

Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations

2021 Guideline

This guideline is designed to assist establishments producing non-intact and intact cuts intended for raw non-intact beef products to:

- Understand the adulterant status of STEC in beef products;
- Design supportable control measures for STEC;
- Develop ongoing verification measures to ensure that STEC control measures are functioning as intended;
- Respond when the HACCP system fails to prevent, or reduce STEC to below detectable levels.

Preface

What is the purpose of this guideline?

The Food Safety and Inspection Service (FSIS) is publishing this guideline to assist small and very small processing establishments that produce raw non-intact beef products (e.g., ground beef, mechanically tenderized beef), raw intact beef products intended for non-intact use, or raw intact beef products where the intended use is not clear, meet Agency regulatory requirements. This guideline is designed specifically to: help establishments understand the adulterant status of Shiga toxin-producing *Escherichia coli* (*E. coli*) or STEC in raw beef products; design supportable control measures for STEC; develop ongoing verification measures to demonstrate that the establishment's Hazard Analysis and Critical Control Point (HACCP) system is functioning as intended to reduce STEC to below detectable levels; develop grinding logs to track source materials and products made from those materials; and respond to positive STEC sample results.

This guideline represents FSIS' best practice recommendations, based on the most current science and practical considerations. Establishments do not have to adopt the recommendations in this guideline; they may choose to adopt different procedures as long as they have documented scientific support for doing so. This guideline represents FSIS' current thinking on this topic and should be considered usable as of the issuance date.

This guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide these types of establishments with assistance under the Small Business Regulatory Enforcement and Fairness Act (SBREFA). It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. However, the recommendations in this guideline apply to all FSIS regulated meat establishments, regardless of their size.

FSIS posts frequently asked questions and answers regarding Agency policy to the [askFSIS](#) Website and also publishes directives and notices that, in part, provide Agency inspection program personnel (IPP) with instructions for conducting sampling, testing and other verification activities related to STEC. This guideline assimilates the most current research, Agency policy, and inspection program instructions on STEC in beef products, and is intended to assist small and very small establishments understand the features and preventive measures that are necessary to address STEC in raw non-intact beef products and product components when designing a HACCP system.

Regarding this guideline:

- When the guideline references beef, the information also pertains to veal;
- When the guideline references non-intact products, it includes:
 - Non-intact product components (e.g., head meat, cheek meat, and weasand meat),
 - Products intended for non-intact use, and
 - Products where the intended use is unclear; and
- Products that are intended for intact use (that will not be ground or otherwise rendered non-intact either at Federally Inspected establishments or retail) are not covered by this

guideline, because STEC is not an adulterant in those products (see page 8 for more information).

What changes have been made to the guideline from the last version?

This guideline updates and combines information from the following guidance documents which are now retired and replaced:

- *Draft Guidance for Small and Very Small Establishments on Sampling Beef Products for Escherichia coli O157:H7* (August 12, 2008); and
- *Sanitation Guidance for Beef Grinders* (January 2012).

FSIS has made changes to this guideline since its previous issuance. FSIS has also issued new revisions of [FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#), and [FSIS Directive 10,010.2, Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#), to its IPP. This guideline incorporates current Agency thinking on the use of antimicrobial treatments, establishment STEC sampling and testing programs, and other measures that can be incorporated in the establishment's HACCP system to mitigate STEC to non-detectable levels in the raw beef products covered.

Comments were received on the previous version of this guideline from three industry trade organizations and three individuals. The following changes have been made to the guideline in response to these comments:

- The text was reviewed, and language modified or deleted to lessen the inference that the information provided in the guideline constitutes regulatory requirements;
- The section on lymph node removal and references to *Salmonella* have been removed from this document to reduce confusion and increase clarity regarding STEC policy; and
- Additional examples and scenarios using supplier based verification programs have been added to illustrate additional verification options for establishments;
- After additional internal review, FSIS added a brief question and answer section addressing antimicrobial interventions and retained water in beef trim intended for grinding. This section was added in response to concerns expressed by stakeholders to Agency leadership; and
- After additional internal review, FSIS added language from [FSIS's Microbiology Laboratory Guidebook \(MLG\)](#), stating that, when testing for STEC, if the initial screen test result is negative for the Shiga toxin gene (stx) or the intimin gene (eae), then the test result is considered to be negative for an adulterant. This addition was created to clarify FSIS policy regarding STEC in relation to product recalls.

Is this version of the guideline final?

Yes, this version of the guideline is final. FSIS has responded to public comments. FSIS will update this guideline, as needed, in response to FSIS policy changes and additional public comments.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit

questions through [askFSIS](#). Documenting these questions will help FSIS improve and refine present and future versions of this guideline and associated issuances.

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter: **Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations.**

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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Why was this guideline developed?

FSIS developed this guideline because many small and very small establishments have had difficulty designing and supporting HACCP systems (e.g., HACCP plan, Sanitation Standard Operating Procedures (sanitation SOPs), or other prerequisite programs) that effectively reduce STEC to below detectable levels in raw non-intact beef products. Relatedly, FSIS continues to receive questions from small and very small establishments regarding STEC and HACCP systems. This guideline consolidates current science and research and information found in past industry guidelines and Q and A's posted to [askFSIS](#). It serves as a comprehensive resource for small and very small establishments that further process raw beef to use when developing HACCP systems that address STEC.

As required by the HACCP regulations contained in 9 CFR 417, each establishment must conduct a hazard analysis of its production process to determine the hazards that are reasonably likely to occur (RLTO). STEC contamination is recognized as a food safety hazard that can be introduced during the slaughter and processing of raw beef products. Therefore, establishments producing raw non-intact beef products or intact product intended for non-intact product must address STEC in their HACCP systems; if STEC is not addressed, the HACCP system will likely be deemed inadequate. [9 CFR 417.1](#) defines a HACCP System as:

the HACCP plan in operation, including the HACCP plan itself. This guideline applies to a wide range of production practices at combination beef slaughter-processing establishments and establishments that only further process raw beef products. It provides small and very small establishments with the information they need to: understand and control STEC; make well-informed decisions regarding the adequacy of control measures used to address STEC; verify that STEC control measures are effective in reducing STEC to below detectable levels; and assure that ongoing verification activities used to verify that STEC control measures, when functioning as intended, are adequate. Lastly, this guideline provides multiple options for designing and implementing effective HACCP systems for minimizing the risk of STEC in raw beef products.

Where does STEC come from?

Cattle have been identified as an important reservoir for STEC. The intestinal tract, hide, and hooves of cattle can contain STEC. Contamination can be transferred to the carcass during the slaughter process. Slaughter establishments typically employ a variety of controls to prevent, eliminate or reduce STEC during the slaughter process.

“STEC” is an acronym for **S**higa **t**oxin-producing **E. coli**. Some strains of STEC may cause severe illness due to the presence of Shiga toxin and other virulence factors.

Although there are many other Shiga toxin-producing *E. coli* (STEC), as stated in the *Federal Register* ([76 FR 58157](#)), *E. coli* O157:H7 and six non-O157 serogroups (O26, O45, O103, O111, O121 and O145) are adulterants in raw non-intact beef and raw intact beef products intended for non-intact use and are referred to collectively by FSIS as STEC. FSIS policy applies only to the seven serogroups mentioned above which are adulterants in raw non-intact beef and raw beef intended for non-intact use under the Federal Meat Inspection Act ([21 U.S.C. 601\(m\)\(1\)](#)).

Note: As indicated in [FSIS' Microbiology Laboratory Guidebook \(MLG\)](#), when testing for STEC, if the initial screen test is negative for the Shiga toxin gene (*stx*) or the intimin gene (*eae*), then the test is negative for an adulterant.

The ability of slaughter operations to control STEC begins with effective sanitary dressing procedures that minimize contamination combined with effective methods to maximize decontamination. For more information on STEC control at pre-harvest and in slaughter establishments see the following guidance documents:

- [Sanitary Dressing and Antimicrobial Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices](#) (Aug. 2015);
- [Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing *Escherichia coli* Shedding in Cattle: An Overview of Current Research](#) (Aug 2014); and
- [Industry Guideline for Minimizing the Risk of Shiga Toxin producing E.coli \(STEC\) and Salmonella in Beef \(including veal\) Slaughter Operations 2021](#).

Which requirements apply to hazard analysis decision-making for STEC?

Establishments need to refer to the requirements in both [9 CFR 417.2\(a\)\(1\)](#) and [9 CFR 417.5\(a\)\(1\)](#) when performing their hazard analysis and developing their HACCP system. [9 CFR 417.2\(a\)\(1\)](#) states: “Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the measures that can be applied to prevent, eliminate or reduce those hazards to an acceptable level. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment....”. [9 CFR 417.5\(a\)\(1\)](#) requires establishments to maintain all supporting documentation for decisions made in the hazard analysis. These two regulations work collaboratively; [9 CFR 417.2\(a\)\(1\)](#) requires establishments to determine the hazards associated with their process and [9 CFR 417.5\(a\)\(1\)](#) requires establishments to support the adequacy of their HACCP system to address the hazards. Historically, foodborne outbreaks of human illness have occurred as a result of STEC-contaminated non-intact beef products. Therefore, as explained in the *Federal Register* ([76 FR 58157](#)), establishments need to consider both the potential presence and potential outgrowth of STEC when developing HACCP systems for the production of beef products to ensure STEC is reduced to below detectable levels in the products.

FSIS considers any control that is validated to control *E. coli* O157:H7 to also be effective against non-O157 STEC. Therefore, a hazard analysis may list each of the 7 STEC individually, *E. coli* O157:H7, or STEC, since all of these are considered the same adulterant (i.e., STEC) ([76 FR 58157](#)).

Temperature controls can inhibit the further growth of STEC when present in raw beef products; however, such controls cannot rid a product of STEC when present in these products as a result of contamination during slaughter or processing. For example, if STEC is present at a certain level, freezing would inhibit further growth of STEC but would not reduce STEC to below a detectable level. Establishments need to control for both the presence and outgrowth of STEC, to ensure their products are not adulterated.

Is STEC considered an adulterant in all beef?

No. STEC is not an adulterant on raw intact beef products, such as steaks and roasts, which are “intended” for intact consumer use. This is because STEC contamination would be limited to the exterior surfaces of intact beef products and, if these products remain intact, normal consumer cooking will destroy any STEC on the outer surfaces, even if the product is cooked to a rare or medium internal state. STEC is an adulterant in raw non-intact beef products and raw intact beef products intended for raw non-intact use or in products for which the intended use is not clearly defined or supported. To make supportable decisions in a hazard analysis, establishments need a thorough understanding of the characteristics of STEC and the final product’s intended use. As is discussed below, the establishment is required to identify the intended use or consumers of the final product ([9 CFR 417.2\(a\)\(2\)](#)). When STEC is present on the meat’s exterior and the product does not remain intact, STEC may be translocated to the interior of the product during non-intact processing (e.g., grinding, tenderizing). In such cases, normal cooking to a rare or medium-rare internal state may not be sufficient to destroy STEC that is present throughout the product. Understanding this key concept is crucial to understanding the adulterant status of STEC and evaluating the adequacy of the STEC controls in place in the HACCP system.

Non-intact beef products include: ground beef; chopped beef; flaked or, minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than $\frac{3}{4}$ inch (dial setting) in any one dimension on average.

[9 CFR 417.2\(a\)\(2\)](#) requires each establishment to identify the intended use or consumers of the finished product. The product’s intended use may affect the STEC controls required at both the establishment that produces beef source materials and the receiving establishment that produces raw non-intact beef products from those source materials. Establishments that purchase beef products from slaughter establishments should be aware of the slaughter establishment’s intended use for any products they receive. Slaughter establishments should have a system in place to communicate the product’s intended use to its customers. Not all products produced by a slaughter establishment are intended for non-intact use and, in some cases, primals and subprimals may be designated by the slaughter establishment as intended solely for intact use. When any receiving establishment plans to use a raw beef product in a manner that conflicts with the supplier’s intended use for that product, the receiving establishment would need to implement additional control measures for STEC. The communication of the intended use of a raw beef product, identified at each level of the distribution chain, including retail, is important; each receiving establishment needs to consider the intended use of the raw beef products it receives when addressing STEC and developing a supportable HACCP system.

Are validated cooking instructions on labels or customary cooking practices enough to address STEC in raw non-intact beef products?

Validated Cooking Instructions

No. Validated cooking instructions provided on product labels cannot serve as a control or critical control point (CCP) to address STEC in the production of raw non-intact beef products. Because of the history of severe outbreaks of human illness associated with the consumption of undercooked non-intact beef products, FSIS concluded in its *Federal Register* notice ([64 FR 2803](#)) that many non-intact raw beef products present a significant public health risk because STEC may be introduced below the product's surface. [9 CFR 317.2\(e\)\(3\)\(iii\)](#) requires that labels for raw or partially cooked needle or blade tenderized beef products destined for household consumers, hotels, restaurants or similar institutions contain validated cooking instructions because these non-intact beef products do not always appear non-intact to the consumer. However, it should be noted that if non-intact beef products (including partially cooked needle or blade tenderized products) are determined to be adulterated because they are contaminated with STEC, validated cooking instructions on the label will not negate the adulteration classification or prevent the product from being recalled, nor will such instructions provide a means for product disposition. The inclusion of validated cooking instructions on the label serves solely as a measure to inform the consumer of the need to cook the product thoroughly. These validated cooking instructions also do not replace the need for establishments to address STEC in their HACCP systems and to ensure that products are safe and wholesome before being distributed into commerce.

Customary Cooking Practices

The customary preparation of raw ground beef and non-intact steaks (i.e., cooking to a rare or medium state) does not destroy STEC throughout the product or render the product safe. However, FSIS recognizes that there are some raw non-intact beef products that are customarily cooked by the consumer to a well-done state (i.e., cooking the product to a time and temperature combination sufficient to destroy STEC throughout the product). These products include:

- Raw corned beef;
- Thinly sliced raw beef derived from reconstructed beef products used in "philly" style cheese steaks;
- Multi-ingredient raw ground meat or poultry products in which the ground meat component other than beef is more predominant by weight than is ground beef;
- Shaped and formed raw ground beef products other than patties (e.g., meatballs, meatloaf); and
- Raw beef sausages (e.g., fresh sausages, beef chorizo).

Establishments electing to use customary cooking practices as a means to support their hazard analysis decisions for the raw non-intact beef products listed above, or other raw non-intact beef products, must maintain the necessary documentation described below to support that the products are customarily thoroughly cooked. Failure to maintain sufficient supporting documentation could implicate these products as adulterated if produced from the same source material as other STEC-positive raw non-intact products without any other evidence of microbiological independence. In the absence of sufficient supporting documentation and under the circumstances just described, FSIS may request the recall of raw non-intact products even if consumers are likely to fully cook them.

As part of an establishment's decision making regarding STEC in its hazard analysis, the intended use of each product must be clearly stated ([9 CFR 417.2\(a\)\(2\)](#)). Establishments also need to have documentation on file supporting their hazard analysis decisions ([9 CFR 417.5\(a\)\(1\)](#)), which may include describing the customary preparation practices for the safe consumption of the product and the basis for the establishment's determination that these practices constitute customary preparation. The establishment also needs to document in its hazard analysis, or associated decision-making documents, any contractual controls it may have in place to ensure its customers will prepare the non-intact beef product in a manner whereby STEC would not be a significant health risk. This may include decisions to incorporate additional special handling instructions (not just the required safe handling instruction label per [9 CFR 317.2\(l\)](#)) or more descriptive cooking instructions on the product label to assist consumers in safely preparing the product and a statement as to why the establishment has concluded that these instructions will be effective. Finally, as with any raw meat process, the establishment needs to also document in its hazard analysis necessary controls that must be maintained (e.g., purchase specification information, cold chain maintenance, other sanitary controls throughout the process) to minimize microbial growth or to prevent re-contamination to a level such that customary cooking practices would not be sufficient to render the product safe.

What controls are needed to address STEC for raw non-intact beef products?

The source of the raw beef products used to produce raw non-intact beef products and the intended use for the source materials should guide hazard analysis related decisions regarding STEC. Since STEC is associated with contamination during slaughter and dressing, each establishment must develop its own STEC control measures based on its knowledge and level of assurance of the STEC controls applied at slaughter.

Establishments that conduct raw non-intact processing can typically receive beef source materials in two distinct ways: from an external source (e.g. outside slaughtering establishment, broker) or directly from their own in-house slaughter operations (internal source). If a raw non-intact processing establishment uses beef source materials from both internal and external sources, it would have to consider and address STEC for both the internal and external sources in the context of its operations and HACCP system. [Appendix 1](#) includes a flow diagram to guide the decision-making process for STEC controls when using internal and external source materials in raw non-intact beef processing operations.

Internal Source: Combination Slaughter-Processing

In establishments that both slaughter and process to produce source materials used within the establishment for the production of raw non-intact beef products, STEC controls implemented during slaughter are known and are part of the establishment's overall HACCP system. To reduce STEC to below detectable levels during slaughter, the HACCP system typically incorporates a multi-hurdle approach that includes:

- Properly implemented and verified sanitary dressing procedures;
- Zero tolerance carcass examinations;
- Application of a validated antimicrobial intervention CCP to reduce any incidental nonvisible STEC contamination on carcasses or parts; and
- Proper cold chain management of carcasses and parts to prevent STEC growth.

If a slaughter-processing establishment has a validated slaughter HACCP program that is functioning as intended and the establishment controls its process by properly monitoring sanitation and product temperature, the establishment may be able to support that STEC has been reduced to below detectable levels by its antimicrobial CCP in the slaughter process. Ongoing verification (e.g., sampling and testing) would need to be in place to, in part, demonstrate that the STEC controls continue to function as intended. The establishment's hazard analysis may be able to support that STEC was reduced to below detectable levels by the STEC multi-hurdle approach deployed during slaughter.

External Source: From an Outside-Supplier

For establishments that produce non-intact beef products that receive source materials from external suppliers (also referred to as receiving establishments), knowledge of the STEC controls at slaughter is not self-contained within their HACCP systems. The establishment receiving source materials from an external supplier needs to either obtain detailed information from the supplier indicating it is meeting the receiving establishment's purchase specifications, including those that address STEC, or the receiving establishment needs to apply control measures through its HACCP system to address STEC. The receiving establishment's ability to support whether STEC has been reduced to below detectable levels in the source materials received from an external source will determine whether it can address STEC through purchase specifications or whether it must use in-house STEC controls. Establishments may use a combination of prerequisite programs and CCPs to address STEC presence and growth during the production of raw non-intact beef products produced from source materials received from one or more external suppliers.

To address STEC in source materials from external suppliers, the receiving establishment can use a purchase specification prerequisite program to support that the controls previously applied by the suppliers demonstrate STEC is below detectable levels in the products received. For a non-intact beef processing establishment to determine that STEC is not reasonably likely to occur (NRLTO) for external source materials at receiving, FSIS recommends a three-component approach:

- A Letter of Guarantee (LOG) from each supplier that describes the CCP(s) that address STEC, the monitoring of the CCP(s) and the use of any antimicrobial interventions. A LOG should be maintained for each external supplier of source materials used by the receiving establishment. The LOG should be reviewed frequently to assure it reflects the supplier's current STEC control procedures and updated, as needed; and
- A Certificate of Analysis (COA) or similar documentation should be received from the supplier to demonstrate that STEC has been reduced to below detectable levels in each lot of product received. The information received on the COA or similar documentation should include the actual test result, sampling method (e.g., N-60), testing method, amount analyzed (i.e., sample portion size) and product description to assure it matches the purchased product. The COA or similar documentation should be obtained for each lot of product received, on a lot-by-lot basis; and
- Ongoing verification in accordance with [9 CFR 417.4](#) (e.g., product testing) to demonstrate the receiving establishment's HACCP system continues to function as intended. [Ongoing verification](#) is discussed later in this document.

Determining that STEC is RLTO does not mean that the specific product is positive for STEC. It means the establishment has to address the hazard in its HACCP plan.

In situations where an establishment receives source materials from an external supplier and is unable to obtain COAs or similar documentation to support that STEC is NRLTO in the materials received, the following alternative options are available to the establishment to demonstrate that STEC is below detectable levels:

- **Product Sampling and Testing Programs** – This option can be used to demonstrate that STEC is below detectable levels in the source material received or the non-intact beef products produced from the source materials. Establishments can test the incoming source material or finished non-intact beef product. Establishments should be aware that sampling and testing is not a STEC control; it is a verification activity. For receiving establishments that lack knowledge of the STEC controls applied by an external source during slaughter and that choose not to apply an in-house microbial reduction step to these materials, but instead choose to implement a sample and testing program as its only measure to address STEC, the sampling and testing should occur on a lot-by-lot basis. This option can be cost prohibitive for some. In addition, FSIS does not recommend that such sampling and testing programs be used alone, as doing so relies on the detection or non-detection of STEC on a lot-by-lot basis in lieu of applying one or more systematic controls for STEC.
- **STEC Reduction** – This option incorporates a process to reduce STEC on the intact meat surface to below a detectable level before non-intact beef processing. Establishments can apply: an antimicrobial intervention, a lethality treatment, or treat/wash the intact product and trim the entire outer surface. Ideally, the STEC reduction step would be a CCP in the further processing establishment's HACCP plan. The recordkeeping, monitoring, and verification that are required would then make this the strongest approach for STEC control for beef source materials from external sources. However, in lieu of a CCP, it may be acceptable to include the STEC reduction procedures as part of a validated pre-requisite program that also includes recordkeeping, monitoring, and verification procedures to ensure that STEC is below detectable levels in the non-intact beef product produced. Establishments must properly design and fully validate the STEC reduction method used to reduce STEC to below detectable levels regardless of whether it is a CCP or a prerequisite program. More information on validation is available in the [FSIS Compliance Guideline HACCP Systems Validation](#).

There is no specific regulatory requirement that establishments test beef products for STEC. Establishments may choose to test beef products for STEC to support decisions in their hazard analysis and/or as an ongoing verification activity to show their HACCP system continues to function as intended. However, testing is not the only means to support hazard analysis decisions or satisfy ongoing verification requirements.

NOTE: Establishments that receive raw ground beef and repackage the raw ground beef without reducing the particle size or adding other source materials (e.g., portioning), should address STEC in their hazard analysis as a potential hazard in raw non-intact beef products.

A list of antimicrobial interventions and supporting documentation is provided in Appendix 3, [Resources and References](#), of this guideline. The list is not all inclusive but includes common interventions and associated operational parameters for STEC control. FSIS encourages the use of multiple interventions, where possible, as part of a systematic approach. The application of multiple interventions (or “hurdles”) has been shown to be more effective than using a single intervention. Establishments should be aware that use of certain antimicrobial interventions may impact their eligibility to export certain beef products to some countries. Eligibility requirements for U.S products intended for export to specific countries can be found in the [FSIS Export Library](#).

[FSIS Directive 7120.1](#) does not describe a specific level of STEC reduction and is not sufficient scientific support documentation for an antimicrobial’s effectiveness.

There is not one “superior” antimicrobial intervention for STEC. When searching for an antimicrobial treatment to use as an intervention for STEC, establishments should review the supporting documentation available and choose an intervention based on its overall HACCP system. Establishments should review [FSIS Directive 7120.1](#), *Safe and Suitable Ingredients in the Production of Meat, Poultry and Egg Products*, to ensure the chemical intervention is applied in a safe and suitable manner and does not violate any applicable concentration or labeling requirements. [FSIS Directive 7120.1](#) cannot be used alone to support the efficacy of a chemical intervention; additional scientific supporting documentation is needed to show that the substance is effective against STEC.

STEC outgrowth needs to be addressed in addition to the presence of STEC. A temperature control program can be implemented to prevent STEC outgrowth during the production process. Temperature controls can inhibit the growth of STEC, but even freezing would not reduce STEC that is present at a detectable level to a non-detectable level. As is noted above, establishments need to control for both the presence and outgrowth of STEC. Maintaining a proper product temperature during storage and processing is one way to ensure STEC will not grow from a previously undetectable level to a detectable level.

What is initial validation and how does it differ from ongoing verification?

As explained in the [FSIS Compliance Guidelines HACCP Systems Validation](#) (Apr 2015), and per [9 CFR 417.4](#), the initial validation, ongoing verification and reassessment of the HACCP plan are three distinct activities. These activities apply to the entire HACCP system.

The purpose of validation is to demonstrate that the HACCP system, as designed, is functioning as intended to control identified hazards and produce safe, unadulterated products. The purpose of ongoing verification is to demonstrate that the HACCP system continues to function as intended. It is common for establishments to repeatedly test the adequacy of critical operational parameters or to conduct product sampling and testing during initial

Question: Does the retained water regulation, 9 CFR 441.10, apply to meat and poultry finished product that is further processed into cuts or ground product where an antimicrobial intervention is applied to cuts or trim prior to grinding using a dip or spray?

Answer: Yes, establishments should maintain data on file to account for the net pickup of water, if any, in the final single ingredient finished product that has been further processed. For more information concerning retained water please see the [FSIS Compliance Guideline for Retained Water](#).

validation to show the HACCP system addresses the identified hazards. However, doing so does not negate the need to conduct frequent ongoing verification activities, including sampling and testing for pathogens, and program evaluation to support that the HACCP system continues to function as intended.

Why does FSIS recommend testing as an ongoing verification activity?

A common question posed to FSIS personnel by establishment owners is, “where in the regulations does it say I have to test for STEC?” To be clear, there is not a specific regulatory requirement for testing beef products for STEC.

Per [9 CFR 417.4](#), establishments are required to perform ongoing verification such as, the calibration of process monitoring instruments, direct observation of monitoring and corrective actions, and the review of process and monitoring records; this is not an exhaustive list of all possible ongoing verification activities. For non-intact beef products and beef products intended for non-intact use, the HACCP system needs to function to reduce STEC to below detectable levels. Because microbial contamination is not visible, establishments often perform microbiological testing to verify the HACCP system is functioning as intended to reduce STEC to below detectable levels. Each establishment must develop its own approach to controlling STEC and implement an appropriate method of ongoing verification. Sampling and testing can play a critical part in that systematic approach. Testing of product provides varying degrees of statistical confidence that a product is not contaminated with STEC. However, negative test results do not provide 100% certainty that the entire lot is not contaminated and subsequent testing of the lot during ongoing verification may find STEC previously not detected. For that reason, testing is a verification activity that demonstrates that a HACCP system is functioning as intended rather than a control for pathogens.

When a testing program is part of a prerequisite program, the testing results can serve as supporting documentation for decisions made in the hazard analysis, per [9 CFR 417.5\(a\)\(1\)](#).

NOTE: Generic *E. coli* data required under 9 CFR 310.25 should not be used to verify whether the establishment’s HACCP system is addressing STEC. Differences in laboratory method sensitivity demonstrate that STEC can still be recovered from a sample when below the limit of detection of direct plate generic *E. coli* methods. Further, detectable levels of generic *E. coli* do not mean STEC specifically is present. Therefore, testing for generic *E. coli* is not an effective verification procedure for assessing STEC controls.

How often does ongoing verification of STEC controls in non-intact beef processing establishments need to be conducted?

Ongoing verification should be designed to ensure that the HACCP system is functioning as intended. Factors that raw non-intact beef processing establishments should consider when developing ongoing verification programs and defining frequencies for conducting ongoing verification activities include:

- Knowledge of controls applied to address STEC at slaughter;
- The source materials and types of products produced from the source materials;
- The intended and final use of the source materials and finished products;
- Production volume;
- Past HACCP system failures at slaughter and processing; and
- Other unique STEC control factors or circumstances.

A non-intact beef processing establishment needs to evaluate if its on-going verification program and associated frequencies for ongoing verification activities provide meaningful data about its HACCP system that can show the system continues to function as intended, specifically, that STEC is below detectable levels. As discussed above, establishments that produce beef intended for raw non-intact use or raw non-intact beef products must develop measures to ensure STEC is reduced to below detectable levels on a lot-by-lot basis. This can be accomplished by receiving lot-specific COAs or applying an antimicrobial treatment in-house. These types of STEC control measures are distinctly different from ongoing verification activities, such as sampling and testing for STEC. Ongoing verification assures the STEC control measures that are part of the establishment's HACCP system continue to function as intended, which in this case, is to reduce STEC to non-detectable levels. The frequencies that ongoing verification procedures or activities are conducted must be supported as per [9 CFR 417.5\(a\)\(2\)](#). FSIS recognizes that scientific support for ongoing verification that involves sampling and testing product at a specific frequency may be difficult for small and very small establishments to provide because there are many different combinations of STEC controls and critical operating factors (listed above) deployed by the industry. Because providing a universal frequency for sampling and testing in light of all these combinations is impossible, FSIS is providing the following minimum frequencies for establishments that conduct sampling and testing as an ongoing verification activity for products intended for raw non-intact use or for finished raw non-intact products, based on the volume of production. Establishments that elect to use this guideline as support for their ongoing verification program for STEC controls that perform the verification activities less frequently than listed would need to provide additional support to justify that frequency.

A Letter of Guarantee (LOG) from a supplying establishment alone would not be considered meaningful ongoing communication with the supplier.

- > 250,000 lbs. weekly - sample at least once per month (12 times annually);
- 5,000-250,000 lbs. weekly - sample at least once every 2nd month (6 times annually); and
- < 5,000 lbs. weekly - sample at least once every 3rd month (4 times annually).

Studies have shown that cattle shed STEC more during the warmer months. Establishments electing to follow the above minimum testing frequencies should increase the recommended testing frequencies during the high prevalence months (April through October). These minimum testing frequencies are recommended when sampling and testing is the only ongoing verification activity conducted to assure STEC controls are working as intended and may change as more information becomes available to FSIS. Establishments that receive beef source materials from suppliers that have a history of HACCP system failures (i.e., positive results or high event periods) should consider increasing their ongoing verification sampling and testing frequency and include in their written decision-making documentation justification for the selected ongoing

In the absence of a STEC control or prevention measures, establishments cannot rely solely on ongoing verification testing at the frequencies listed to support a decision that STEC is NRLTO.

verification procedure and frequency that describes why they are adequate to ensure the system continues to function as intended.

Example: An establishment producing 150-lbs. of non-intact beef daily would be in the “< 5,000-lbs. per week” category for ongoing verification, and FSIS recommends at least “quarterly” sampling during the winter months (October to April) and increased sampling during the summer months (e.g., twice-per-quarter from April to October), for a total of 6 samples annually.

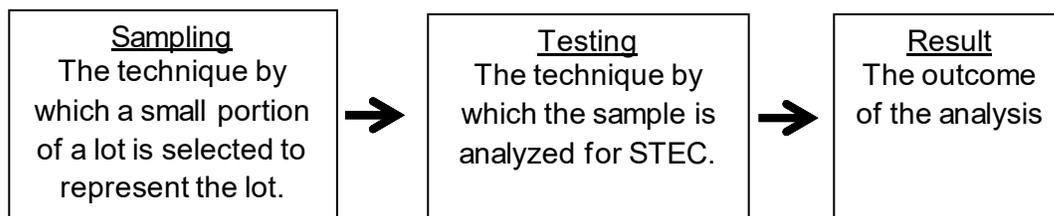
Establishments need to collect ongoing verification data to support that their HACCP systems are addressing STEC. Frequent communication with suppliers, third-party audits, supplier verification programs, establishment testing, and FSIS testing can all be incorporated into a well-designed ongoing verification program. The design of the ongoing verification procedures, frequencies, and the data generated should assure that a determination can be made by the establishment that the HACCP system is functioning as intended.

FSIS does not prohibit establishments from using FSIS test results as part of their ongoing verification testing programs as these results can provide meaningful process control verification data. The frequency with which FSIS conducts sampling is not designed to support each individual HACCP system, and establishments should not rely solely on FSIS test results. However, if an establishment elects to use an FSIS sample result in lieu of utilizing its own in-house sample result, the establishment’s written ongoing verification program must provide detailed decision-making outlining how the FSIS result meets the established design of its written program, rather than simply relying upon FSIS testing. An example of an establishment using FSIS results to document its ongoing verification is provided in [Scenario #3](#) in the Scenario and Analyses section of this guideline.

Under certain circumstances a receiving establishment could develop ongoing communication with its supplier(s) and obtain the supplier’s ongoing verification test results. These supplier test results would show that the supplier is effectively implementing its HACCP system and would support that the purchased specification program at the receiving establishment is functioning as intended. An example of a supplier-based verification program is provided in [Scenario #4](#) in the Scenario and Analyses section of this guideline.

How do I design supportable “sampling” and “testing” protocols?

Frequently, the terms “sampling” and “testing” are used interchangeably. However, they are two distinct processes, and the establishment should maintain adequate support for both its sampling protocol and testing protocol.



FSIS recommends that establishments conduct sampling and testing of beef products at a frequency that provides a high probability of finding any STEC contamination that makes it through the slaughter and dressing operation (optimally, for every production lot) to protect against adulterated product entering commerce ([79 FR 47420](#)). Sampling and testing for STEC can provide evidence or verify that an establishment's STEC controls are effective and its HACCP system is functioning as intended. It is important to note that a negative test result does not guarantee that all of the beef from the sampled production lot is free of the pathogen. Such assurance cannot be provided by sampling and testing for the following reasons:

- Pathogens are not homogeneously distributed throughout food products which means sampling may miss isolated pockets of contamination;
- The product may have become cross-contaminated after it was sampled; or
- The STEC population may grow from below a detectable level to a detectable level if for example, it is not stored at appropriate temperatures.

As previously discussed, STEC initially contaminates the meat's exterior surface during slaughter. When large muscle cuts are ground, the grinding process mixes the exterior surface and any contamination, if present, with the internal muscle portions. Due to the sporadic low-level nature of STEC contamination, the sampling plan selected should be robust and focus on collecting thin pieces of the trim's exterior surface (e.g., N60 method) throughout the production lot to maximize the likelihood of detecting any STEC contamination, if present. FSIS continually assesses advancements in sampling methodologies and may adopt innovative approaches or methods other than incision and grab sampling (e.g., surface sampling). More information on sampling beef for STEC is available in the [FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* \(STEC\) Organisms or Virulence Markers](#).

STEC illness can be caused by the consumption of only a few cells of the pathogen ([76 FR 58158](#)). Therefore, when evaluating and selecting a testing method, it is important that the method is validated and includes the appropriate enrichment time and temperature to allow injured cells to recover and be detected. Enrichment permits very low levels of STEC contamination to be identified during testing. Changing the incubation time, temperature, or excluding some of the sample from analysis, without proper validation, can result in a lack of support for the testing method. Alternatively, FSIS recognizes some establishments conduct their own analyses in-plant and, based on the available equipment, may have to test multiple individual sub-samples of product independently (e.g., 65-g portions) as opposed to combining subsamples and testing them collectively. In both situations, the testing method would need to be validated for the chosen test portion. More information on testing methods validated for STEC is in [Foodborne Pathogen Test Kits Validated by Independent Organizations](#).

NOTE: Regardless of whether the testing occurs in-house, or at a third-party laboratory, the testing method should be equivalent to that used by FSIS laboratories. More information on FSIS methods and third party laboratories can be found in the [FSIS Microbiology Laboratory Guidebook](#) (MLG) and the [Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory](#).

Establishments should have procedures in place to hold or control product that is represented by a sample that they are testing for STEC pending receipt of results to prevent adulterated product from entering commerce. FSIS recommends that establishments complete pre-

shipment review in stages for product that is on hold pending receipt of test results so that it can move in commerce as soon as an adequate STEC test result is obtained.

NOTE: Product that FSIS tests for adulterants will not be allowed to move into commerce until acceptable results become available; the product must be held or controlled by the establishment pending acceptable results.

Are there regulations for determining a raw beef production “lot”?

Yes, as per [9 CFR 320.1\(b\)\(4\)\(iii\)](#), official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This ground beef recordkeeping lot definition is distinct from the STEC lot definition used to determine what product is to be held pending the receipt of STEC results when FSIS or the establishment perform STEC verification sampling and testing. Where stated, the definition of a lot should assure microbiological independence between the production lot tested and other production lots. As discussed, a “lot” of product, in the context of microbiological independence, is not necessarily limited to the raw ground beef produced between cleanings. FSIS recommends establishments define their production lots of raw beef products based on microbiological independence.

What role does microbiological independence play in controlling STEC?

Microbiological independence establishes the basis for which products are, or are not, implicated in response to a positive result, recalls, outbreak, etc. Lots should be defined so that if a STEC positive result is found for one production lot, product from another production lot would not be implicated. Such production lots are referred to as “microbiologically independent lots”. FSIS does not recognize “clean-up to clean-up” alone as a supportable basis for distinguishing one day or portion of raw beef production from another day or portion of production. STEC are generally not environmental contaminants and are carried in or on the raw beef; therefore, cleaning and sanitizing equipment between two production lots of raw ground beef, when the same source material lot is used (represented by the same lot code or by the same COA), does not create microbiological independence between the two final production lots. Alternatively, cleaning and sanitizing equipment between two production lots of raw ground beef, when two microbiologically independent lots of source material are used, can maintain microbiological independence of these two production lots. Common methods used to support microbiological independence between production lots include, but are not limited to:

- Robust sampling and testing data,
- Application of antimicrobial interventions,
- Source material used,
- Production equipment used, and
- Equipment sanitation.

More information on sanitation and lotting is available in:

- [The Resources and References](#) section of this guideline;
- [Beef Processing Best Practices: Grinders Sanitation, Lotting, and Sampling](#); and
- [FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results](#).

Raw non-intact beef products that are positive or presumptive positive (not confirmed negative) for STEC are adulterated unless they are further processed to destroy STEC. When a sample is positive for STEC, all product represented by the sample (i.e., the lot) is considered positive. When a STEC positive occurs, the establishment must demonstrate what product is affected by the positive result, on a case-by-case basis.

When positive product or an illness outbreak occurs, and the FSIS Recall Committee is convened to determine the amount of adulterated product in commerce, additional factors may be assessed, other than those specifically outlined in this document, to determine the scope of a recall. While following the guidance in this document is a best practice, it may not guarantee microbiological independence in every situation as the guideline cannot encompass all the possible scenarios that are unique to each individual recall case.

How does commingling of products affect a lot determination?

While each lot of ground beef does not have to be produced from source material from a single supplier, if this is done, it simplifies traceback and trace forward activities during an outbreak investigation. If a processing establishment or retail store commingles source materials used to produce ground beef, it should be able to easily identify the sources of the raw materials used to make the finished product. The practice of commingling source materials can complicate traceback and trace forward activities during outbreak investigations and can increase the scope of recalls should finished product be deemed adulterated.

NOTE: Product that contains meat from only one supplier that is mixed with non-meat ingredients (e.g., soy, spices) is still considered “sole source” product for the purposes of lotting, recalls and traceback.

FSIS defines commingling as direct meat-to-meat contact in a package, vat, or other container. Meat exposed to common food contact surfaces does not constitute commingling. Most of the STEC present on meat is the result of cross-contamination events during the slaughter and dressing processes. Unlike *Listeria monocytogenes* in ready-to-eat products, STEC does not persist and multiply to significant levels in the raw beef production environment. Therefore, provided the sanitation procedures are sufficient, food contact surfaces are typically not a significant source of STEC cross-contamination in raw beef products.

Individually cryovaced raw intact products can be used to create raw non-intact products (e.g., raw ground beef). When determining microbiological independence, the primary factor to consider is whether the source materials were commingled. FSIS recognizes that there may be rare situations when individually cryovaced product becomes commingled at the supplier establishment or further processor. The further processor's reconditioning procedures should address situations when unavoidable commingling occurs within its establishment. An example of acceptable reconditioning procedures at the supplier establishment or further processor

FSIS discourages establishments from mixing source materials from different raw meat suppliers, to allow for better tracking and identification of product up and down the distribution chain.

includes running product that may have been accidentally commingled individually through a validated antimicrobial treatment and ensuring that no commingling occurs after this antimicrobial treatment.

If a further processor wants to demonstrate that individually cryovaced primals or subprimals are a microbiologically independent lot, it would need to be able to demonstrate the individually cryovaced product was not commingled at the supplier establishment (as represented through a purchase specification or some other form of documentation) and is not commingled or cross-contaminated before sample collection. If the further processor is not able to obtain information about the prior history of the cryovaced product regarding commingling by the supplier establishment, or if the individually cryovaced product is commingled before sample collection, then the establishment likely would not be able to support a lot definition consisting of one individually cryovaced product.

When a single cryovaced package is the source material for finished raw non-intact product and the raw non-intact product tests positive for STEC, FSIS carefully evaluates the product's intended use and whether the product was commingled during the traceback investigation or FSIS Recall Committee meeting, to ensure the establishment's lot definitions are supportable and no other product injurious to human health was released into commerce.

Do establishments and retailers that grind beef have to keep grinding records?

Yes. As per *Federal Register* ([80 FR 79231](#)), FSIS amended its recordkeeping regulations in 9 CFR part 320 by adding [9 CFR 320.1\(b\)\(4\)](#) to require official establishments and retail stores that grind raw beef for sale in commerce to maintain specific information about their grinding activities. Specifically, [9 CFR 320.1\(b\)\(4\)](#) requires all official establishments and retail stores that grind beef for sale in commerce to maintain the following records:

- The unique establishment number for each establishment that supplies materials used to prepare each lot of raw ground beef product;
- All supplier lot numbers and production dates;
- The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
- The date and time each lot of raw ground beef product is produced; and
- The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

The above records need to be kept onsite where the product was ground, for at least one year from the grinding date. This rule applies only to establishments and retail stores that grind raw beef. The rule does not apply to other raw non-intact beef processing operations (mechanically tenderizing, cubing, injecting, etc.) conducted in official establishments or retail stores nor does it apply to portioning or repackaging raw ground beef. In addition, the rule only applies to the raw beef component that undergoes grinding to produce raw ground beef and does not apply to any non-meat ingredients added to the raw ground beef before or after grinding. Lastly, if the raw ground beef is fully cooked before it is distributed in commerce or to consumers and the official establishment or retail store maintains records for FSIS review that the raw ground beef product will be fully cooked before movement in commerce, FSIS does not enforce the grinding records requirements.

Each establishment's production process and lotting system is unique. When involved in an illness outbreak or recall situation, detailed records are advantageous to the grinder as they may pinpoint the source of the contamination and may limit the amount of product involved, thereby, limiting the financial impact. The recordkeeping system should be able to track product forward (*from source material, through production, and into the final product produced*) and backwards (*from the final product, back through production, and to the source material used*) throughout the production process. An example of a single-page tracking record is included in [Attachment 2](#). During traceback investigations, other non-intact products may be linked to the positive product if there is no evidence of microbiological independence between products. Therefore, FSIS may request that the establishment recall additional product. The grinding records rule is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that need to be recalled. FSIS has often been impeded in its efforts to trace raw ground beef products back to a supplier because of the lack of documentation identifying all source materials used in their preparation. When there is reason to believe that raw ground beef is adulterated, and it has moved in commerce, FSIS and establishments can trace the adulterated raw ground beef and the source materials used to produce the raw ground beef, through the distribution chain and remove them from commerce, as appropriate, using the production records (also referred to as grinding logs, required by the grinding records rule). These production records or grinding logs can provide the establishment or retail store and the Agency the information necessary to limit the scope of affected product and promptly remove it from commerce. In fact, if the grinding logs are diligently maintained they can serve to benefit the grinder by limiting the size, scope and potential financial impact of recalls.

As per [9 CFR 320.1\(b\)\(4\)\(iii\)](#), official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This lot definition is distinct from the STEC lot definition used to determine what product is to be held pending the receipt of STEC results when FSIS or the establishment perform STEC verification sampling and testing. Where stated, the definition of a lot should assure microbiological independence between the production lot tested and other production lots. As discussed, a "lot" of product, in the context of microbiological independence, is not necessarily limited to the raw ground beef produced between cleanings.

How does FSIS enforce the grinding records rule?

When the production of raw ground beef occurs in an official establishment, FSIS IPP verify the establishment meets the recordkeeping requirements as part of their routine inspection activities. If IPP find that the establishment fails to maintain the required records, FSIS may issue a noncompliance record (NR).

When the grinding and production of raw ground beef occurs in a retail operation, FSIS Compliance Investigators verify that the retail store meets these recordkeeping requirements as part of their routine surveillance activities. When investigators observe violations of the new

It is important to keep accurate records that contain all the necessary information to conduct traceback investigations. If the supplier's lot number on product obtained by a receiving establishment is missing or not legible, the receiving establishment (official establishment or retail store) should contact the supplier to obtain that lot number. If a lot number is not available, FSIS recommends that the grinder write down any other available supplier material information, such as bar code numbers, invoice numbers, etc.

recordkeeping requirements at a retail store they are to inform the management official, designee, owner or product custodian of the violation, obtain supporting evidence (in accordance with [FSIS Directive 8010.3](#), *Procedures for Evidence Collection, Safeguarding and Disposal*) and prepare a Report of Investigation for the violation (in accordance with [FSIS Directive 8010.4](#), *Report of Investigation*). A Letter of Warning or request that the Department of Justice initiate a civil action in Federal court to enjoin the defendant from further violations of the applicable law and regulations may be issued.

Records showing that the positive or presumptive positive product was received by an inspected establishment that ordinarily cooks the product is not sufficient to demonstrate that the product received proper disposition. The establishment that produced the product must obtain records that provide evidence that the entire lot of product was appropriately processed.

What actions are required in the event of a beef product positive for STEC?

If a beef product tests presumptive positive on a screening test, only a confirmatory test (culture) method that isolates STEC from the product can be used as an additional test to confirm or negate the presumptive positive test. If the confirmatory test is not conducted, the presumptive positive result will be considered as a confirmed positive result. Additional non-confirmatory testing of the same lot of beef product is not sufficient to show that the product is not adulterated. For example, if the first screening test is positive for STEC but a second screening test is negative, FSIS considers the entire lot of product adulterated.

Following the identification of the affected lot, the establishment is required to ensure that no product that is injurious to health or otherwise adulterated enters commerce. The amount of affected product will be determined based on the establishment's lotting and HACCP system. However, once the lot has been determined to be presumptive positive or confirmed positive, adding additional product to the lot only increases the affected lot size and does not create any microbiological independence (i.e., adding tested negative trim to tested positive product does not create microbial independence). The implemented corrective actions will depend on whether the positive result represents a CCP deviation requiring corrective actions, per [9 CFR 417.3\(a\)](#), or the positive result represents an unforeseen hazard requiring corrective actions, per [9 CFR 417.3\(b\)](#).

Establishments are required to maintain records showing proper disposal of beef product that is adulterated because the product is positive or presumptive positive for STEC. Specifically, [9 CFR 417.3](#) requires that establishments take corrective actions and [9 CFR 417.5\(a\)\(3\)](#) requires that they maintain records documenting their corrective actions. [9 CFR 417.3\(a\)\(4\)](#) and [\(b\)\(3\)](#) require that establishments' corrective actions ensure that no product that is injurious to health or otherwise adulterated enters commerce. As part of pre-shipment review, [9 CFR 417.5\(c\)](#) requires establishments to review the records associated with the production of adulterated product to ensure corrective actions were taken, including proper disposition of product, before signing the pre-shipment review. Additionally, if the establishment does not address STEC in its HACCP plan, the positive result represents an unforeseen hazard per [9 CFR 417.3\(b\)](#), and the establishment must perform the required reassessment and make any necessary changes to its HACCP system to ensure that no additional adulterated products are produced.

When a STEC-positive raw non-intact beef test result is obtained, the establishment needs to determine the amount of product that is implicated by the positive result. Criteria to support microbiological independence between positive product and other product are explained on [page 18](#) of this guideline. Due to the process used to produce the non-intact product, the pathogen may have already been translocated into the product or comminuted within the product by the time the positive result is received. As a result, the typical options for handling STEC-positive raw non-intact beef products include:

- Cooking the product in-house (at the official establishment that produced it) to a time and temperature combination adequate to eliminate STEC;
- Sending the product to another official establishment to cook the product to a time and temperature adequate to eliminate STEC;
- Sending the product to receive an adequate lethality treatment to eliminate STEC (e.g., High Pressure Processing (HPP) or irradiation);
- Sending the product to a renderer; or
- Sending the product to a landfill operation.

Raw non-intact beef products, beef products that may be intended for raw non-intact use, or beef products with an unknown intended use should not be diverted from an official establishment that is inspected to a retail facility that is exempt from inspection to address STEC. [9 CFR 303](#) specifies that only inspected and passed raw beef source materials are to be used in retail exempt establishments. Source materials for retail exempt processing must be produced under FSIS inspection and a validated HACCP system that addresses STEC.

What controls are needed to ship STEC positive or presumptive positive product?

Product that is positive or presumptive positive (and not confirmed negative) for STEC is adulterated and cannot move into commerce until it receives a treatment sufficient to destroy the pathogen in an FSIS-inspected establishment. Any movement of products that tested presumptive positive or positive for pathogens should be under documented company control (such as company seals or FSIS control). If such product is going to another official establishment, it may move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1).

Product going to a landfill, off-site renderer, or pet food manufacturer (unless shipped under permit below) needs to be denatured before shipment, and include the appropriate controls in place (e.g., seals). Establishments are not to send these products to a broker or independent warehouse facility unless they are able to demonstrate how they control the product when it is at one of these facilities. FSIS considers “disposition” under 9 CFR 416.15 and 417.3 corrective actions to be completed once the establishment can demonstrate the product is inedible and not intended for human food (9 CFR 301.2). The requirements for handling inedible, onsite tanking facilities, denaturing and movement of undenatured inedible for nonfood purposes under a permit (e.g., pet food) are in 9 CFR 314.

Product that is positive or presumptive positive for STEC is eligible to be sent to a pet food manufacturer. FSIS recommends that FSIS-inspected establishments communicate with pet

food manufacturers before sending products containing STEC to a pet food manufacturer, so that the pet food manufacturer is aware that the ingredient they are receiving contains a pathogen which will need to be controlled in their finished pet food.

Pet food facilities required to register with the Food and Drug Administration (FDA) as a food facility must comply with FDA's Preventive Controls for Animal Food (PCAF) regulation, at 21 CFR part 507, unless an exemption applies. Under the PCAF regulation, registered facilities are required, in part, to identify and control any hazards requiring a preventive control that are associated with their incoming ingredients (21 CFR §§ 507.33 and 507.34). As a result, if a pet food facility is receiving ingredients that are or may be positive for STEC, it would be required to identify and evaluate that food safety hazard and implement a preventive control that has been validated to prevent or significantly minimize the hazard (21 CFR §§507.34 and 507.47). A typical preventive control applied is a heat treatment, which is used in the kibble and treat market quite extensively. Without adequate implementation of the PCAF requirements, such as a validated preventive control in place to ensure pathogens are significantly minimized, FDA would consider pet food manufactured from a pathogenic STEC-contaminated ingredient to result in an adulterated product (21 CFR §507.1(a)). Some pet food facilities may not be subject to the hazard analysis and risk-based preventive controls requirements of the PCAF regulation, for example, because they are not required to register as a food facility or because they meet another exemption to the requirements under 21 CFR §507.5. However, these facilities still have an obligation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§331 and 342) not to introduce adulterated pet food into interstate commerce. As a result, FDA expects such facilities to put in place appropriate processes and procedures to ensure that any animal food they produce using ingredients containing microbiological pathogens is not adulterated.

More information on FDA food facility registration requirements is available at: <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>. More information on FDA PCAF requirements is available at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food>.

Scenarios and Analyses

The following scenarios and analyses apply the recommended best practices provided in this guideline in a practical manner; the scenarios presented encompass some of the more common decisions made by establishments that produce raw non-intact beef products when developing HACCP systems to assure these products do not contain STEC at detectable levels.

Scenario #1: *Inadequate Use of Purchase Specifications; Letters of Guarantee (LOG) Only*
A processing establishment receives boxed vacuum packaged subprimals from a variety of different establishments, through a broker, to produce two raw non-intact beef products (i.e., tenderized steaks and raw ground beef). The boxed beef is received from different slaughter establishments each week, based on distributor prices, and the receiving establishment does not have a direct relationship with any of the slaughter establishments. The establishment made the decision that STEC is NRLTO at the receiving step based on the LOG received from each slaughter establishment, updated every 6 months. The LOGs indicate that the product is intended for intact use. The establishment is not able to receive Certificates of Analysis

(COAs) and is unable to show that any of the product received has ever been tested for STEC nor does the establishment apply any further interventions to reduce STEC. The establishment samples the finished raw ground beef six (6) times annually, as outlined in the ongoing verification recommendation for establishments producing <5,000 lbs. of non-intact beef each week.

Analysis - The approach to STEC control used by the receiving establishment in Scenario #1 is flawed because it fails to appropriately address STEC. The LOG required by the receiving establishment identified the product is for intact use and does not provide adequate support that STEC is below detectable levels in the incoming beef (source materials) that will be processed into raw non-intact beef products. The sampling conducted by the receiving establishment would not be considered adequate verification of the establishment's HACCP system by itself, because the establishment does not have an actual control measure for STEC. Subsequently, the six results generated annually would not provide adequate meaningful information about the system's ability to control STEC because the establishment does not conduct sampling and testing on a lot-by-lot basis. The establishment should request from the supplying establishments evidence that the source materials were tested and found negative for STEC (purchase specifications) or would need to develop and validate its own control measures for STEC (in-house controls), such as lot-by-lot testing of product or application of an antimicrobial treatment. When an actual control is in place, the six annual samples could serve as the ongoing verification data necessary to demonstrate the receiving establishment's HACCP system is functioning as intended. The above HACCP system, as designed, is inadequate to address STEC.

Scenario #2: Non-Intact Beef Processor not Adequately Addressing Hazards (STEC)

A low-volume raw non-intact beef processing establishment (<5000 lbs. weekly) does not slaughter but instead receives beef products from multiple suppliers. The establishment receives boxed beef manufacturing trimmings, with a LOG and a COA for each lot to support STEC at non-detectable levels. In addition, the processing establishment also receives boxed vacuum package beef primals and produces various steaks, roasts and bench trimmings to fill daily orders. The receiving establishment has documentation for the primals indicating that they are not intended by the supplier for raw non-intact use. The processing establishment does not apply an antimicrobial treatment to the primals prior to trimming. In its grinding operation, the establishment combines the two types of trimmings and samples the finished raw ground beef six times annually.

Analysis - In this instance the establishment has adequately addressed STEC in the purchased beef manufacturing trimmings: the establishment maintains a LOG, receives a COA for each lot and conducts product sampling and testing as part of its ongoing verification. However, the establishment has not adequately addressed STEC in the bench trimmings created from the primals received because the establishment has changed the intended use of the product and not applied additional controls for STEC to the product. The establishment should request from the supplying establishment evidence that the primal source materials were tested and found negative for STEC (purchase specifications) or should develop and validate its own control measures for STEC (in-house controls), such as lot-by-lot testing of product or application of an antimicrobial treatment. When an actual control is in place, the six annual samples could serve as the ongoing verification data necessary to demonstrate the receiving establishment's HACCP system is functioning as intended. The above HACCP system, as designed, is inadequate to address STEC.

Scenario #3: Slaughter-Processing Operation – Self-Supplier Only

A beef slaughter-processing establishment slaughters 5-10 cattle each week and produces various raw intact and raw non-intact beef products (including raw ground beef and vacuum-marinated steaks), per customer orders. The establishment uses sanitary dressing procedures to limit contamination during slaughter, monitors carcasses for dressing failures, implements a zero-tolerance examination CCP for fecal control, applies a validated antimicrobial treatment at a CCP to reduce STEC to below detectable levels on the carcasses before chilling and maintains the product at temperatures that inhibits pathogen outgrowth. For ongoing verification, the establishment has developed a written sampling program at the recommended quarterly frequency (four samples annually). The written sampling program provides instructions for sample collection by the establishment and allows for the use of FSIS results if collected within the quarterly verification time period. No outside beef (source material) is received or processed into raw non-intact beef product at the establishment.

Analysis - In this example, the establishment uses a systematic approach to address STEC in its Slaughter HACCP plan by using measures to prevent carcass contamination, conduct zero tolerance examinations of carcasses for contamination and reduce STEC with an antimicrobial treatment. Proper cold chain management following slaughter would support that STEC outgrowth would be prevented. The sampling results generated on an ongoing basis from the written sampling program, showing results from establishment and FSIS samples provide adequate support that the Slaughter HACCP plan and temperature controls are functioning as intended to reduce STEC to below detectable levels in the raw non-intact beef products. The above HACCP system is adequate.

Scenario #4: LOG and Tested Product Without Lot-by-Lot COA

A small establishment receives 2,000 lbs. of coarse raw ground beef daily from multiple external suppliers and produces various raw ground beef products and raw ground beef patties. The receiving establishment's purchase specification program requires a LOG from each coarse ground beef supplier that describes the supplier's controls in place for STEC, including one or more validated antimicrobial treatments and product sampling and testing. The receiving establishment is not able to receive a traditional "lot-by-lot" COA from each supplier but does maintain the LOG and shipping invoices or other similar supporting documents from the suppliers, stating that each lot of product was produced from STEC negative lots of beef trim. The documents include the sampling and testing method, amount analyzed, and a description of how the test results show STEC has been reduced to below detectable levels in the lots of coarse raw ground beef received. In addition to the routine lot testing documentation, the receiving establishment requires each supplier to routinely provide the results of their verification sampling and testing to address ongoing verification. The receiving establishment verifies these records for each supplier six times per year. In addition, the receiving establishment has a CCP in place to effectively address cold chain maintenance through the process.

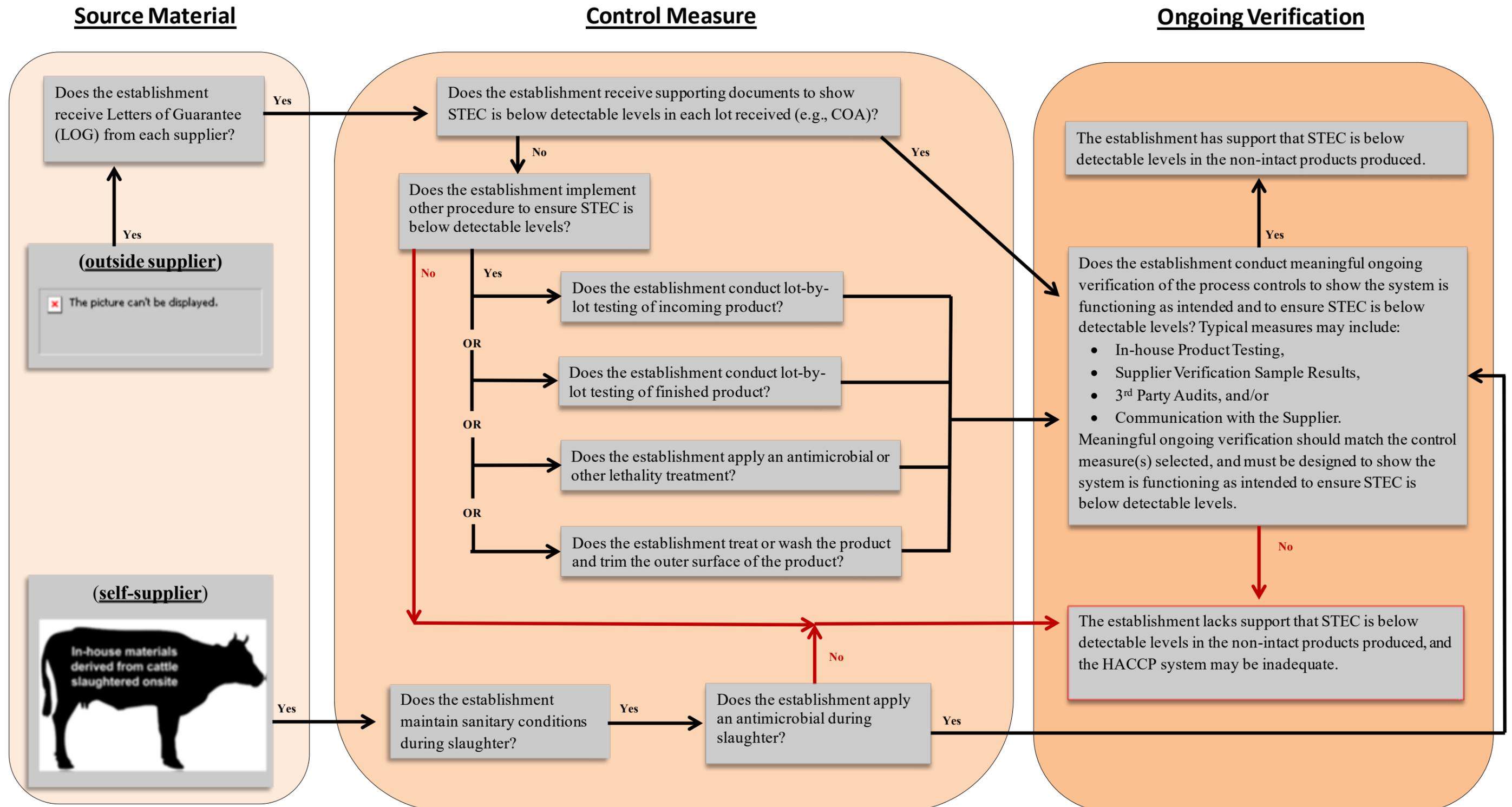
Analysis - The receiving establishment is able to obtain a LOG but is unable to obtain a traditional "lot-by-lot" COA from its external suppliers. However, the receiving establishment is able to gain knowledge of each supplier's slaughter process, STEC controls, and test-and-hold procedures and maintains associated supporting documentation (e.g., statement on the invoice or other document on file). The receiving establishment is also able to show that the product received from its suppliers was derived from source materials that tested negative for STEC and that it received specific information from the suppliers concerning each lot of incoming product that is equivalent to a lot-by-lot COA. The information from suppliers

provides the receiving establishment with the necessary support that STEC is reduced to below detectable levels in the source materials received. The ongoing verification sampling results submitted by the suppliers provides the receiving establishment with the ongoing verification documentation necessary to verify the LOG. The other documentation provided by the suppliers supports that STEC is NRLTO in the incoming beef products and that the receiving establishment's HACCP system is functioning as intended. In addition, the receiving establishment has a CCP in place to effectively address cold chain maintenance of the source materials and "finished" product. The above HACCP system is adequate.

APPENDICES

Appendix 1, STEC Decision-Making Flow Chart Guide

This flow chart can be used as the framework to understand how control measures for internal and/or external source materials and ongoing verification work together to ensure the HACCP system functions as intended to prevent or control STEC to below detectable levels in the products produced. Typically, divergence from the flow pathways on the chart below or supplying a “no” answer with no further options indicates a flaw in the HACCP system. It is acceptable to follow different pathways for different source materials and different non-intact products produced, as long as all source materials used, and every non-intact beef product produced is accounted for within the HACCP system. In addition to the below control measures and ongoing verification, appropriate temperature controls must be in place throughout the process to ensure STEC does not grow from a non-detectable level to a detectable level.



Appendix 2, Grinder's Log

This log template is designed to track the source materials used, the products produced, and any microbiological independence between lots. Establishments are encouraged to use the below template as a guide, and include any additional information in the record to fit their unique production processes.

NEW WAVE STORE

123 Main Street

Anytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name _____ Today's Date _____

Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments

Signature of Store Management Reviewer

Date

Appendix 3, Resources and References

Below is a list of published studies and reference materials that may be useful for small and very small establishments when developing STEC preventive measures. The list includes various reference materials outlining industry best practices for beef operations and numerous publications on antimicrobial treatments commonly used by industry. FSIS does not approve or recommend any one particular antimicrobial treatment over another. Under the HACCP regulations, establishments are required to select the antimicrobial treatment or treatments that best fit the establishment's unique operations, identify the critical factors applicable to the production process, and implement the treatment in a manner consistent with the support.

Organic Acids

- Geornaras, I, Yang, H, Moschonas, G, Munnelly, MC, Belk, KE, Nightingale, KK, Woerner, DR, Smith, GC, and Sofos, JN. 2012. Efficacy of chemical interventions against *Escherichia coli* O157:H7 and multidrug-resistant and antibiotic-Susceptible *Salmonella* on inoculated beef trimmings. *J. Food Prot.* 75: 1960-1967.
- Schmidt, JW, Bosilevac, JM, Kalchayanand, N, Wang, R, Wheeler, TL, and Koochmaraie, M. 2014. Immersion in antimicrobial solutions reduces *Salmonella enterica* and Shiga toxin-producing *Escherichia coli* on Beef cheek meat. *J. Food Prot.* 77: 538-548.
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- Wolf, M. J., Miller, M. F., Parks, A.R., Loneragan, G. H., Garmyn, A. J., Thompson, L. D., Echeverry, A., and Brashears, M. M. 2012. Validation comparing the effectiveness of a lactic acid dip with a lactic acid spray for reducing *Escherichia coli* O157:H7, *Salmonella*, and Non-O157 Shiga toxigenic *Escherichia coli* on beef trim and ground beef. *J. Food Prot.* 75: 1968-1973.

Oxidizer Antimicrobials

- Penney, N., Bigwood, T, Barea, H., Bulford, D. LeRoux, G, Cook, R., Jarvis, G., Brightwell, G. 2007. Efficacy of peroxyacetic acid formulation as an anti-microbial intervention to reduce levels of inoculated *Escherichia coli* O157:H7 on external carcass surfaces of boned beef and veal. *J. Food Prot.* 70: 200-203.

Dry Aging as an Intervention

- Tittor, A.W., Titor, M.G., Brashears, M.M., Brooks, J.C., Garmyn, A.J., and Miller, M.F., 2011. Effects of Simulated Dry and Wet Chilling and Aging of Beef Fat and Lean Tissues on the Reduction of *Escherichia coli* O157:H7 and *Salmonella*. *J. Food Protection*, 74(2): 289-293.

Hide-On Carcass Wash:

- Schmidt, J. W., R. Want, N. Kalchayanand, T. Wheeler, and M. Koochmaraie. 2012. Efficacy of hypobromous acid as a hide-on carcass antimicrobial intervention. *J. Food Prot.* 75(5):955-958.
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- Arthur, T. M., J. M. Bosilevac, D. M. Brichta-Harhay, N. Kalchayanand, S.D. Shackelford, T.L. Wheeler, and M. Koochmaraie. 2006. Effects of a Minimal Hide Wash Cabinet on the Levels and Prevalence of *Escherichia coli* O157:H7 and *Salmonella* on the Hides of Beef Cattle at

Slaughter J. Food Prot. 70: 1076–79.

Steam Vacuum Systems:

- Kochevar, S. L., J. N. Sofos, R. R. Bolin, J. O. Reagan, G. C. Smith. 1997. Steam Vacuuming as a Pre-Evisceration Intervention to Decontaminate Beef Carcasses. J. Food Prot. 60: 107-113.
- Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, and G. R. Acuff. 1999. Decontamination of beef carcass surface tissue by steam vacuuming alone and combined with hot water and lactic acid sprays. J. Food Prot. 62(2), 146-151.

Organic Acid Rinses:

- Gastillo, A, L. M. Lucia, K. J. Goodson, J. W. Savell, G.R. Acuff. 1998. Comparison of Water Washing, Trimming, and combined Hot Water and Lactic Acid Treatment for Reducing Bacteria of Fecal Origin on Beef Carcasses. J. Food Prot. 61: 823-828.
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- Kalchayanand, N., T. M. Arthur, J. M. Bosilevac, D. M. Brichta-Harhay, M. N. Guerini, S. D. Shackelford, T. L. Wheeler, and M. Koohmaraie. 2009. Effectiveness of 1,3-Dibromo-5,5 Dimethylhydantoin on reduction of *Escherichia coli* O157:H7- and *Salmonella*-inoculated fresh meat. J. Food Prot. 72(1): 151-456.

Hot Water Rinses:

- Castillo, A., L. M. Lucia, K. J. Goodson, J. W. Savell, G. R. Acuff. 1998. Comparison of Water Wash, Trimming, and Combined Hot Water and Lactic Acid Treatments for Reducing Bacteria of Fecal Origin on Beef Carcasses. J. Food Prot. 61: 823-828.
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Steam Pasteurization:

- Davey, K. R. and M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. *Int. J. Food Sci Tech.* 24: 305-316.
- Dorsa, W.J., C. N. Cutter, G. R. Sirgusa, and M. Koohmaraie. 1996. Microbial Decontamination of Beef and Sheep carcasses by Steam, Hot water Spray Washes, and a Steam-vacuum Sanitizer. J. Food Prot. 59: 127-135.

- AMI Lethality model, demonstrating lethality at 160°F at carcass surface.
- Nutsch, A. L., R. K. Phebus, M. J. Riemann, J. S. Kotrola, R. C. Wilson, J. E. Boyer, and T.L. Brown. 1998. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. *J. Food Prot.* 61:571-577.
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High Pressure Processing (HPP)

- Alpas, H, Kalchayanand, N, Bozoglu, F, and Ray, B. 2000. Interactions of high hydrostatic pressure, pressurization temperature and pH on death and injury of pressure-resistant and pressure-sensitive strains of foodborne pathogens. *International J. of Food Microbiology.* 60: 33-42.
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Beef Processing Best Practices: Grinders Sanitation, Lotting, and Sampling

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- Best practices for purchasers of raw beef for non-intact use, (2016), https://www.bifsc.org/Media/BIFSCO/Docs/guidance_for_purchasers_of_raw_beef_for_non-intact_use_final.pdf
- Guidance document for sampling and lotting of beef products and sample analysis for

pathogens,

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- Guidance for minimizing impact associated with food safety hazards in raw ground meat and other FSIS regulated products, (2002),
<http://www.haccpalliance.org/sub/food-safety/BeefGrindGuide.pdf>



<https://www.fsis.usda.gov/contact-us/askfsis>

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