

**COMPLIANCE GUIDELINES FOR ESTABLISHMENTS ON THE
FSIS MICROBIOLOGICAL TESTING PROGRAM AND OTHER
VERIFICATION ACTIVITIES FOR *ESCHERICHIA COLI* O157:H7**

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I. Risk-Based Verification Sampling

The revised [FSIS Directive 10,010.1](#), entitled ‘Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef and Beef Patty Components’ includes instructions to FSIS inspection personnel and other program investigators on sampling and other verification activities for *Escherichia coli* O157:H7 (*E. coli* O157:H7) in raw beef products. All official establishments producing raw ground beef products, raw ground beef components, or raw beef patty components may be sampled.

In 1994, FSIS declared all raw ground beef contaminated with *E. coli* O157:H7 to be adulterated unless it is further processed to destroy the pathogen. In the January 19, 1999 Notice (64 FR 2803), FSIS stated that intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, because pathogens may be introduced below the surface of these products when they are processed into non-intact products. Non-intact raw beef products are ground or chopped beef, or beef that has been injected with solutions, or mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees. Examples of non-intact raw beef products include beef that has proteolytic enzymes applied to or injected for tenderizing, beef that has been scored to incorporate a marinade, or formed and shaped products such as gyros. The following products are adulterated if contaminated with *E. coli* O157:H7 unless further processed to destroy the pathogen: 1) non-intact raw beef products and 2) intact raw beef products that are intended to be processed into non-intact products such as manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts are removed).

FSIS has been collecting samples of raw ground beef products from establishments for *E. coli* O157:H7 testing to verify establishment control of the pathogen. In the revised Directive 10,010.1, FSIS may also sample raw ground beef components and raw ground beef patty components, which are source materials for raw ground beef and other non-intact raw beef products. FSIS will collect raw ground beef products from grinding establishments, and may collect raw ground beef components and raw beef patty components from establishments that supplied source materials implicated in FSIS-collected raw ground samples that tested positive for *E. coli* O157:H7. Retail facilities and import establishments producing raw ground beef products will also be sampled by FSIS.

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

Raw beef patty components include all products listed above in raw ground beef components; as well as partially defatted chopped beef (PDCB); finely textured PDCB; heart; and partially defatted beef fatty tissue (PDBFT).

FSIS intends to develop a risk-based verification sampling program for raw ground beef products. Sampling is expected to be based on factors that may influence prevalence of and exposure to *E. coli* O157:H7, such as the volume of production of raw ground beef products, season of the year, and the number of suppliers for an establishment. The FSIS risk assessment on *E. coli* O157:H7 has determined that volume of production is a better determinant of the risk of *E. coli* O157:H7 than size of the establishment. It also determined that the prevalence of *E. coli* O157:H7 in cattle, and the incidence of foodborne illness and of products positive for *E. coli* O157:H7 are higher during the warmer months. Therefore, an establishment producing a large volume of ground beef products will likely be sampled more frequently than an establishment producing a lower volume of raw ground beef products. Likewise, FSIS will sample more frequently and with a higher number of samples during the high prevalence season. An establishment that has designed and implemented sampling plan and verification testing with a high degree of confidence of finding the pathogen in both the trim and finished ground product presents a lower risk of producing an adulterated product, and therefore will be sampled less frequently than other establishments. FSIS may also sample establishments that form ground beef patties but do not grind product.

Establishments should have already reassessed their HACCP plans to comply with the FSIS Notice (October 7, 2002) requiring establishments that had not already reassessed their HACCP plans for raw beef products to do so in order to determine whether *E. coli* O157:H7 contamination was reasonably likely to occur in their production process for raw beef products. The Notice also stated that establishments receiving product for grinding should address *E. coli* O157:H7. Establishments that slaughter, fabricate and grind could employ control methods in their food safety systems, i.e., HACCP plans Sanitation SOPs or prerequisite programs to address the pathogen. Some control methods that can be included are the following:

- Use of intervention treatments validated to control *E. coli* O157:H7
- Use of purchase specifications restricting source materials to those that have undergone validated intervention treatment
- Use of source materials that have been rigorously tested for *E. coli* O157:H7 to verify that process controls to produce source material were effective
- Use of less risky source material, such as use of beef manufacturing trimmings only
- Use of more rigorous sanitation program
- Verification testing that control programs are effective

These control methods are discussed in the “Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and *Salmonella* in Beef Slaughter Operations” and the “Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products- Guide for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products” found on the FSIS website:

www.fsis.usda.gov/OPPDE/rdad/FRPubs/docs_00-022N.htm Another guidance document that would be useful for slaughter, fabrication and grinding establishments is the BIFSCO Best Practices. Best Practices offer guidelines for processing and handling

of raw ground beef products as well as slaughter and fabrication safety measures. The document can be found at <http://www.bifsc.org/BestPractices.htm>

II. Sample Collection of Raw Ground Beef Products

FSIS will routinely collect samples of the following raw ground beef products:

- Raw ground beef products which include raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, beef patty mix, or raw ground beef product containing any amount of beef product derived from advanced meat recovery (AMR) systems.

FSIS will collect samples of the following raw beef products generally as a result of a supplier producing or shipping raw ground beef components that, once ground and made into ground beef, tested positive for *E. coli* O157:H7:

- Beef manufacturing trim, including raw product consisting only of beef from AMR systems
- Beef carcasses

FSIS will not be collecting samples of the following products:

- Ground or chopped products made from both beef and other meat or poultry products, such as a ground beef and pork product
- Beef sausage products

FSIS will be notifying establishment management before collecting samples in order to provide enough time for the establishment to hold the lot to be sampled. The establishment will also be informed of the reason for collecting samples. Establishments may be sampled for any of the following reasons:

- 1) routine FSIS verification testing;
- 2) follow-up sampling in response to an *E. coli* O157:H7 positive;
- 3) traceback sampling;
- 4) follow-up sampling in response to an *E. coli* O157:H7 outbreak of foodborne illness.

FSIS will typically be collecting one sample per lot. However, more than one sample could be collected if FSIS has a reason to believe that the product is at high risk of being contaminated with *E. coli* O157:H7 because of :

- illness or outbreaks that may have been associated with the establishment, or
- the establishment or its suppliers have previously produced product that tested positive in FSIS verification samples for *E. coli* O157:H7.

Samples for the current day's production will be collected in their final packaged form and will be shipped after the establishment has completed its pre-shipment review.

III. Sampled Lot

The establishment defines the sampled lot for raw ground beef products. The establishment should have a scientific or other supportable basis for defining the sampled lot. The establishment could consider factors, such as the following, in defining the sampled lot:

- the establishment's definition of a lot included in its *E. coli* O157:H7 sampling plan (if applicable);
- the establishment's history of setting lot size;
- product coding ;
- how products are intermingled or queued during processing and packaging;
- if the same equipment was used for all the products;
- process control performance including those for other pathogens;
- establishment HACCP plan monitoring and verification activities;
- sanitation SOP records; and
- types of raw beef components used.

Establishments that test for *E. coli* O157:H7 usually have a sampling plan. A sampling plan would include the definition of what the sample represents, i.e., the sampled lot, whether a single combo, 5 combos or an entire trailer load. It would also include the number of samples to be collected and whether testing is to be done in-plant or by an external laboratory. The sampling plan would include a written protocol for sample collection, procedures for microbial analysis and reporting results, and action to be taken in the event of a positive result.

FSIS will recognize the establishment's definition of the sampled lot, provided the establishment has a supportable basis for defining the sampled lot. However, FSIS cautions that the defined lot size does not relieve an establishment from its responsibility to consider whether there are connections between lots. Possible scenarios:

- If multiple lots of beef trim were produced from source materials from the same production lot of a single supplier, and some of this product were found positive for *E. coli* O157:H7, FSIS would expect the establishment to have a supportable basis that justifies why any other trim produced from those source materials should not be considered to be adulterated.
- A grinding establishment must have supporting documentation that a lot is not adulterated with *E. coli* O157:H7 if the lot comes from the same source material in which the other lots produced were found contaminated with *E. coli* O157:H7.
- If the establishment mixes raw materials from different suppliers and one supplier's raw material was found positive for *E. coli* O157:H7, FSIS would expect the establishment to have a supportable basis that justifies why any product from these source materials should not be considered to be adulterated.

It should be noted that if an establishment has a validated control system and verifies throughout each shift by sampling and testing, that specific lots of product are negative for *E. coli* O157:H7, this information could possibly be a basis for determining that one *E. coli* O157:H7-positive lot does not implicate other lots produced on the same day.

In situations where recall, detention or seizure is necessary, more product than the product from clean-up to clean-up under the HACCP plan may be represented by the sample. More product than the establishment's definition of a sampled lot, or all products produced from the same source materials may be determined as representing the sample. An establishment's detailed production records will help the establishment in establishing the product that is represented by the sample. Records that are useful in tracebacks (i.e., tracing back the source of contamination) would include grinding logs showing the times of each grind, the formulation or blend of raw ingredients together with amounts used, and supplier lot identification numbers and results of any tests conducted on the raw materials or finished products. The "Product Recall Guidelines for Firms", which is an attachment for FSIS Directive 8080.1 includes some examples of how records will help in defining the lots that are affected by a sample testing positive for *E. coli* O157:H7. This document will be posted on the FSIS web site.

It is recommended that the establishment consider staging the production of raw ground beef in a manner such that this product is handled prior to the production of raw beef product in which the equipment or source materials not specifically controlled to prevent, eliminate, or reduce the level or presence of *E. coli* O157:H7 are handled. This process would involve handling the least risky product prior to the more risky product. Below is a list of products believed to be ranked from the least risky product to the more risky product:

- 1) Source materials that have undergone intervention treatments during slaughter and fabrication that are validated to eliminate or reduce *E. coli* O157:H7 to non-detectable level, and statistically-based verification testing of the lot resulted in a negative test for the pathogen.
- 2) Source materials that have undergone validated intervention treatments, but not verified as testing negative for *E. coli* O157:H7.
- 3) Source materials that were verified as testing negative for *E. coli* O157:H7 but have not undergone validated intervention treatments.
- 4) Source materials that have not undergone validated intervention treatments, nor verification testing for *E. coli* O157:H7.

For any of the four categories of source materials mentioned above, the different kinds of source materials could also be queued from lowest to the highest risk product in the following order:

- a) Source materials that are intact products intended for non-intact product
- b) Source materials that are from only one supplier source
- c) Source materials that include AMR products, raw esophagus (weasand) meat, head meat, cheek meat, and diaphragm (skirt) meat, lean finely textured beef (LFTB), partially defatted chopped beef finely textured (PDCBFT) or partially defatted beef fatty tissue (PDBFT).
- d) Rework products

IV. FSIS-Collected Sample That Tests Positive for *E. coli* O157:H7

FSIS laboratories will screen samples for the presence of *E. coli* O157:H7 and confirm any presumptive positive samples. The Agency notifies the establishment if a sample collected by FSIS is presumptive positive or confirmed positive for *E. coli* O157:H7.

A test is considered presumptive positive when analytical steps of microbiological analysis indicate the strong possibility that *E. coli* O157:H7 is present, but additional steps are needed to confirm the presence or absence of the organism. Rapid screening methods can be used to detect the pathogen as presumptive positive, but additional steps are needed to confirm its presence or absence.

The test is confirmed positive when biochemical, serological and /or genetic testing result in a finding of *E. coli* Serotype O157:H7, O157:H7:NM (non-motile), or O157:H7-indeterminate. A sample is confirmed to contain the bacterial isolate of *E. coli* O157:H7 through testing conducted by either FSIS or non-FSIS laboratories.

Establishments should have information on the suppliers of source materials because this information will be needed if a sample tests positive for *E. coli* O157:H7. The information provided by the establishment will help in tracing the source of contamination.

FSIS will be asking for the following information:

- 1) Name and phone number of the supplying establishment and point of contact (name, title, e-mail address and fax number)
- 2) Supplier lot number
- 3) Production date

If the source materials for the for the sampled raw ground beef products are from a foreign establishment, the following information will be needed:

- 1) Country of origin
- 2) Foreign establishment number
- 3) Shipping mark
- 4) Import house
- 5) Barcodes or any other information that identifies the origin of the product

When a sample collected by FSIS is found positive for *E. coli* O157:H7 the sampled lot is adulterated. The establishment should have records on file to determine the lots implicated by the positive sample. FSIS will determine if the affected product lots will be retained, detained or recalled.

Establishments should take the following actions if a sample collected by FSIS tests positive for *E. coli* O157:H7:

- 1) An establishment must ensure proper disposition of affected products. All affected product lots must be further processed to destroy the pathogen (e.g.

cooking, irradiation), or the product could be destroyed. This could be done on-site or at another inspected establishment, renderer, or landfill. Disposition of the product must be documented (Procedures for documenting transfer and disposition of positive products are discussed in Section VII).

- 2) An establishment that has one or more validated CCPs for *E. coli* O157:H7 should take corrective actions in accordance with 9 CFR 417.3 (a).
- 3) An establishment that does not have one or more validated CCPs for *E. coli* O157:H7 should take corrective actions according to 9 CFR 417.3 (b).
- 4) An establishment that has purchase specifications addressing *E. coli* O157:H7 in their prerequisite programs and do not address *E. coli* O157:H7 in its HACCP plan should take corrective actions according to 9 CFR 417.3 (b) and, if the establishment addresses *E. coli* O157:H7 in its Sanitation SOP, 9 CFR 416.15.

V. Establishment Testing of Product for *E. coli* O157:H7

Some establishments test their finished products for *E. coli* O157:H7 to verify that their control methods are effective and that their products are not adulterated. Establishments testing their finished products should use FSIS testing methods, or methods that are equal to or better in sensitivity. FSIS testing methods can be found on the FSIS website:

www.fsis.usda.gov/OPHS/microlab/mlgbook.htm

Following are the criteria for a testing method to be considered or accepted as equivalent to the FSIS method:

- The sample test portion (analytical unit) must equal at least 325 grams, analyzed as individual sub-samples having a maximum weight of 75 grams.
- Evidence must be provided that demonstrates the method is equal to or greater in sensitivity than the current FSIS method.

[Notes: (a) The current FSIS *E. coli* O157:H7 method employs an immunomagnetic separation (IMS)-based technique for cultural confirmation of screen-positive test results which has significantly increased the sensitivity of the method. (b) In lieu of cultural confirmation methods, reliance on positive results from screen tests approved by AOAC International or other internationally recognized scientific organizations could be deemed equivalent to the FSIS method.]

When an establishment tests its own finished product for *E. coli* O157:H7 for verification purposes, pre-shipment review will not fulfill its purpose unless the results of the tests are known. However, while the establishment is awaiting test results, it may move product to different locations. In this case, FSIS is providing establishments the flexibility to move product prior to conducting pre-shipment review as long as the establishment maintains control of the product. The establishment has to maintain control of the product, so that in case the samples test positive for *E. coli* O157:H7, the establishment can conduct procedures for proper disposition of the product.

This allows an establishment to conduct pre-shipment review even if the product is at a location or at locations other than the producing establishment, provided the producing

establishment maintains control of the product. FSIS should have access to results of any testing and any monitoring activities performed by the establishment which may have an impact on the hazard analysis. If the establishment moves product before test results become available and the lot tests presumptive positive or positive, the establishment should complete pre-shipment review only after it has records showing that the product received proper disposition.

When establishment testing finds the product to be positive for *E. coli* O157:H7, the sampled lot is considered adulterated. If the product is found presumptive positive and the establishment does not test to confirm the presence or absence of the pathogen, the sampled lot is not eligible to bear the mark of inspection. Thus, the establishment must take corrective actions and ensure appropriate disposition of the product. The establishment may further process the product from the sampled lot on-site or transport the product to another official establishment or to renderers or landfills for further processing to destroy the pathogen or for destruction. FSIS will review the records associated with the testing conducted by the establishment or FSIS and verify if the establishment implemented corrective actions and ensured proper disposition of the positive products.

VI. Transfer of Products That Test Presumptive Positive or Positive for *E. coli* O157:H7

A. Producing or Shipping Establishments

Establishments should provide for the disposition of products that tested presumptive positive or positive for *E. coli* O157:H7. As mentioned above, establishments may further process the product from the sampled lot on-site or transport the product to another official establishment for further processing to destroy the pathogen, or establishments may move such product to a renderer or landfill. Any movement of products that tested presumptive positive or positive for *E. coli* O157:H7 should be under documented company control (such as company seals) to safeguard the products. If such product is going to another official establishment, it may also move under FSIS control (e.g., under USDA seal or accompanied by FSIS form 7350-1).

Establishments that produced products that are presumptive positive or positive should obtain documentation evidencing proper disposition from the official establishment, renderer, or landfill where disposition will occur.

A producing establishment that transports presumptive positive or positive product or product for which results are pending should maintain the following:

- 1) Records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;
- 2) Records identifying the official establishment that is to receive the product for which results are pending;
- 3) Control of product destined for a landfill operation or renderer while the product is in transit (e.g., through company seals);

- 4) Control of product destined for an official establishment while the product is in transit (e.g., through company seals) or ensures the product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS form 7350-1);
- 5) Records showing that the presumptive positive or positive product, including product that was moved pending test results, received proper disposition, including documentation from the official establishment, renderer or landfill operation where disposition occurred, showing that the product received proper disposition.

The producing establishment should complete pre-shipment review (of corrective action records) for product from a lot that tested presumptive positive or positive only after it has the records described in paragraph #5 above for that particular product.

B. Receiving Establishments

An establishment receiving *E. coli* O157:H7 presumptive positive or positive product for further processing should document the following:

- 1) Receipt of the presumptive positive or positive product;
- 2) That the receiving establishment maintains control of the product;
- 3) *E. coli* O157:H7 is addressed in the establishment's hazard analysis and HACCP plan.

Presumptive positive or positive products can be further processed to destroy the pathogen by lethality treatments, e.g. cooking, irradiating. FSIS will verify these processes and the resulting documentation. The documentation of the lethality treatment should be sent to the producing establishment.

A receiving establishment that is producing ready-to-eat and irradiated products and also not ready-to eat products and not irradiated products should segregate product from a sampled lot that is presumptive positive or positive for *E. coli* O157:H7 from those that are not to be further processed to destroy the pathogen.

VII. Use of Instructional or Disclaimer Statements Concerning *E. coli* O157:H7

An instructional statement concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples of instructional statements concerning *E. coli* O157:H7 in raw ground beef components, raw beef patty components, and ground beef products may include, “for full lethality treatment” or “for cooking only.”

A disclaimer statement concerning *E. coli* O157:H7 is a statement regarding the type of controls or 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”. Establishments are not required to include instructional or disclaimer statements concerning *E. coli* O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty

components; however, some establishments may choose to include such statements on the labels of these products.

A. Establishments that Place Instructional or Disclaimer Statements on Their Product Label

To use labels on raw ground beef products, raw ground beef components, or raw beef patty components that include an instructional or disclaimer statement concerning *E. coli* O157:H7, establishments must obtain sketch approval from FSIS Labeling and Consumer Protection Staff and maintain a sketch approval in the company's required labeling records (see 9 CFR 317.4(a)). The labeling of ground beef products, single-ingredient raw ground beef components, or single-ingredient raw beef patty components that include special instructions or disclaimer statements concerning *E. coli* O157:H7 cannot be generically approved because FSIS considers these special instructions or disclaimers to be special claims (see 9 CFR 317.5(b)(2)).

Labeling products with instructional (e.g., "for cooking only") or disclaimer statements (e.g., "not tested for *E. coli* O157:H7") is not a means to control pathogens. These statements should not be used to justify a determination that *E. coli* O157:H7 is not a hazard reasonably likely to occur in their production of raw ground beef products, raw ground beef components, or raw beef patty components. Therefore, such statements cannot be used as a CCP or intervention for *E. coli* O157:H7. If an establishment has determined that *E. coli* O157:H7 is a hazard reasonably likely to occur in its production of ground beef products, raw ground beef components, or raw beef patty components, the establishment must have an intervention to address the hazard, and NOT use labels that include disclaimer or instructional statements on these products as a means of addressing the hazard presented by *E. coli* O157:H7.

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

The placement of any instructional statement addressing *E. coli* O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty components must be reflected in an establishment's decision-making documents (9 CFR 417.5(a)(2)), and hazard analysis, (9 CFR 417.2(a)(1)).

For example, if an establishment places the statement "for cooking only" or "for full lethality treatment" on raw ground beef products, raw ground beef components, or raw beef patty components, the establishment's hazard analysis should show how the

establishment is ensuring that the product will go for cooking only, or for other full lethality treatment only. If the establishment places a “for cooking only” statement on the product and cooks the product in the establishment, the establishment’s flow chart should show the cooking steps the product will undergo. If the establishment places a “for cooking only” statement on the product and ships it to outside establishments, the shipping establishment should have controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that is not intended for cooking, it should have controls in place to segregate product intended for cooking from product not intended for cooking. If an establishment places the statement “for cooking only” on its finished product, but the establishment has not addressed the intended use of its finished product in its decision-making documents or hazard analysis, the establishment’s hazard analysis and decision-making documents would not be consistent with the information contained in the instructional statement.

Note: Product labeled “for cooking only” may go to an establishment that cooks product intended for additional further processing. As long as the cooking establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

B. Establishments Receiving Products with Instructional or Disclaimer Statements on the Label

Establishments receiving raw ground beef products, raw ground beef components, or raw beef patty components with a label that includes an instructional statement meant to address *E. coli* O157:H7 (e.g., “for cooking only” or “for full lethality treatment”) or disclaimer statements should: 1) address the use of the incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with *E. coli* O157:H7; and 2) follow the instructional statements on incoming product. For example, if the establishment receives ground beef products, raw ground beef components, or raw beef patty components that bear the instructional statement, “for cooking only,” the establishment should cook the product so that the product receives an adequate lethality treatment.

Note: An establishment that receives product labeled “for cooking only” may cook product that is intended for additional further processing. Even if the product will undergo further treatment before it is fully processed, as long as the establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

VIII. Purchase Specifications

One of the methods that establishments producing raw ground beef product can use to control *E. coli* O157:H7 in ground beef is the use of purchase specifications to ensure

receipt of source materials that have undergone interventions that eliminate or reduce *E. coli* O157:H7 to an undetectable level. The Agency has determined that beef grinders can include purchase specifications addressing *E. coli* O157:H7 in their HACCP plan, or their Sanitation SOP, or other prerequisite programs.

An establishment that decides that *E. coli* O157:H7 is not a hazard reasonably like to occur due to the presence of purchase specifications included in its Sanitation SOPs or its prerequisite program should include information on its relevant prerequisite programs in its supporting documentation (417.5(a)(1)). The hazard analysis should include scientific support and the decision-making documents associated with the development and use of this program in order to support through recordkeeping requirements (Section 417.5(a)(2)) that this pathogen continues to be a hazard not reasonably like to occur because of the established program.

The establishment should be able to demonstrate that the design and execution of its purchase specification program ensures that the pathogen is not likely to occur in its production process as a direct result of this prerequisite program. The establishment with purchase specifications should require documentation from the suppliers accompanying the product showing that the purchase specifications are being met. The receiving establishment should verify that the purchase specifications are being met at some frequency. There should be a process whereby the supplier notifies the establishment when the supplier determines that its interventions have been ineffective or not appropriately applied, and for the receiving establishment to verify that the supplier is regularly meeting the receiving establishment's specifications. This documentation and other verification activities are necessary to ensure that the food safety hazard is not reasonably likely to occur, and for the establishment to determine that it will not have to develop a CCP in the HACCP plan.

A grinding establishment that has a purchase specification program and is receiving source materials for grinding from an establishment that is utilizing a validated pathogen reduction intervention on beef carcasses and routinely verifying the intervention through *E. coli* O157:H7 testing should receive documentation from the supplier stating that a validated intervention is being used, and that the intervention is operating effectively as shown by negative tests for the pathogen during verification testing. The document should also specify the interventions of the supplying establishment. The documentation should accompany each shipment. A single annual letter from a supplier stating that it has interventions in place or just sending photocopies of the same information with each shipment of product is not enough supporting documentation to provide for good decision-making to support that this food safety hazard is not likely to occur. Adequate documentation would provide information to the receiving establishment concerning the control of this pathogen at the establishment supplying the product on an ongoing basis. The documentation should show that the interventions were operating effectively.

Establishments with purchase specifications that are receiving source materials for grinding should find out what the supplying establishments are doing to prevent, eliminate or reduce *E. coli* O157:H7 to undetectable levels. They should find out whether the supplying establishments have CCPs addressing *E. coli* O157:H7, and if they conduct

verification testing for the pathogen. If an establishment has purchase specifications addressing *E. coli* O157:H7 in its prerequisite program and has determined that *E. coli* O157:H7 is not a hazard reasonably likely to occur in its production because of the purchase specifications, the establishment should have supporting documentation showing that its suppliers have CCPs addressing *E. coli* O157:H7.

If a grinder has incorporated purchase specifications addressing *E. coli* O157:H7 as a CCP at receiving, and upon verification testing finds that product received under purchase specifications is positive for *E. coli* O157:H7, the grinder should conduct corrective actions specific to this CCP. Examples of corrective actions include among others, no longer buying from that supplier, or contacting the supplier so that the supplier could determine what controls may have failed. If the supplier makes any appropriate changes to its controls or interventions so that the supplier could certify that it had effectively eliminated any *E. coli* O157:H7, the grinder could continue purchasing from that supplier.

FSIS recommends that establishments that have purchase specifications to prevent *E. coli* O157:H7 from entering the facility include testing for *E. coli* O157:H7 as part of their verification activities (67 FR 62331). In addition, given the nature of *E. coli* O157:H7, FSIS recommends that receiving establishments that have purchase specifications addressing *E. coli* O157:H7 determine whether CCPs preventing *E. coli* O157:H7 growth or contamination after product receipt are necessary (67 FR 62330). Whether letters of guarantee obtained when meat was received at a given establishment will be sufficient to satisfy the requirements of a second receiving establishment, should the first receiving establishment ship the product, depends on whether the first receiving establishment can guarantee that it prevented any *E. coli* O157:H7 growth or contamination of the product after its receipt and whether the second receiving establishment is willing to accept a letter of guarantee from the establishment that initially supplied product to the first receiving establishment.

IX. Validation of Critical Control Points (CCPs)

An establishment that determines that *E. coli* O157:H7 is a food safety hazard reasonably likely to occur must have one or more CCPs that are validated to eliminate or reduce *E. coli* O157:H7 below detectable levels. The receiving establishment does not have the responsibility for validating the CCPs used at the supplying establishment. The receiving establishment must:

- Ensure that the supplier meets purchase specifications;
- Verify that the purchase specifications prevent the pathogen from entering the plant in product received;
- Verify suppliers validated CCPs are effective on an ongoing basis
- Maintain supporting documentation on their verification activities (417.5(a)(2));and
- Validate and CCPs in their HACCP plan.

If an establishment finds positive *E. coli* O157:H7 product and has not identified the pathogen as a hazard reasonably likely to occur, and therefore does not have a CCP for *E. coli* O157:H7 in its HACCP plan, the positive test would be considered an “unforeseen hazard”. In this case the plant must conduct corrective actions, including reassessing its HACCP plan under 9 CFR 417.3 (b). However, if an establishment has CCPs that address *E. coli* O157:H7, and the establishment or FSIS testing detects the pathogen, reassessment is not required but corrective actions under 9 CFR 417.3(a) should be taken. The establishment should examine its intervention methods. They should determine why they are not working. In slaughter establishments carcass mapping may be conducted to determine areas of carcass contamination. In addition, if FSIS testing finds *E. coli* O157:H7, the establishment may decide to intensify its verification program or ensure that the sensitivity of its testing method is equivalent to FSIS’.

A. Use of peer-reviewed studies for validation

Peer-reviewed articles can be used as validation for a critical limit addressing *E. coli* O157:H7. Guidance materials that FSIS developed for slaughter establishments, grinders, and suppliers on minimizing the risk of *E. coli* O157:H7 contamination included the parameters of certain peer-reviewed studies. If using a peer-reviewed article, validation activities consist of repeatedly testing the adequacy of the CCPs, critical limits, monitoring, recordkeeping procedures, and corrective actions. Initial validation demonstrates that the establishment is able to repeatedly meet the parameters in the peer-reviewed article and verification that the pathogen is not detected. In order to determine that the intervention derived from the peer-reviewed article is controlling the pathogen, the validation process must be carried out in the establishment, subject to the establishment’s facilities, processes, and unique conditions.

All the parameters used in the study must be applied to the establishment’s process. For example, a peer-reviewed scientific article has four parameters to be followed for the intervention to be effective. The establishment is only capable of meeting one of the parameters defined in the article. Then, the establishment cannot use the article to support the use of the intervention method. Additional validation would be needed using the new combination of parameters. This is important because if one parameter is changed, the interaction of the new combination of parameters will also change the results and the effectiveness of the intervention method. A challenge study (using pathogens) is one means to validate a process. Challenge studies should be conducted in a laboratory outside the establishment facility (i.e., do not conduct studies in an establishment if pathogens are intended to be introduced into the operation).

B. Use of indicator organisms

Intervention treatments to control *E. coli* O157:H7 should be validated by conducting challenge studies using *E. coli* O157:H7. However, these studies should not be conducted in the plant. Indicator organisms that are not pathogens can be used to demonstrate in-plant process control. Even though indicator organisms are not a true marker for the likely elimination or reduction of *E. coli* O157:H7, they are useful in studying the general effectiveness of plant interventions and making determinations about

process control. FSIS recognizes that there is no true non-pathogenic surrogate organism that mimics pathogenic *E. coli* O157:H7. However, if at some point in the future, establishments can demonstrate through valid studies that there is an organism that can be used as an indicator for *E. coli* O157:H7 this information should be submitted to the appropriate FSIS office.

C. CCP for finished product testing to determine product disposition

In most cases, a CCP based on finished product testing to determine product disposition would be inappropriate. However, for an establishment that conducts its own slaughter, fabrication, and grinding, and does not use product from other establishments, a CCP for disposition that relies on product testing may be acceptable. If the establishment includes CCPs at slaughter and fabrication, and a CCP for disposition based on finished product testing at a level sufficient to find the pathogen if present at very low frequency, then a CCP for disposition may be appropriate.

In this case, the establishment would have identified *E. coli* O157:H7 as a hazard reasonably likely to occur and would have interventions for the pathogen. A positive test would therefore signify a deviation from the critical limit at the CCP. The critical limit for this CCP would have been that *E. coli* O157:H7 is non-detectable because of the intervention. Therefore the positive result would trigger corrective actions required under 9 CFR 417.3 (a), but not necessarily a reassessment of the HACCP system. The corrective actions may include examining the parameters used in the intervention method to ensure that they are used correctly, or determining whether the verification program needs to include more frequent testing, or conducting carcass mapping to determine areas of the carcass where contamination is more concentrated.

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