

Microbiological Testing Program and Other Verification Activities or *E. coli* O157:H7 in Raw Ground Beef Products, Raw Ground Beef Components and Beef Patty Components

All plants that produce raw ground beef products, raw ground beef components, and beef patty components may be subject to FSIS sampling and testing for *E. coli* O157:H7. FSIS will implement this Directive beginning May 17, 2004.

Previous Provisions	Provisions as of May 17, 2004
<p>Products covered</p> <ul style="list-style-type: none"> • Raw ground beef products <p>Products <u>not</u> covered</p> <ul style="list-style-type: none"> • Raw ground beef components • Raw beef patty components • Products that contain another type of livestock or poultry (although previous version of Directive did not specify “poultry”) species in addition to beef. 	<p>Products covered</p> <ul style="list-style-type: none"> • Raw ground beef products • Raw ground beef components • Raw beef patty components <p>Products <u>not</u> covered</p> <ul style="list-style-type: none"> • Products that contain another type of livestock or poultry species in addition to beef • Beef sausage products
<p>Reasons for 1998 issuance</p> <p>FSIS began its microbiological testing program for <i>E. coli</i> O157:H7 on October 17, 1994. A 1998 Directive and various notices issued since have changed and refined the program.</p>	<p>Reasons for issuance</p> <p>The revised Directive makes sampling more risk-based than in the past. It provides new instructions for FSIS inspection program personnel on:</p> <ul style="list-style-type: none"> • FSIS’ <i>E. coli</i> O157:H7 policies, • Verifying control of presumptive and positive beef product, and • Follow-up actions after a positive.

In - Plant Sampling	
Previous Provisions	Provisions as of May 17, 2004
<p>FSIS collection of product samples for <i>E. coli</i> O157:H7 testing from plants</p> <ul style="list-style-type: none"> • Only raw ground beef products were sampled for <i>E. coli</i> O157:H7. • Office of Public Health Science (OPHS) scheduled sampling. • FSIS Notices dated November 20, 2002, and April 18, 2003, updated procedures for inspection program personnel. They were instructed to: <ul style="list-style-type: none"> – Collect a raw ground beef sample <u>whenever</u> they received the sample request form (<u>no exceptions</u>). – Notify plant management and allow enough time for the plant to hold the sampled lot. – Tell plant management the reason for collecting the sample. – Collect samples from the current day's production, in their final packages whenever possible. – Refrigerate sample if it must be held overnight. – Freeze sample if it must be held longer than overnight. 	<p>FSIS collection of product samples for <i>E. coli</i> O157:H7 testing from plants</p> <ul style="list-style-type: none"> • Raw ground beef products, raw ground beef components, and raw beef patty components may be sampled. (This is a major change; in the past, only raw ground beef products were sampled for <i>E. coli</i> O157:H7.) <p>The following steps represent no change in policy:</p> <ul style="list-style-type: none"> • Office of Public Health Science (OPHS) schedules sampling. • Inspection program personnel: <ul style="list-style-type: none"> – Notify plant management and allow enough time for the plant to hold the sampled lot. – Tell plant management the reason for collecting the sample. – Collect samples from the current day's production, in their final packages whenever possible, or an aseptic sample (not a policy change, just a clarification).

In - Plant Sampling	
Previous Provisions	Provisions as of May 17, 2004
<p>— After the plant completes the reshipment of record review, send the sample(s) to the laboratory on the first available Federal Express pick-up.</p> <p>Between February 1, 1998, and the April 18, 2003 Directive, FSIS inspection personnel normally <u>did not</u> collect samples at plants which implemented one of following measures (these exceptions have been rescinded):</p> <ol style="list-style-type: none"> 1. Conducted routine daily <i>E. coli</i> O157:H7 testing of their raw ground beef products or boneless beef to be used in raw ground products. 2. Required suppliers of boneless beef to certify that each lot received had been tested and found negative for <i>E. coli</i> O157:H7. 3. Used validated pathogen reduction interventions on beef carcasses, routinely verified the interventions' effectiveness through testing for <i>E. coli</i> O157:H7, and prevented the use of boneless beef or carcasses from outside sources. 	<p>— Refrigerate sample if it must be held overnight.</p> <p>— Freeze sample if it must be held longer than overnight.</p> <p>— Keep the sample under FSIS security until it is shipped.</p> <p>— After the plant completes the preshipment record review, send the sample(s) to the laboratory on the first available Federal Express pick-up.</p>

In - Plant Sampling	
Previous Provisions	Provisions as of May 17, 2004
<p>However, even if the establishment implemented one of the measures above, FSIS would collect a sample if OPHS directed sampling or if the plant had a positive <i>E. coli</i> O157:H7 test result within the past six months.</p> <p>FSIS inspection program personnel verified, through record reviews, that plants had implemented one or more of the three options listed above and had a testing protocol on file, testing records to document results, or certificates. They also observed the pathogen reduction interventions and reviewed related records.</p>	

Enforcement	
Previous Provisions	Provisions as of May 17, 2004
<p>Definition of positive</p> <p>Directive included only the definition for “positive sample.”</p>	<p>Definitions of positive</p> <ul style="list-style-type: none"> • “Presumptive positive” – when the microbiological analysis indicates the strong possibility that <i>E. coli</i> O157:H7 is present but additional steps are needed to confirm results. • “Confirmed positive” or “positive” – a sample is confirmed to contain the bacterial isolate of <i>E. coli</i> O157:H7 when biochemical, serological, or genetic testing results in a finding of <i>E. coli</i> Serotype O157:H7, O157:H7:NM (nonmotile), or O157:H7-indeterminate.
	<p>Presumptive positive</p> <p>Since most presumptive positives become confirmed positives, FSIS:</p> <ul style="list-style-type: none"> • Informs the plant that the sample was found to be presumptive positive. • Informs plant that it should begin to gather supplier information, whether the source is domestic or foreign.
	<p>District Office (DO) notified</p> <ul style="list-style-type: none"> • DO is notified of a positive through the FSIS Biological Information Transfer and E-Mail System (BITES).

Enforcement	
Previous Provisions	Provisions as of May 17, 2004
<p>FSIS enforcement action after a confirmed positive in response to FSIS sampling</p> <p>Very similar to the current requirements. However, requirements for verifying corrective actions, including proper disposition of positive product have been added to the revised Directive.</p>	<p>FSIS enforcement actions after a confirmed positive in response to FSIS sampling (not plant testing)</p> <ul style="list-style-type: none"> • District Office (DO) contact is notified. • DO contact puts information in the electronic System Tracking <i>E. coli</i> O157:H7 – Positive Suppliers (STEPS). • DO and/or Recall Management Staff (RMS) determine need for retention, detention, or recall. <p>Inspection program personnel:</p> <ul style="list-style-type: none"> • Because of the positive, automatically issue a Noncompliance Record (NR) using the “verification” trend indicator. • As soon as possible after the plant implements corrective action, perform a HACCP 02 procedure for the specific production that tested positive. • Verify corrective action. • Verify proper disposition of positive product. • Note: FSIS no longer requires adulterated product to move under FSIS control. FSIS is modifying the regulations to reflect this policy change. <ul style="list-style-type: none"> – Plant must maintain control of positive product if it is in transit to another establishment or a landfill operation or renderer for disposition.

Enforcement	
Previous Provisions	Provisions as of May 17, 2004
	<ul style="list-style-type: none"> – Plant must maintain records of proper disposition. – If plant does not maintain proper control of adulterated product while it is in transit or does not have records indicating that the product received proper disposition, FSIS investigates to determine if the plant sold or transported adulterated product that had not been inspected and passed. • Follow specific procedures to notify the DO that adulterated product is being transported.
<p>Follow-up sampling in response to an FSIS confirmed positive sample</p> <ul style="list-style-type: none"> • The February 1, 1998, Directive required inspection program personnel to collect subsequent samples from new lots daily until 15 consecutive ground beef samples tested negative for <i>E. coli</i> O157:H7. <p>The April 18, 2003 Directive eliminated the 15 follow-up samples and provided flexibility for FSIS to determine the appropriate number of follow-up samples.</p>	<p>Follow-up sampling in response to an FSIS confirmed positive sample</p> <ul style="list-style-type: none"> • If inspection program personnel identify no significant problems through the HACCP 02 procedure, they collect one follow-up verification sample, as soon as possible after the plant takes corrective action. • If inspection program personnel identify noncompliance during the HACCP 02 procedure, they: <ul style="list-style-type: none"> – Issue an NR and collect one follow-up sample, as soon as possible after the plant takes corrective action. – Contact the DO if positive product

<p style="text-align: center;">Enforcement</p>	
<p style="text-align: center;">Previous Provisions</p>	<p style="text-align: center;">Provisions as of May 17, 2004</p>
	<p>moved without controls or if the plant does not have records showing appropriate disposition.</p> <ul style="list-style-type: none"> • If disposition of the positive product will be delayed: <ul style="list-style-type: none"> – Inspection program personnel work with their front-line supervisor to determine when to collect the sample and how to work with plant to ensure proper and timely disposal of the product. • If inspection program personnel have concerns about whether the design of the plant’s HACCP system is adequate to ensure food safety, they: <ul style="list-style-type: none"> – Do not collect a sample, – Notify their front-line supervisor. <p>DO may bring in an Enforcement Investigations and Analysis Officer (EIAO) to conduct a comprehensive assessment of the plant’s food safety systems.</p> <ul style="list-style-type: none"> – Take a follow-up verification sample if the EIAO determines that the plant’s corrective actions are appropriate and effective. • If a follow-up sample is found positive, The DO determines follow-up action. • If the EIAO determines that the corrective actions are inappropriate or ineffective, the EIAO

Enforcement	
Previous Provisions	Provisions as of May 17, 2004
	<p>recommends an enforcement action, for example:</p> <ul style="list-style-type: none"> – Notice of Intended Enforcement (NOIE), – Withholding, or – Suspension. <ul style="list-style-type: none"> • If the DO decides to either defer a decision on suspending the plant or a suspension action is taken and then put into abeyance: <ul style="list-style-type: none"> – FSIS will conduct follow-up sampling to verify that the corrective action is appropriate and effective. – DO will determine the number of follow-up samples to be taken, based on guidance that provides enhanced statistical confidence for finding low levels of <i>E. coli</i> O157:H7 but is not designed to provide validation of the plant's food safety system.
Plants which Produce Raw Ground Beef Components and Raw Ground Patty Components	
Previous Provisions	Provisions as of May 17, 2004

Raw ground beef components and raw beef patty components	FSIS verification activities in plants producing raw ground beef components or raw beef patty components
<p>These products were not sampled.</p>	<ul style="list-style-type: none">• If a plant supplies the components used to produce raw ground beef that tests positive at a second plant or retail facility, FSIS inspection program personnel:<ul style="list-style-type: none">– Conduct a HACCP 02 procedure at the <u>supplying plant</u>.– May test raw ground beef components and raw beef patty components at the <u>supplying plant</u>.<ul style="list-style-type: none">◆ Inspection program personnel are instructed to collect only samples from components intended for use in raw, non-intact product, but if the intended use is unclear, they handle the product as though it were intended for use in raw non-intact product.• If raw ground beef product tests positive at the same plant which produced the raw ground beef components, FSIS inspection program personnel:<ul style="list-style-type: none">– Conduct a HACCP 02 procedure for the source materials used in the ground product. The HACCP 02 may be initiated from the slaughter process through the grinding operation.

Plants which Produce Raw Ground Beef Components and Raw Ground Patty Components	
Previous Provisions	Provisions as of May 17, 2004
	– FSIS may sample and test the raw ground beef components at the plant.

Plant Testing for <i>E. coli</i> O157:H7	
Previous Provisions	Provisions as of May 17, 2004
<p>While some plants tested their products, the FSIS Directive did not address FSIS enforcement actions related to establishment testing.</p>	<ul style="list-style-type: none">• Plants may have their product tested by non-FSIS labs.• Prior to conducting pre-shipment review, plants may analyze samples while the product is being moved but is still under their control.• FSIS has access to the results of any testing and monitoring activities that may have an impact on the establishment's hazard analysis.<ul style="list-style-type: none">– FSIS inspection program personnel review these results at least weekly.• A presumptive positive or positive result from plant testing alone does not warrant a Noncompliance Record (NR).<ul style="list-style-type: none">– An NR in response to a positive or presumptive positive result is only issued if the plant fails to take appropriate corrective actions, as required by FSIS regulations.– Inspection program personnel follow very specific procedures, listed in the Directive, for verifying plant control of product and product disposition.

When Plants Receive Raw Ground Beef Components and Raw Beef Patty Components that are Positive for <i>E. coli</i> O157:H7	
Previous Provisions	Provisions as of May 17, 2004
<ul style="list-style-type: none">The previous directive and notices did not address establishments receiving raw ground beef products, raw ground beef components and raw beef patty components that are positive for <i>E. coli</i> O157:H7.	<ul style="list-style-type: none">When FSIS inspection program personnel in such a plant conduct a HACCP 01 or 02 procedure, they verify that the plant:<ol style="list-style-type: none">1. Documents the receipt of presumptive positive or positive product;2. Maintains control of the product; and3. Has addressed <i>E. coli</i> O157:H7 in its hazard analysis and HACCP plan.FSIS takes appropriate action if it finds noncompliance. (FSIS Directive 5000.1, Chapter IV).

<p align="center">Instructional or Disclaimer Statements</p>	
<p align="center">Previous Provisions</p>	<p align="center">Provisions as of May 17, 2004</p>
<p>The FSIS directive and notices did not address instructional or disclaimer statements concerning <i>E. coli</i> O157:H7 for raw ground beef products, raw ground beef components, or raw beef patty components.</p>	<p>An instructional statement concerning <i>E. coli</i> O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples:</p> <ul style="list-style-type: none"> –“for full lethality treatment” –“for cooking only” <ul style="list-style-type: none"> • Instructional statements can only be used on products that go to another plant where they receive adequate lethality treatment • They must be approved by the FSIS Labeling and Consumer Protection Staff (LCPS). <p>A disclaimer statement concerning <i>E. coli</i> O157:H7 is a statement regarding the type of verification activities that were <u>not</u> used in producing the product. An example is:</p> <ul style="list-style-type: none"> –“product has not been tested for <i>E. coli</i> O157:H7” <ul style="list-style-type: none"> • They must be approved by the FSIS Labeling and Consumer Protection Staff (LCPS). • Products with disclaimer statements can only go to a plant that addresses <i>E. coli</i> O157:H7 in its HACCP plan. <p>The Directive has very specific verification procedures that inspection program personnel are to conduct at</p>

Instructional or Disclaimer Statements	
Previous Provisions	Provisions as of May 17, 2004
	plants that place these labels on products and at plants which receive products bearing these labels.

Retail Sampling for <i>E. coli</i> O157:H7	
Previous Provisions	Provisions as of May 17, 2004
<ul style="list-style-type: none"> • Compliance Officers randomly selected the stores to sample and collected samples. (FSIS has converted most of its Compliance Officer positions to other titles, including Program Investigators or Enforcement Investigations and Analysis Officers (EIAOs.) • Between the February 1, 1998 Directive and the April 18, 2003 Directive, after a positive, Compliance Officers collected samples daily until 15 consecutive samples had tested negative. 	<p>The revised Directive makes retail sampling more risk-based than in the past.</p> <ul style="list-style-type: none"> • OPHS schedules sampling. <p>Program Investigators:</p> <ul style="list-style-type: none"> • Attempt to notify the retail store the day before they plan to collect raw ground beef samples so the retailer can hold the lot. • If notification the day before sampling is not possible, they arrive as close to the beginning of the grinding operation as possible. • Collect sample. • Record information on the source material. • <u>They do not:</u> <ul style="list-style-type: none"> – Collect raw ground beef product that is received and sold as case-ready or is only repackaged by the retail store. – Collect product that has been ground at retail if the facility only regrinds a product previously ground at an inspected plant, <u>unless</u> the retail store conducts a practice that might introduce the pathogen into the product (such as adding store trim). <p>If there is a positive:</p> <ul style="list-style-type: none"> • Program Investigator notifies retail store.

Retail Sampling for <i>E. coli</i> O157:H7	
Previous Provisions	Provisions as of May 17, 2004
	<ul style="list-style-type: none">• FSIS determines the necessity of:<ul style="list-style-type: none">– Product retention,– Detention, or– Recall.• Follow-up sampling:<ul style="list-style-type: none">– FSIS will collect one follow-up sample.– When feasible, FSIS will schedule verification activities, including testing, at the supplying establishment.

<p style="text-align: center;">Import Sampling for <i>E. coli</i> O157:H7</p>	
<p style="text-align: center;">Previous Provisions</p>	<p style="text-align: center;">Provisions as of May 17, 2004</p>
<p>The process for sampling imports has not changed significantly.</p>	<p>Sample collection from import establishments <u>has not changed</u></p> <ul style="list-style-type: none"> • Import inspector receives assignment from AIIS to collect sample. • Import inspector notifies the import establishment of the reason for sampling. <ul style="list-style-type: none"> – Importer, broker or applicant may elect to voluntarily hold the product until the results are reported. • Import inspector collects sample. <p>When a sample is confirmed positive – <u>has not changed</u></p> <ul style="list-style-type: none"> • FSIS verifies whether shipment is held at the import establishment or has entered commerce. • Import inspector sends form 9540-1 and the foreign health certificate to OIA/IID. • If the product is on hold at the import establishment, import inspector: <ul style="list-style-type: none"> – Notifies import establishment, which notifies importer of record. – Initiates refused entry procedures on the entire lot. • If the lot has moved into commerce: <ul style="list-style-type: none"> – FSIS initiates recall procedure. – FSIS notifies import establishment, which notifies importer of record.

Import Sampling for <i>E. coli</i> O157:H7	
Previous Provisions	Provisions as of May 17, 2004
	<ul style="list-style-type: none">• OIA notifies head of foreign inspection service of positive results and requests appropriate follow-up. <p>Sampling after a positive <u>has not changed</u></p> <ul style="list-style-type: none">• Intensified sampling for next 15 shipments from the foreign establishment.<ul style="list-style-type: none">– Shipment is placed on FSIS hold when sample is collected, until results are known.