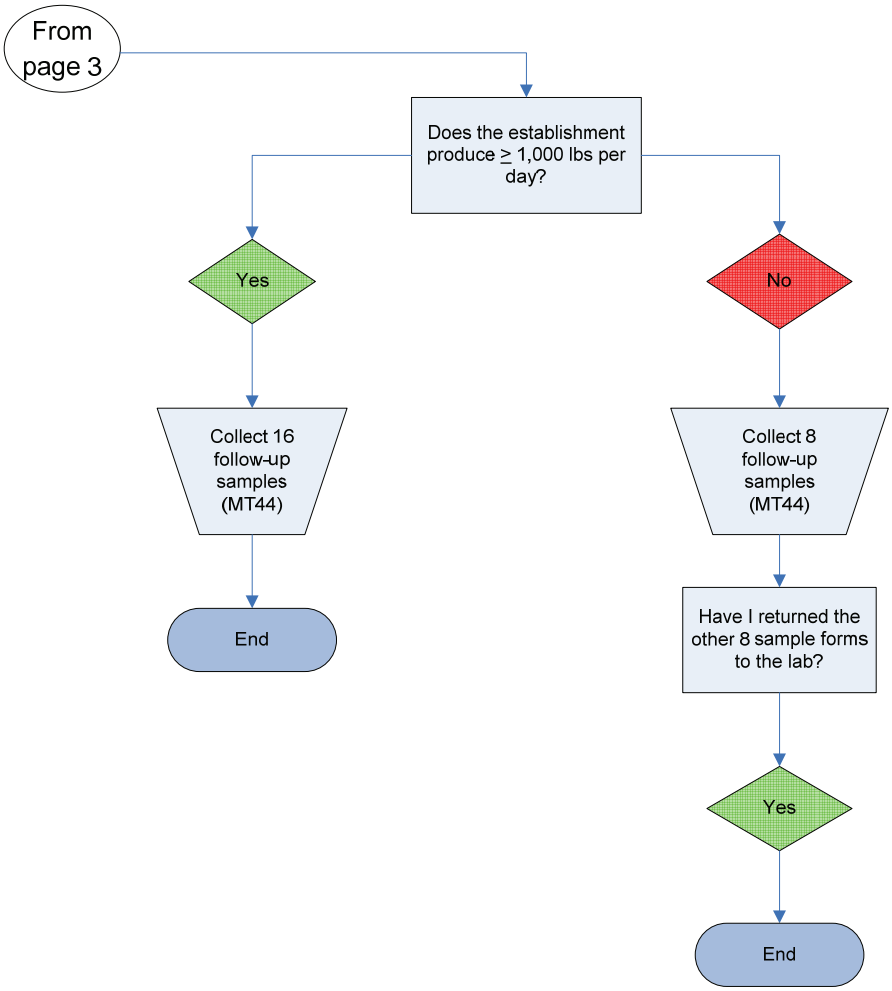
FSIS Sampling and Related Verification Activities – page 3

Attachment 1



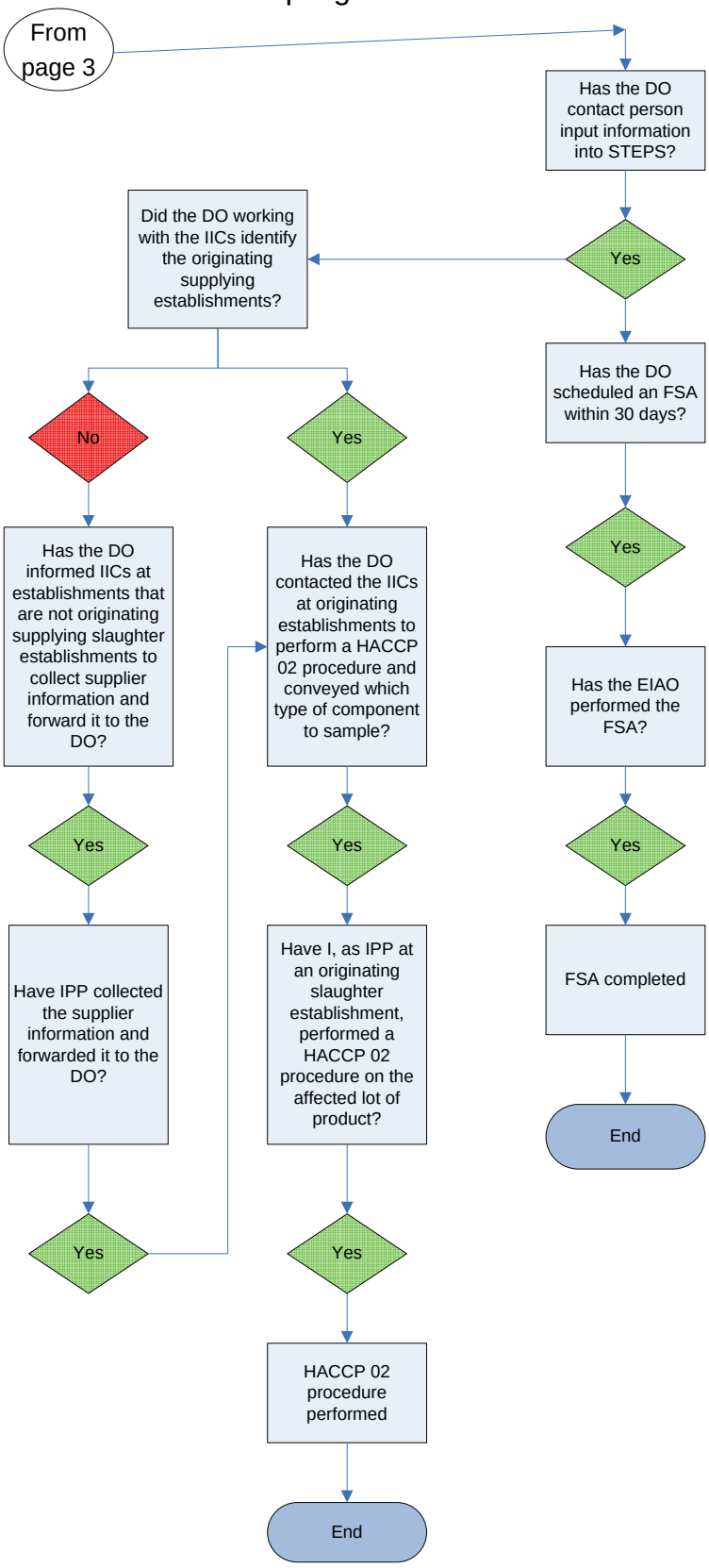
FSIS Sampling and Related Verification Activities – page 4

Attachment 1



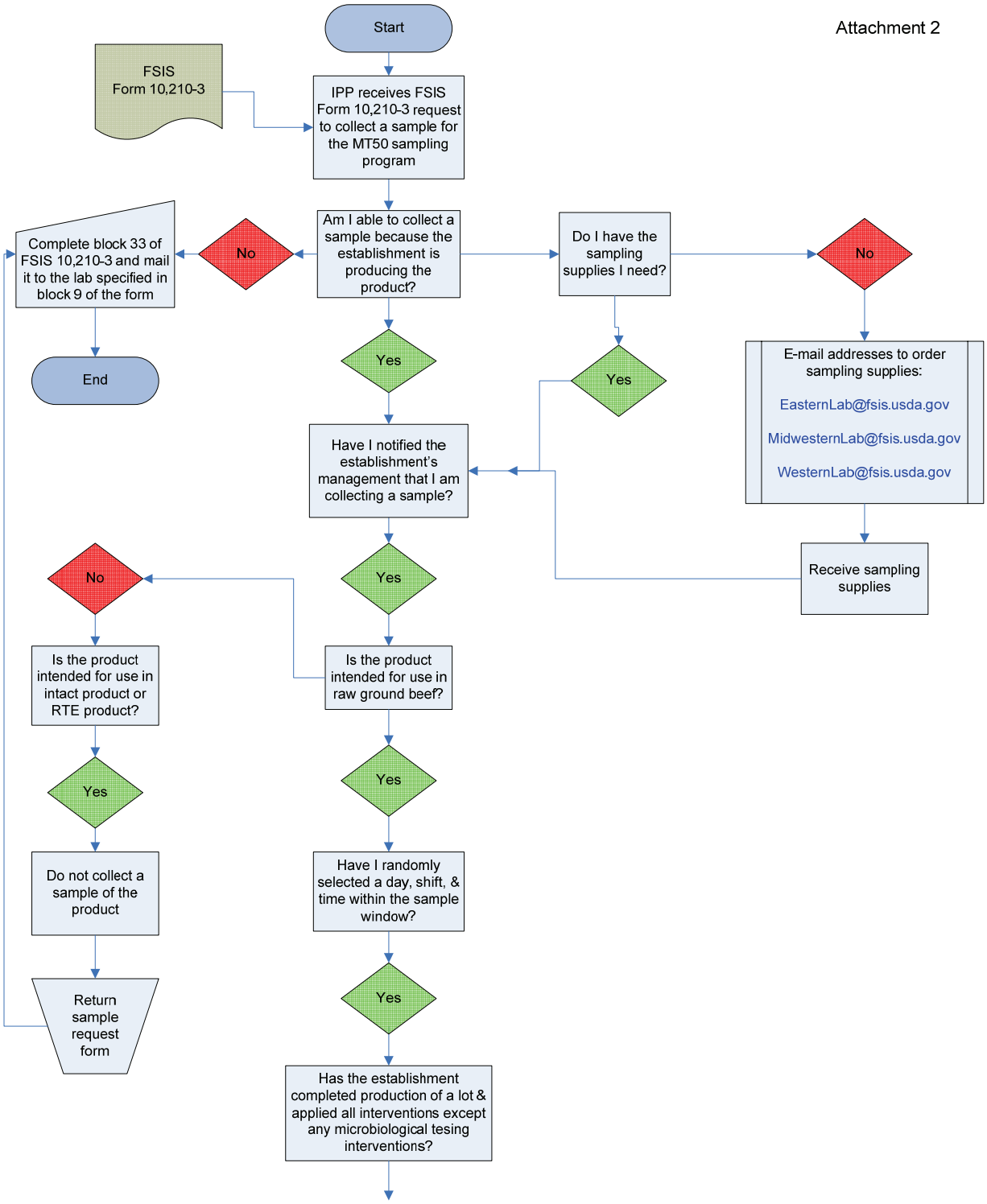
FSIS Sampling and Related Verification Activities – page 5

Attachment 1



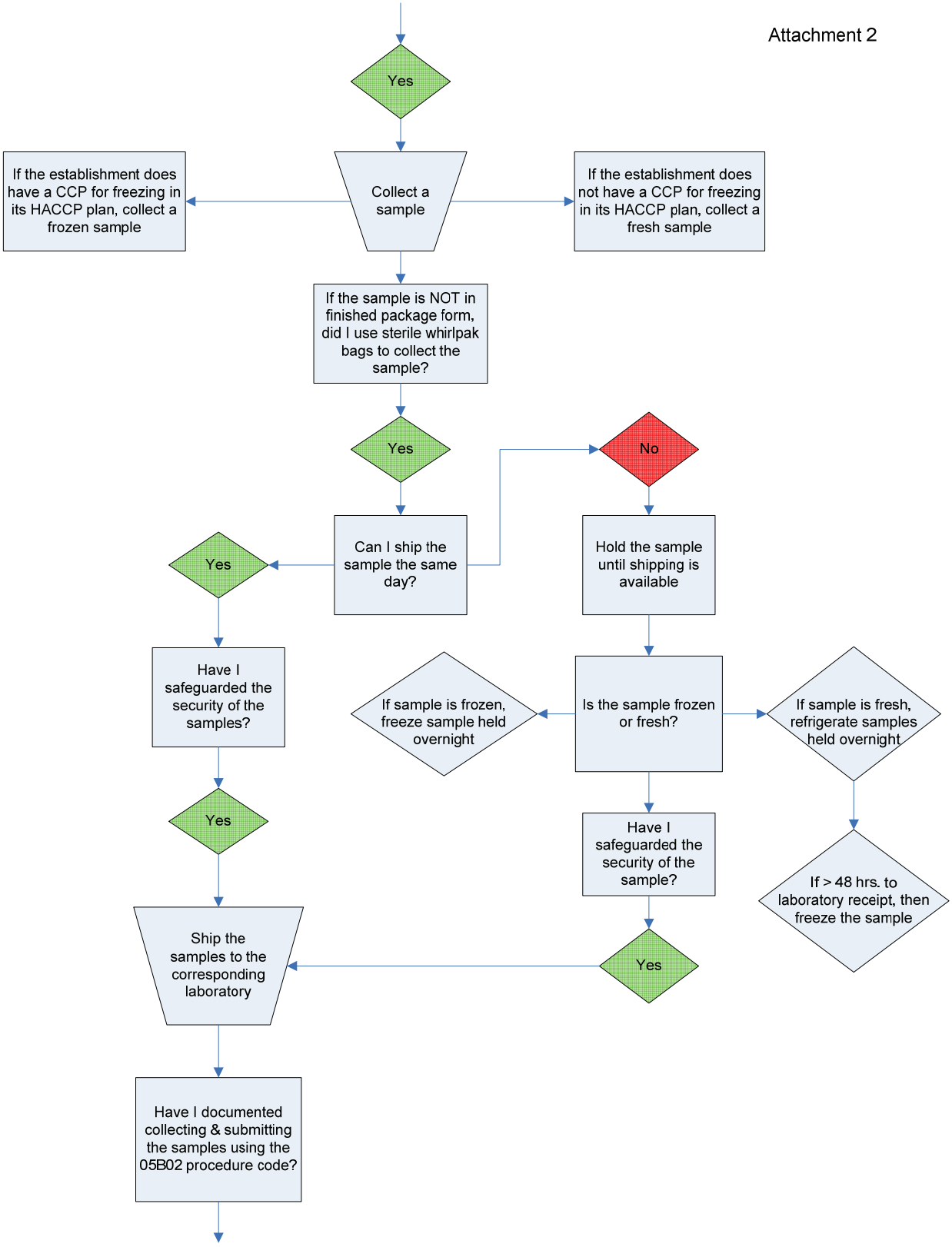
FSIS Sampling and Related Verification Activities – page 1

Attachment 2



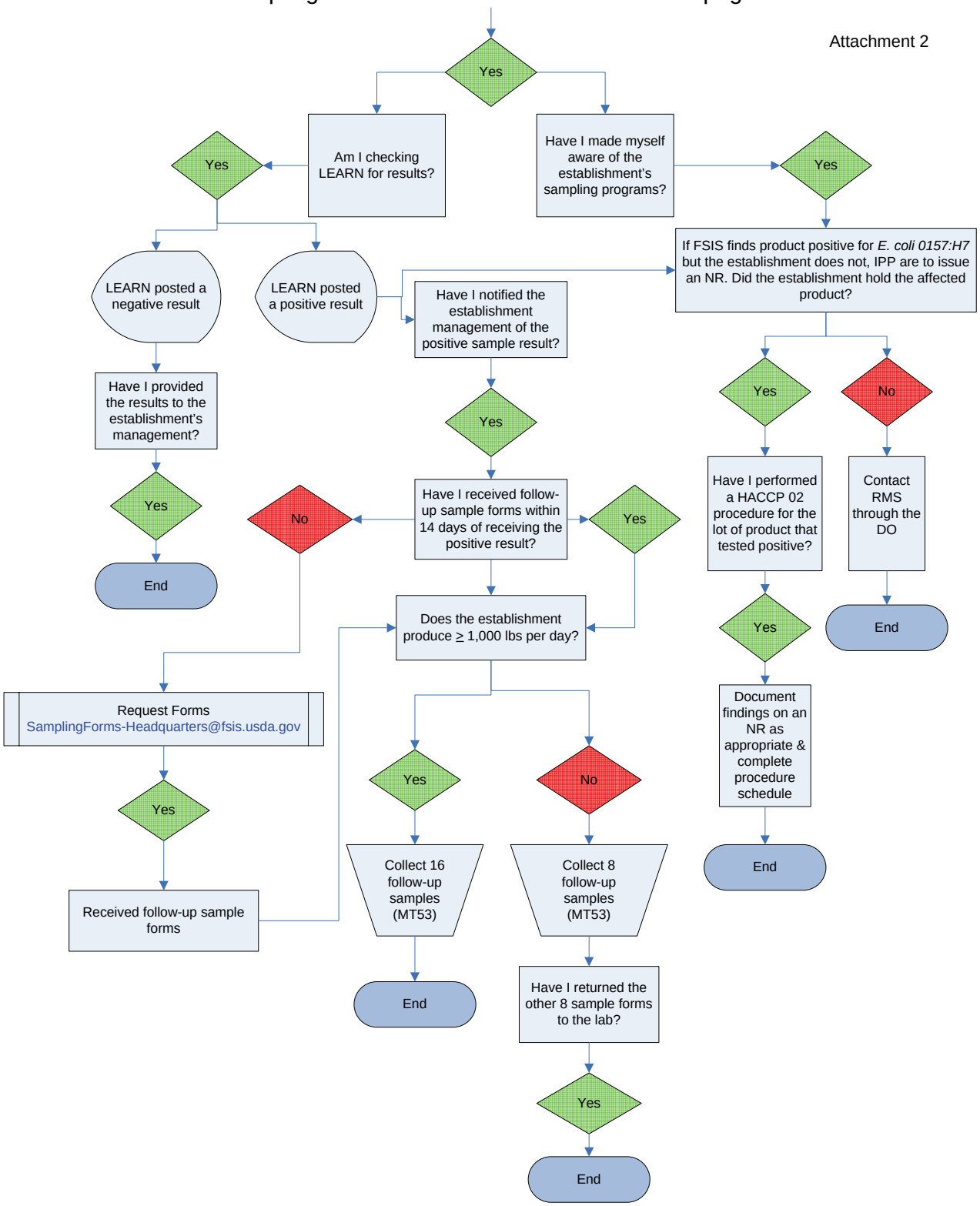
FSIS Sampling and Related Verification Activities – page 2

Attachment 2



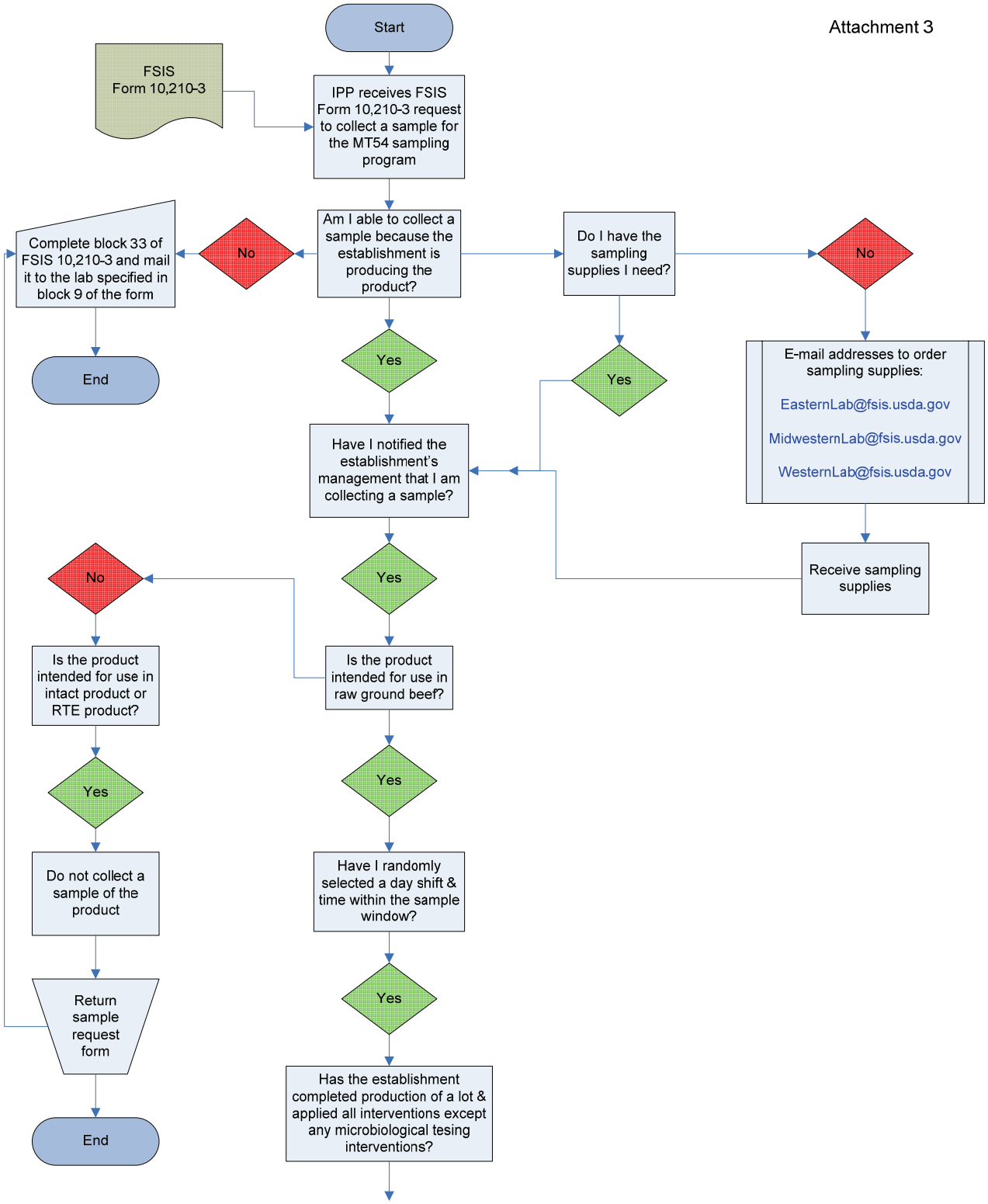
FSIS Sampling and Related Verification Activities – page 3

Attachment 2



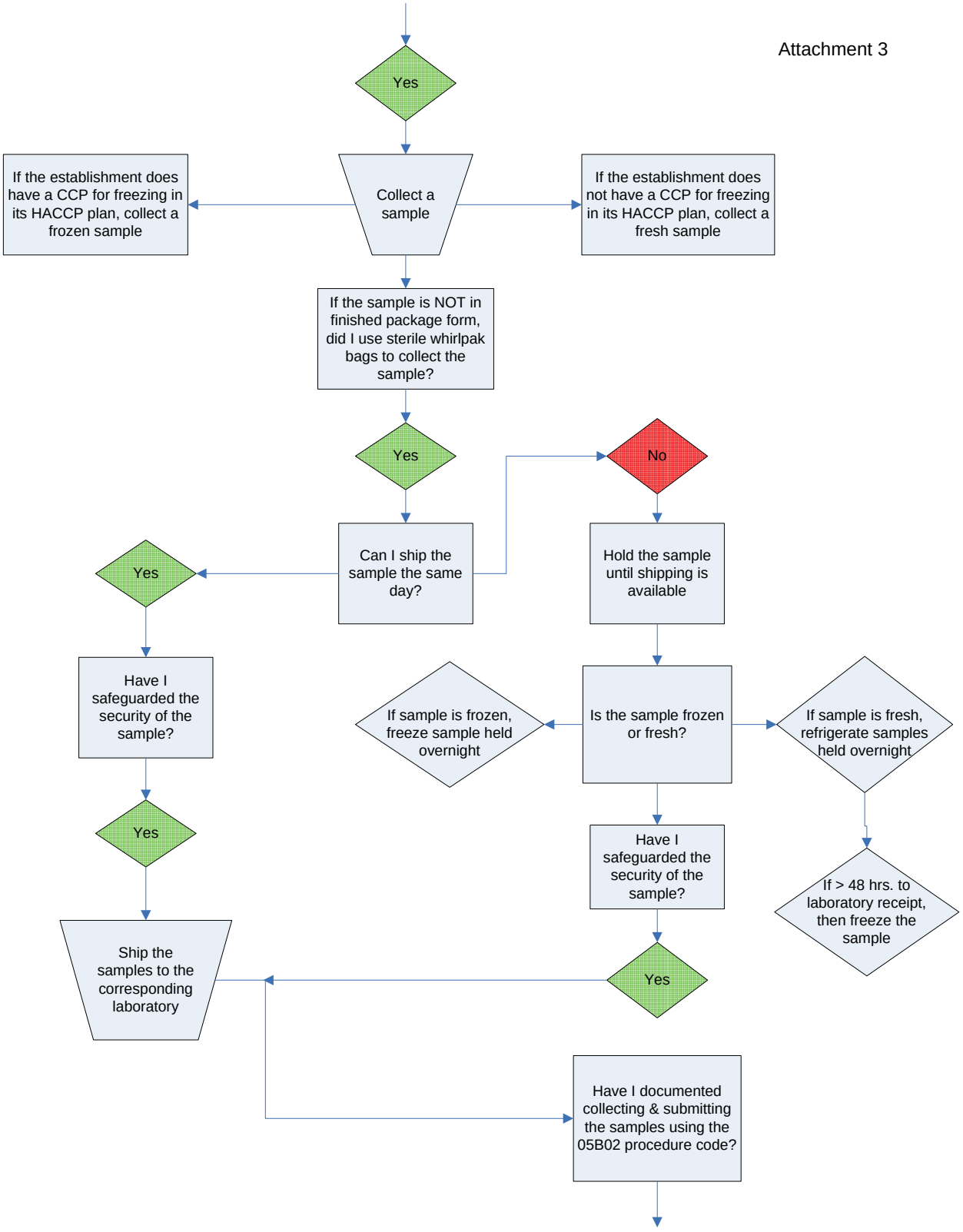
FSIS Sampling and Related Verification Activities – page 1

Attachment 3



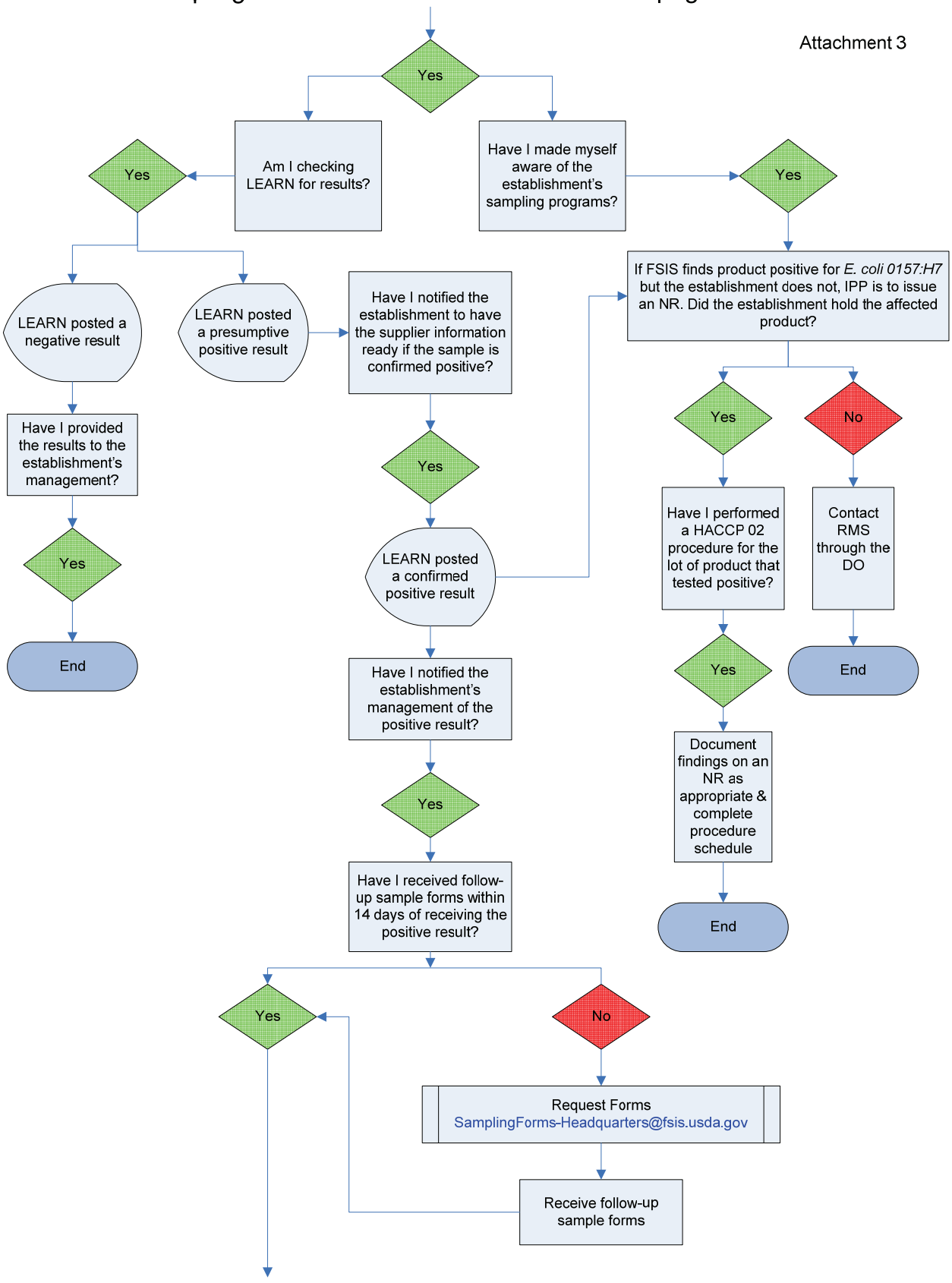
FSIS Sampling and Related Verification Activities – page 2

Attachment 3



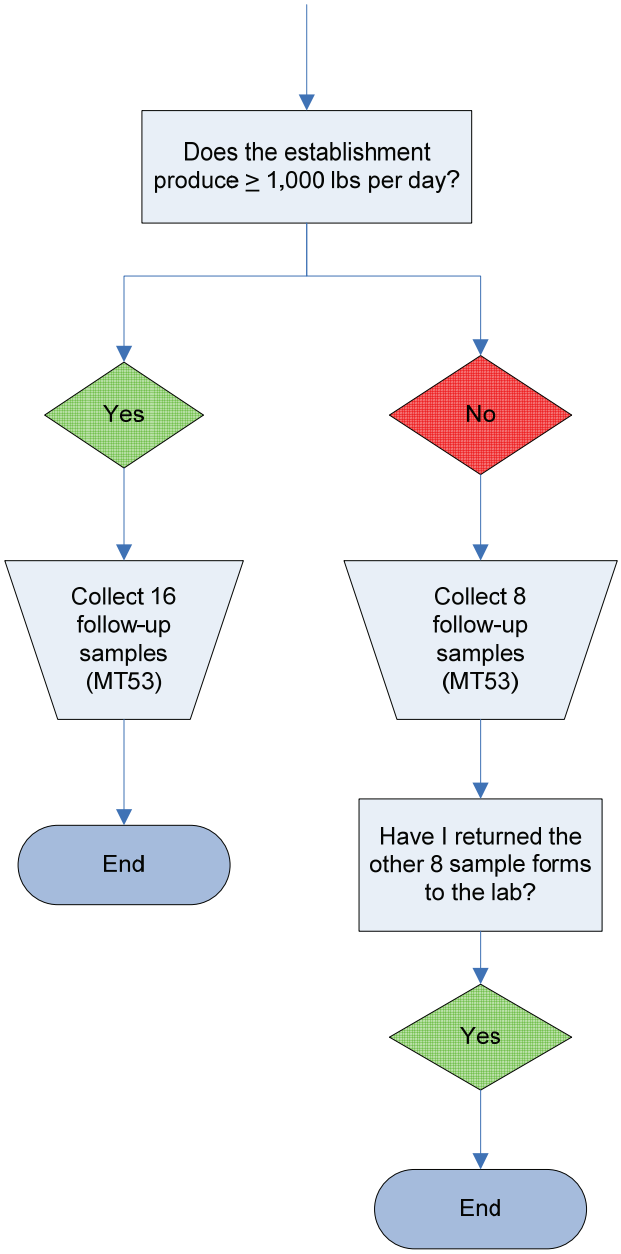
FSIS Sampling and Related Verification Activities – page 3

Attachment 3



FSIS Sampling and Related Verification Activities – page 4

Attachment 3



Offsite Product Disposition for *E. coli* O157:H7 Positive Product (Product Adulterated = Does Not Enter Commerce)

Attachment 4

Producing Establishment

Personnel

FSIS or Establishment Positive or Presumptive Positive *E. coli* O157:H7 Test Result
- Inspection Program Personnel (IPP) issue NRs if appropriate
- Begin the HACCP 02 procedure to verify the appropriate corrective actions under 9 CFR 417.3 (if pathogen addressed in HACCP system) & 416.15 (if pathogen addressed in Sanitation SOP).

If product disposition will occur off-site:

Does the establishment send product to a **renderer** or **landfill**?

NO

Does the establishment send product to a **warehouse**?

NO

Does the establishment send product to an **official establishment**?

YES

The producing establishment is responsible for ensuring that the product moves under appropriate controls. **Verify** that the producing establishment maintains control of product using controls (such as company seals) or that product moves under **FSIS control** (USDA seal or accompanied by FSIS Form 7350-1).

YES

Verify that the establishment moves product using **company controls** (such as company seals) and denatures the product before it leaves the establishment.

Complete the HACCP 02 procedure

Verify that by the time the establishment completes preshipment review, the product has received appropriate disposition at the receiving location, either by being treated in a way that renders it no longer adulterated (by being cooked or irradiated) or being rendered or placed in a landfill. If product disposition is delayed, contact the FLS to determine how to work with the establishment to ensure proper and timely disposal of the product.

If the establishment did not maintain control or maintain necessary records, contact the DO. The DO will determine whether the establishment committed the prohibited act of selling or transporting adulterated product.

Receiving Establishment

Verification at the Official Establishment Receiving Positive Product

Receiving

Periodically, when performing a HACCP 01 or 02 Procedure, verify that the receiving establishment:

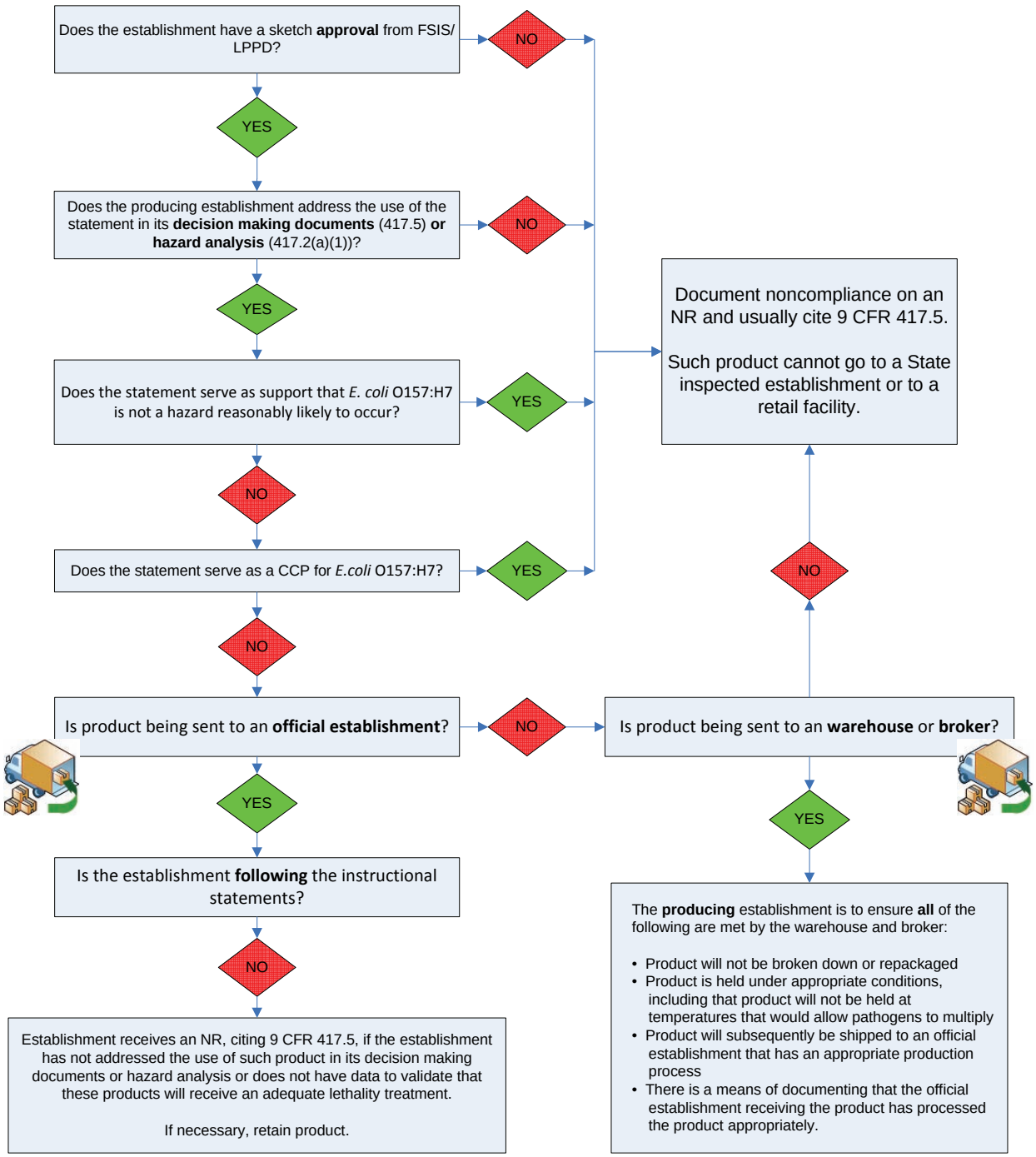
- Documents receipt under seal of presumptive positive products, as required under 9 CFR 417.5.
- Maintains control of product
- Addresses *E. coli* O157:H7 in its hazard analysis and HACCP plan
- Implements an adequate lethality treatment to the product

If non-compliant, document noncompliance and take regulatory control action if necessary.

Instructional Statements
(Product Not Adulterated = Enters Commerce)

Instructional Statement: Addresses how an establishment should prepare or handle product to ensure the pathogen is eliminated or reduced to acceptable levels:

Examples: ***"For Cooking Only," "For Full Lethality Treatment"***

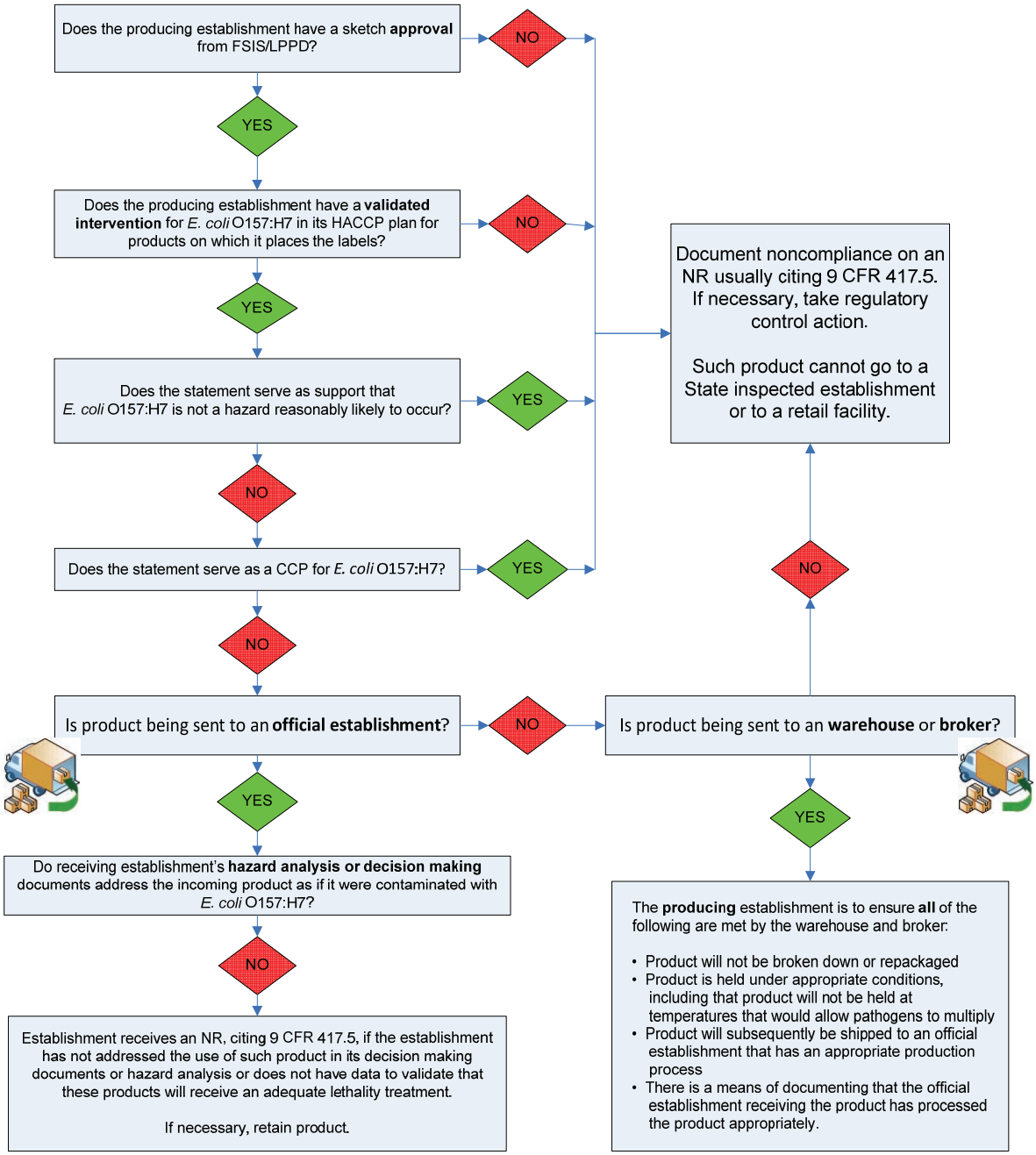


Disclaimer Statements
(Product Not Adulterated = Enters Commerce)

Attachment 6

Disclaimer Statement: Addresses the types of verification activities the the establishment did **NOT** perform.

Examples: ***"Product has not been tested for E. coli* O157:H7"**



LABORATORY SAMPLING

Sampling Program for *E. coli* O157:H7 In Imported Raw Ground or Veal Products; Imported Raw Ground Beef or Veal Components; and Imported Beef or Veal Patty Components (Project MT08/MT 51)

Frozen Beef Trimmings Sampling – n12

n12 sampling sites for top face of a single block