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

2017 Compliance Guideline

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

- 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.
- Develop grinding logs that identify and track source materials and products produced.
- Respond when the HACCP system failed to prevent, or reduce STEC to below detectable levels

Preface

What is the purpose of this Compliance Guideline?

The Food Safety and Inspection Service (FSIS) published this guideline to assist small and very small processing establishments that produce raw non-intact beef products (e.g., ground beef and mechanically tenderized beef), raw intact beef products intended for non-intact use, or raw intact beef products where the intended use is not clear. This guideline is designed to help establishments understand the adulterant status of STEC in beef products, design supportable control measures for STEC, develop ongoing verification measures to demonstrate that the HACCP system is functioning as intended to reduce STEC to below detectable levels, develop grinding logs to track products, and respond to positive STEC sample results.

This document provides guidance to assist establishments in meeting FSIS regulations. This guideline represents FSIS' best practice recommendations, based on the best scientific and practical considerations, and does not necessarily represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline. 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 small and very small establishments with compliance 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 policy guidance to the askFSIS Website and publishes directives and notices that provide Agency personnel with instructions for testing and other verification activities related to STEC. This guideline brings together the most current policy material and guidance on STEC in beef products, and aids small and very small establishments in understanding the features and preventive measures that are necessary to address STEC in non-intact beef product and product components when designing a HACCP system.

For the purpose of this document:

- When the document references beef; veal is also included
- When the document references non-intact products, also included are:
    - non-intact product components (e.g., as head meat, cheek meat, and weasand meat);
    - products intended for non-intact use; and
    - products where the intended use is unclear.
- 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 document, because STEC is not an adulterant in these products (see page 4 for more information).
- The procedures described in this document to reduce STEC will also assist establishments in reducing *Salmonella*.

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

This single guideline updates and combines information from the following guidance documents, which will now be considered retired and replaced.

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

FSIS has made policy changes since issuing the previous guidelines. 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 inspection program personnel. This guideline incorporates current Agency thinking on the use of antimicrobial treatments, establishment sampling programs, and other measures in the establishment's HACCP system.

How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days after the date of publishing November 6, 2017 and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Mail, including CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: *FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing* Escherichia coli *(STEC) in Raw Beef (including Veal) Processing Operations*. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Although FSIS is requesting comments on this guideline and may update it in response to comments, FSIS encourages establishments to utilize the information contained in this guideline as it reflects FSIS's current position.

Is this version of the guideline final?

FSIS will update this guideline in response to comments as necessary.

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

If the desired information cannot be found within the Compliance 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 helps FSIS improve and refine present and future versions of the Compliance 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: **FSIS Compliance 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?

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 intact beef products intended for non-intact use. Although there are many other Shiga Toxin-producing *E. coli* (STEC), this document only refers to the 7 serogroups listed above, which are collectively referred to as STEC.

FSIS is revising this document because it has seen that many small and very small establishments have had difficulty in designing and supporting their HACCP system (e.g., HACCP plan, Sanitation Standard Operating Procedure, or other prerequisite program) in a manner to prevent, eliminate, or reduce STEC to an acceptable level. Consequently, FSIS continues to receive questions related to STEC and HACCP systems. In addition, FSIS continues to take enforcement actions at processing establishments for HACCP systems that inadequately address STEC. This guideline combines past compliance guidelines, incorporates guidance posted to askFSIS, and serves as a comprehensive source of information for small and very small establishments when developing a sound HACCP system that address STEC in raw non-intact beef processing operations.

"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. STEC includes *E. coli* O157:H7 and six non-O157 serogroups: O26, O45, O103, O111, O121, and O145. Raw non-intact beef products and beef products intended for non-intact use may be injurious to the public's health if contaminated with STEC. Therefore, all seven serogroups above are considered adulterants in raw non-intact beef and beef intended for non-intact use under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)).

As required by the HACCP regulations contained in 9 CFR 417, each establishment must conduct a hazard analysis for its production process to determine the hazards that are reasonably likely to occur (RLTO). STEC contamination is a food safety hazard during the slaughter and processing of raw beef products. Establishments producing raw non-intact beef product should address STEC in their HACCP systems. This guideline applies to a wide range of production practices at both beef processing establishments and combination beef slaughter-processing establishments, and provides establishments with the comprehensive framework to understand and control STEC, and verify those controls are effective in reducing STEC to below detectable levels. This guideline provides small and very small establishments with the information necessary to make well-informed decisions regarding the adequacy of the controls in place for STEC and methods used to verify that the controls are functioning as intended. FSIS recognizes that extensive, high frequency sampling and testing may be cost prohibitive for small and very small establishments. Therefore, designing and implementing an effective HACCP system for minimizing the risk of STEC is outlined in this document.

Non-intact products include: ground beef; beef that an establishment has injected with solutions; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling, cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; and diced beef less than ¾ inch in any one dimension.

Where does STEC come from?

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

The effectiveness of any slaughter process to control STEC begins with effective sanitary dressing procedures to minimize contamination in conjunction with 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)
- FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin producing *E.coli* (STEC) and *Salmonella* in Beef (including veal) Slaughter Operations 2017.

FSIS considers controls that are validated to control *E. coli* O157:H7 are also effective against non-O157 STEC. Therefore, a hazard analysis may specifically list each of the 7 STEC individually, or *E. coli* O157:H7, or STEC, etc. These are all considered the same adulterant (i.e., STEC) (76 FR 58157).

Since STEC contamination has historically occurred in the production of raw non-intact beef products, FSIS recommends that processing establishments incorporate additional procedures into their HACCP systems to support that STEC is not a hazard in the finished product(s). This document discusses measures processing establishments may implement to ensure that STEC has been reduced below detectable limits on products intended for raw non-intact use.

What HACCP regulatory requirements apply to STEC?

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.

From the HACCP perspective, these two regulations work collaboratively. In short, 9 CFR 417.2(a)(1) requires establishments to determine the hazards associated with the process and 9 CFR 417.5(a)(1) requires them to support the adequacy of the HACCP system to address the hazards. STEC contamination of non-intact beef products has historically occurred and caused human health illnesses. Therefore, as explained in the *Federal Register* (76 FR 58157), establishments need to consider both the potential presence and potential outgrowth of STEC in the product, as they both play a critical role in ensuring STEC has been reduced to below detectable levels in raw non-intact beef products.

Temperature controls can inhibit the growth of STEC, but even freezing would not reduce STEC to below a detectable level. Establishments need to control both the presence and outgrowth of STEC, to ensure the products are not adulterated.

Is STEC considered an adulterant in all beef?

No, STEC is not considered an adulterant on raw beef products "intended" for intact consumer use (e.g., steaks and roasts). That is because when STEC is present on the meat's exterior surfaces and the product remains intact (intended use), normal consumer cooking will destroy any STEC that may be on the outer surface, even if the product is cooked to a rare or medium internal state. STEC is considered an adulterant in raw non-intact beef products and intact beef products intended for non-intact use (e.g., ground or needle tenderized) or when the intended use is not clearly defined or supported. In order 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 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 the non-intact process (e.g., grinding, tenderizing). In this case, normal cooking to a rare or medium rare internal state may not be sufficient to destroy STEC 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.

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 in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment's intended use for the specific 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 for intact use only. When the receiving establishment plans to use the product in a manner that conflicts with the supplier's intended use for that product, the receiving establishment would need to implement additional controls for STEC. The communication of the intended use of the product, identified at each level of the distribution chain including retail, is an important component for each establishment to consider when addressing STEC and developing a supportable HACCP system.

An establishment may receive and grind source materials that were not intended for grinding. However, the receiving establishment must address that specific use in its hazard analysis.

Are customary cooking practices or validating cooking instruction labels enough to address STEC in raw non-intact beef products?

No. Validated cooking instructions cannot serve as a control or critical control point to address STEC in the production of raw non-intact products. Because of the history of severe outbreaks and illness associated with the consumption of undercooked non-intact beef products, FSIS

concluded in the *Federal Register* (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 on raw or partially cooked needle or blade tenderized beef products destined for household consumer, hotels, restaurants, or similar institutions contain validated cooking instructions, because these non-intact products do not always appear non-intact to the consumer. If non-intact beef products (including partially cooked needle or blade tenderized products) are found to be adulterated, validated cooking instructions on the label do not prevent the product from being recalled nor do they provide a means of product disposition. That is because the label is a measure to inform the consumer of the need to cook the product thoroughly. However, these labels do not replace for need for establishment to address STEC in its HACCP system to ensure that the product is safe and wholesome before being distributed into commerce.

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 non-intact raw 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 block other than beef is more predominant by weight than is ground beef;
- Shaped and formed 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 certain non-intact products described above, must maintain all the supporting documentation described below that supports 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 of other STEC positive products without any other evidence of microbiological independence. Therefore, in the absence of this additional support, FSIS may request that the product may be recalled, even if consumers are likely to cook the product.

As part of the establishment's decision making regarding STEC in the hazard analysis, establishments need to clearly state the intended use of the product (9 CFR 417.2(a)(2). Establishments also need to have documentation on file supporting their 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 the hazard analysis or decision-making documents any contractual controls the establishment may have in place to ensure their customers will prepare the non-intact product in a manner whereby STEC would not be a significant health risk. This may include decisions associated with having 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 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 the 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 non-intact products?

There is no one, absolute way for an establishment to prevent or control STEC. The primary factors that guide the development of effective food safety measures are the source of the beef and the product's intended use. Since STEC is primarily associated with cross-contamination during slaughter, each processing establishment must develop its own measures to address STEC based on knowledge and level of assurance of the STEC controls applied at slaughter.

Establishments that conduct raw non-intact processing typically receive beef source materials in two distinct ways: from an outside slaughtering establishment or directly from their own in-house slaughter operations. In establishments that use beef from both sources, the establishment would have to consider and address STEC for both aspects of its operation. Attachment 1 includes a flow diagram to guide a decision-making process for STEC control in each of the pathways.

Combination Slaughter-Processing or "Self-Supplier"

In establishments that conduct both slaughtering and processing, knowledge of the slaughter controls for STEC are readily available within the establishment and are self-contained within the HACCP system. To reduce STEC to below detectable levels, the HACCP system's decision-making process typically uses a multi-hurdle approach, including:

- 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; and
- Proper cold chain management to prevent STEC growth.

If an establishment has a validated HACCP plan that is functioning as intended, and the establishment controls its process through 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. In addition, verification (e.g., sampling) must be in place to demonstrate the system continues to function as intended, on an ongoing basis. On-going verification is discussed later in this document. In other words, the establishment's raw non-intact HACCP program may be able to support that STEC was reduced to below detectable levels by the STEC multi-hurdle approach contained in its slaughter HACCP program.

Receiving Establishment or "Outside-Supplier"

In establishments that receive product from suppliers, knowledge of the STEC controls at slaughter is not self-contained within the receiving establishment's HACCP system. The establishment either needs detailed information that the supplier is meeting necessary purchase specifications or needs to apply additional procedures to address STEC. The receiving establishment's ability to support whether STEC has been reduced to below

detectable levels in the products received will determine whether the establishment is able to address STEC using purchase specifications or use in-house controls. Establishments may use a combination of prerequisite programs and CCPs to address STEC presence and growth during the production of raw non-intact products from beef products received from an outside supplier.

To address STEC in products at receiving, a purchase specification prerequisite program often can be used to provide the additional knowledge and support for the controls previously applied to demonstrate STEC is below detectable levels in the products received. If the establishment determines that STEC is NRLTO 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. An LOG should be maintained for each establishment's meat used, and be updated routinely at a frequency sufficient to be credible;
- A Certificate of Analysis (COA) or similar information 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 should include the actual test result, the sampling method (e.g., N-60), the testing method, amount analyzed, and product description to match the purchased product. The COA or similar information should be received for each lot of product received, on a lot-by-lot basis.
- A method of ongoing verification in accordance with 9 CFR 417.4 (e.g., product testing) must be in place at the receiving establishment to demonstrate its HACCP system continues to function as intended, on an ongoing basis. On-going verification is discussed later in this document.

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

In situations where an establishment receives beef and is unable to receive COAs or similar information supporting that STEC is NRLTO in the product the establishment has the following options to demonstrate that STEC is below detectable levels:.

- Product Testing – This method functions by demonstrating STEC is already below detectable levels in the product received and produced. Establishments have the option of testing either incoming product or finished product. Due to the lack of knowledge concerning the controls applied during slaughter and lack of a microbial reduction applied in-house, when sampling is selected as the only measure to address STEC, it should occur on a lot-by-lot basis, and establishments should be aware that sampling and testing is not a control; sampling and testing are verification activities. This option can be very cost prohibitive, and FSIS does not recommend it alone, as it relies on the detection or non-detection of STEC on a lot-by-lot basis rather than a systematic control for STEC.

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.

- STEC Reduction – These methods function by reducing STEC on the meat surface to below a detectable level before non-intact processing. Establishments can apply an antimicrobial intervention, another lethality treatment, or treat or wash the product and trim the entire outer surface. Ideally, the STEC reduction method would be a CCP

because the recordkeeping, monitoring, and verification make it the strongest approach. However, it may be acceptable to create a validated pre-requisite program that includes recordkeeping, monitoring, and verification procedures to ensure STEC is below detectable levels in the product produced. Establishments must properly design and fully validate the 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 in:
FSIS Compliance Guideline HACCP Systems Validation (April 2015).

NOTE: Establishments that receive ground beef and repackage the ground beef without reducing the particle size or adding other source materials (i.e., portioning), should address STEC in their hazard analysis as STEC is a potential hazard in raw non-intact beef products. However, portioned ground beef products are not subject to FSIS verification testing.

A list of antimicrobial interventions and supporting documentation is in the Resources and References section of this guideline. The list is not all encompassing, but includes common interventions and operational parameters for developing STEC controls in small and very small operations. FSIS encourages multiple interventions where possible, as part of the systematic approach. The application of multiple interventions (or "hurdles") has shown to be more effective than using a single intervention alone. Establishments should be aware that use of certain antimicrobial interventions may impact the product's export eligibility to some countries. Eligibility requirements for export to other 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 supporting documentation for an antimicrobial's effectiveness.

There is not one "superior" antimicrobial intervention against STEC. When searching for an antimicrobial treatment, establishments should review the supporting documentation available and choose an intervention based on the HACCP system, available equipment, facility requirements, product type, and financial situation. Establishments should review FSIS Directive 7120.1, *Safe and Suitable Ingredients in the Production of Meat, Poultry and Egg Products,* to verify the chemical intervention is being applied in a safe and suitable manner, and does not violate any applicable concentration or labeling requirements. FSIS Directive 7120.1 does not support a chemical's efficacy; additional scientific supporting documentation is needed to show that the substance is effective against STEC.

A temperature control program is necessary to prevent STEC outgrowth during the production process. Temperature controls can inhibit the growth of STEC, but even freezing would not reduce STEC to below a detectable level. As is noted above, establishments need to control both the presence and outgrowth of STEC, to ensure the products are not adulterated. Maintaining a proper product temperature during storage and processing ensures STEC will not grow from a previously undetectable level to a detectable level.

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

As is fully explained in the validation guidance (see link below), initial validation, ongoing verification, and reassessment are three distinct components of 9 CFR 417.4. These HACCP principles are relevant not only to a CCP; they apply to the entire HACCP system.

The purpose of validation is to demonstrate that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product. The purpose of ongoing verification is to demonstrate that the HACCP system continues to function as intended. It is common for establishments to measure the critical operational parameters or conduct product testing during initial validation to show the HACCP system addresses the hazard. However, doing so does not negate the need for frequent ongoing verification activities, such as testing, for appropriate pathogens and program evaluation, to support that the HACCP system continues to function as intended. More information on validation is in FSIS Compliance Guidelines for HACCP Systems Validation.

Why does FSIS recommend testing as a 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 requirement for product testing. However, understanding why product testing is so common and why it is so important for a sound HACCP system relates to the complexity of the hazard itself.

Per 9 CFR 417.4, establishments perform verification procedures such as, calibrating process monitoring instruments, directly observing monitoring and corrective actions, and reviewing the records. This list is not all encompassing, and does not include all ongoing verification activities necessary for every HACCP system. For non-intact beef products and beef products intended for non-intact use, the HACCP system needs to reduce STEC 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 develop a method of ongoing verification. Sampling and testing can play a critical part in that systematic approach. Testing of product provides a statistical confidence that the product is not contaminated with STEC. However, negative test results do not provide 100% certainty that the product is not contaminated. For that reason, testing is a verification activity that demonstrates that a HACCP system is functioning as intended rather than a control for pathogens.

How often does ongoing verification need to be conducted?

Ongoing verification should be designed to ensure that the HACCP system is functioning as intended. Knowledge of individual controls applied to address STEC, the number and types of products produced, the intended and final actual use of the product, the production volume, past HACCP system failures, and other factors should be considered when developing ongoing verification procedures and frequencies.

Each establishment needs to evaluate if the selected verification procedures and associated frequency provides meaningful data about the HACCP system and are adequate to show that the system continues to function as intended to ensure 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, such as receiving COAs, applying an antimicrobial and testing product. These measures are separate from ongoing verification. Ongoing verification

is the HACCP principle responsible for verifying that the HACCP system measures are functioning as intended. When testing is used for ongoing verification, FSIS recommends the following minimum frequencies for establishments conducting sampling as an ongoing verification activity for either products intended for raw non-intact use or for finished raw non-intact products (based on volume of production):

- >250,000 lb weekly - sample at least once per month (12 times annually);
- 5,000-250,000 lb weekly - sample at least once every 2nd month (6 times annually);
- <5,000 lb 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 frequencies should increase the recommended frequencies during the high prevalence months (April through October) by at least a factor of 2. These minimum frequencies are recommended when sampling is the only ongoing verification method selected, and may change as more information becomes available to FSIS. Establishments that receive products from numerous sources or have a history of HACCP system failures (i.e., positive results or high event periods) should consider increasing the ongoing verification frequency and include in their written decision-making documentation rationale justifying why the selected ongoing verification procedure and frequency are adequate to ensure the system continues to function as intended.

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

Establishments need to collect ongoing verification data to verify that its HACCP system is addressing STEC. Frequent on-going communication with suppliers, third party audits, and testing can all be incorporated into a well-designed ongoing verification process. FSIS encourages establishments to conduct verification testing at the minimum frequencies based upon product volume listed above, but also recognizes that the expenses associated with frequent testing can be cost-prohibitive.

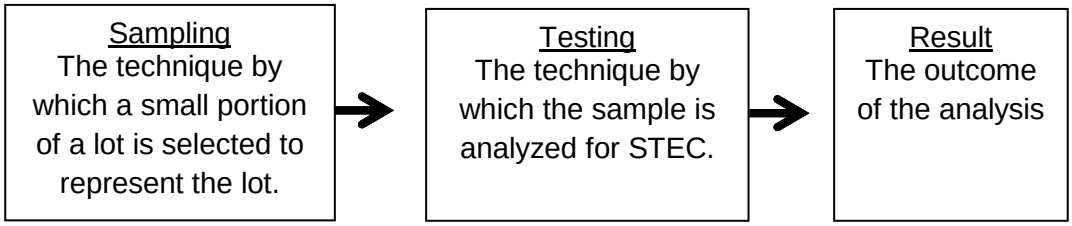
In the absence of a control or prevention measures, it is not appropriate for establishments to apply the recommended minimum frequencies. Without a control or preventive measure in place, sampling should occur on a lot-by-lot basis.

Focus and thought should be placed on the design of the ongoing verification procedures, frequencies, and the data generated to show how the HACCP system is functioning as intended, instead of where any given data point comes from (establishment or FSIS result). For that reason, FSIS does not prohibit establishments from using FSIS test results when documenting the establishment's sampling plan implementation, as the 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 results. However, if an establishment elects to use an FSIS sample result in lieu of collecting its own in-house sampling, 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.

How do I design supportable "sampling" and "testing" protocols?

Frequently, the terms "sampling" and "testing" are used interchangeably. However, as explained below, they are two distinct processes, and the establishment should maintain adequate support for both the sampling protocol and testing protocol.



FSIS recommends frequent sampling at multiple points in the process (e.g., before and after the non-intact processing). A negative test result on a sampled lot does not imply, with 100% certainty, that a given lot is free of STEC for the following reasons:

- the sampling may have missed 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.

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 potential contamination 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 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 other methods other than incision and grab sampling (e.g., surface sampling). More information on sampling beef for STEC is in FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers.

STEC illness can be caused the consumption of only a few cells. 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 for injured cells to recover. Through enrichment, very low levels of STEC contamination can be identified during testing. Changing the incubation time, temperature, or excluding parts of the sample portion from analysis, without proper validation, can result in a lack of support for the sampling and testing methods. Alternatively, situations may arise when the testing occurs on multiple individual sub-samples (e.g., 65-g portions) rather than the entire sample all at once. In both situations, the testing methodology should be validated for the test portions selected and the entire sample portion should be analyzed. More information on testing methods validated for STEC is in Foodborne Pathogen Test Kits Validated by Independent Organizations.

- Regardless of whether the testing occurs in-house, or at an external laboratory, the method of analysis should be equivalent to that used by FSIS laboratories. More information on FSIS methods and external laboratories is in FSIS Microbiology Laboratory Guidebook (MLG) and Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory

Establishments should have procedures in place to hold or control the product that is represented by the test result to prevent adulterated product from entering commerce. Establishments are required to hold or control the product pending FSIS, State, or other Federal test results. FSIS recommends that establishments hold or control the product pending establishment results to complete pre-shipment review on tested product. The amount held would include all products from the sampled and tested lot that are intended for non-intact use or when the product's intended use in not clearly defined. More information on production lot criteria is in the next section.

How do establishments determine a production "lot"?

A production lot can be defined in many ways. FSIS does not recognize "clean-up to clean-up" alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. This is because STEC are generally not environmental contaminants and, therefore, would not be completely addressed through cleaning and sanitizing.

Common criteria used to determine microbiological independence between products include, but are not limited to:

- robust sampling and testing data;
- antimicrobial interventions applied;
- source material used;
- production equipment used; and
- equipment sanitation.

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 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 when determining the scope of a recall. While following the guidance in this document is a best practice, it may not necessarily guarantee microbiological independence in every situation as the guideline cannot encompass all the possible scenarios that are unique to each individual recall case.

While each lot of ground beef does not have to be from a single supplier, using a single supplier for each lot can be very beneficial for tracing the product back to the supplier during an investigation. For that reason, commingling product from multiple suppliers is not considered to be a best practice. Product that contains meat from only one supplier but is mixed with other non-meat ingredients (e.g., soy, spices) is still considered "sole source" product for 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*, STEC does not persist and multiply to significant levels in the production environment. Therefore, provided the sanitation procedures are sufficient, food contact surfaces are typically not a significant source of STEC contamination in raw beef products.

Individually cryovaced products are not routinely 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 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 lot, they 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. If a single cryovaced package is the source material for finished non-intact product and the non-intact positive tests positive for STEC, FSIS will carefully evaluate the product's intended use and whether the product was commingled during the traceback investigation, to ensure the establishment's lot definitions are supportable and no other product injurious to human health was released into commerce.

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

More information on sanitation and lotting is in:

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

Do establishments and retailers that grind beef have to keep a "Grinding Log"?

As part of any well-designed HACCP system, detailed records are important when documenting the production process. In addition, the regulations require that retailers and establishments that grind or chop beef keep certain records listed below. Records tracking each product lot and its source material(s) can serve a vital public health purpose. When there is reason to believe products are adulterated or misbranded, FSIS and establishments track affected products up and down the distribution chain to remove them from commerce. These production records can serve as a roadmap to provide the establishment and the Agency with the information necessary to limit the scope of affected product and promptly remove the product from commerce.

> It is important to keep accurate records that contain all the necessary information to conduct traceback investigations. If the supplier lot number on the received product is missing or not legible, official establishments and retail stores should contact the supplier to obtain that lot number. If no lot number is available, FSIS recommends that the grinder write down any other available supplier material information, such as bar code numbers, invoice numbers, etc.

In the case of raw ground beef products in official establishments and retail stores, 9 CFR 320.1(b)(4)(iii) defines a lot 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. These production records are necessary for traceback investigation if source material is implicated by positive test results or illness investigations. This lot definition is separate from FSIS sampling of STEC, where, pending test results, official establishments must define and hold the sampled lot on the basis of microbiological independence from other production lots. A "lot" of product, in the context of microbiological independence, is not necessarily limited to the ground beef produced between cleanings.

FSIS explained in the *Federal Register* (80 FR 79231), 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 identifying number of each establishment supplying the 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 strictly to establishments and retail stores that grind beef. It does not apply to other raw non-intact beef processing (mechanically tenderizing, cubing, injecting, etc.) nor does it apply when ground beef is only portioned or repackaged. This rule only applies to the beef component of the product; it does not apply to any non-meat ingredients added. If the ground product is fully cooked before being sent into commerce and the businesses maintains necessary records for FSIS to verify the final use, FSIS does not enforce these recordkeeping requirements.

Each establishment's production process and lotting system is unique. Detailed records are crucial when attempting to track affected product associated with an outbreak or limit the scope of a recall. 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.

How will the new "Grinding Log" rule be verified and enforced?

FSIS will use different personnel to verify the new requirement, depending on whether the ground beef is produced in an official establishment or in a retail store. When produced in an official establishment, FSIS Inspection Program Personnel (IPP) will verify the official establishment meets these new requirements as part of their routine inspection activities. If IPP find that the establishment failed to maintain the required records, FSIS may issue a noncompliance record (NR), a Letter of Warning, or request the Department of Justice to initiate a civil processing in Federal court to enjoin the defendant from further violations of the applicable law and regulations.

When produced in a retail operation, FSIS Compliance Investigators verify the retail store meets these new requirements as part of their surveillance activities. When Investigators observe recordkeeping violations of the new recordkeeping requirements the Investigators are to inform the management official, designee, owner, or product custodian of the violation, and 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*.

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

If the 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 results will be considered the same as a confirmed positive result. Additional non-confirmatory testing of the same lot of 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 still 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. Once the lot has been determined to be presumptive positive or positive, adding additional product to the lot only increases the affected lot size and does not provide any microbiological 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 evidencing 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 preshipment 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 preshipment 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. In addition, the establishment needs to address STEC in its HACCP plan as a hazard reasonably likely to occur.

When a positive occurs, 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 12. 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 positive STEC 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.

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 actually received a proper disposition. The establishment that produced the product must obtain records evidencing that the entire lot of product was appropriately processed.

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. If the product is shipped off-site for lethality treatment, the shipping establishment must maintain control of the product until the pathogen is destroyed (under company seals or FSIS form 7350-1). The shipping establishment must receive and maintain sufficient documentation from the receiving establishment that shows each lot of positive product received a lethality treatment.

Product that is positive or presumptive positive for STEC cannot be denatured and sent to a pet food manufacturer. For guidelines on FDA's authorization for salvage of food considered to be adulterated for its intended use by diverting that food to an acceptable animal feed use, access Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use.

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). Products going to a landfill or off-site renderer need 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 the facility.

Whether positive for STEC or not, it is not appropriate to divert raw non-intact products, products that may be intended for non-intact use, or products with an unknown intended use from an inspected process to a retail exempt process to address STEC. The retail exempt processing requirements of 9 CFR 303 specifies that only inspected and passed product sources are to be used. If the products are not produced by a validated HACCP system to address STEC, the products are not fit for use in retail exempt processing.

Should grinding establishments address lymph nodes?

Recent publications, cited in the Resources and References section of this guideline, have identified major peripheral lymph nodes (identified below) as a potential source of pathogenic bacteria, including *Salmonella*, for ground beef products. Slaughter and dressing processes and/or typical interventions used to reduce pathogens on carcass surfaces may not be effective at reducing the pathogens, including *Salmonella,* which may be contained within the lymph nodes. Comprehensive systematic control of *Salmonella* should include addressing the potential presence of *Salmonella* from the inclusion of lymph nodes.

Slaughter and processing establishments may want to develop lymph node removal procedures and incorporate them into their HACCP system to ensure the beef products produced do not contain certain lymphatic tissue. Establishments that receive beef products for further processing may want to request documentation, such as an LOG, from their suppliers to support that their suppliers have procedures in place to ensure the removal of lymph nodes that are not incidental to the process. More information on lymph node removal is in:

- FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin producing E.coli (STEC) and *Salmonella* in Beef (including veal) Slaughter Operations 2017

Scenarios

As a whole, this document includes guidance to small and very small establishments for minimizing the risk of STEC in raw non-intact beef operations by covering multiple topics, including: the adulterant status of STEC in beef products; intended use; developing and designing supportable control measures for STEC; and development of ongoing verification measures to ensure STEC is reduced to below detectable levels. The following scenarios cover common HACCP program decisions observed when establishments attempt to address STEC.

Scenario #1: *Inadequate use of Purchase Specifications; Letters of Guarantee (LOG) only*
A processing establishment receives boxed subprimals from a variety of different establishments through a broker, to produce two non-intact products (i.e., tenderized steaks and 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 establishment is not able to receive a Certificate of Analysis (COA), 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 ground beef six (6) times annually, as outlined in the ongoing verification recommendation for establishments producing <5,000 lb of non-intact beef each week.

Analysis - The establishment's approach to STEC is inherently flawed because the establishment has failed to appropriately address STEC at the receiving facility. The LOG required by the receiving establishment does not provide adequate support that STEC is below detectable levels in the incoming beef that will be processed into non-intact product. The sampling conducted by the 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 6 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 must request from the supplying establishment 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 6 annual samples could serve as the ongoing verification data necessary to demonstrate the system is functioning as intended. The above HACCP system, as designed, is inadequate to address STEC.

Scenario #2: *Non-intact processor not adequately addressing hazards*
A low volume processing establishment (<500 lb weekly) does not slaughter but instead receives boxed beef manufacturing trimmings, along with an LOG and a COA for each lot. In addition, the establishment receives boxed beef primals, and produces various steaks, roasts, and bench trimmings to fill daily orders. The establishment is unable to receive COAs for the primal products (indicating that they are not intended by the supplier for non-intact use). In the grinding operation, the establishment combines the two types of trimmings and samples the finished ground beef 6 times annually.

Analysis - In this instance the establishment has adequately addressed STEC in the purchased trimmings; the establishment maintains an 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. That is because the establishment has changed the intended use of the product, but not applied additional controls for STEC to the product. The establishment must request from the supplying establishment evidence that the primal 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 6 annual samples could serve as the ongoing verification data necessary to demonstrate the 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 ground beef and vacuum-marinated steaks), per customer orders. The establishment uses sanitary dressing procedures to limit cross-contamination during slaughter, monitors carcasses for dressing failures, implements a zero tolerance examination CCP for fecal control, and applies a validated antimicrobial treatment at a CCP to reduce STEC to below detectable levels on the carcass before chilling, and maintains the product at temperatures that inhibit pathogen outgrowth. The establishment collects trim samples at the recommended quarterly frequency (6 samples annually) as part of its ongoing verification. No outside beef is received or processed into non-intact product.

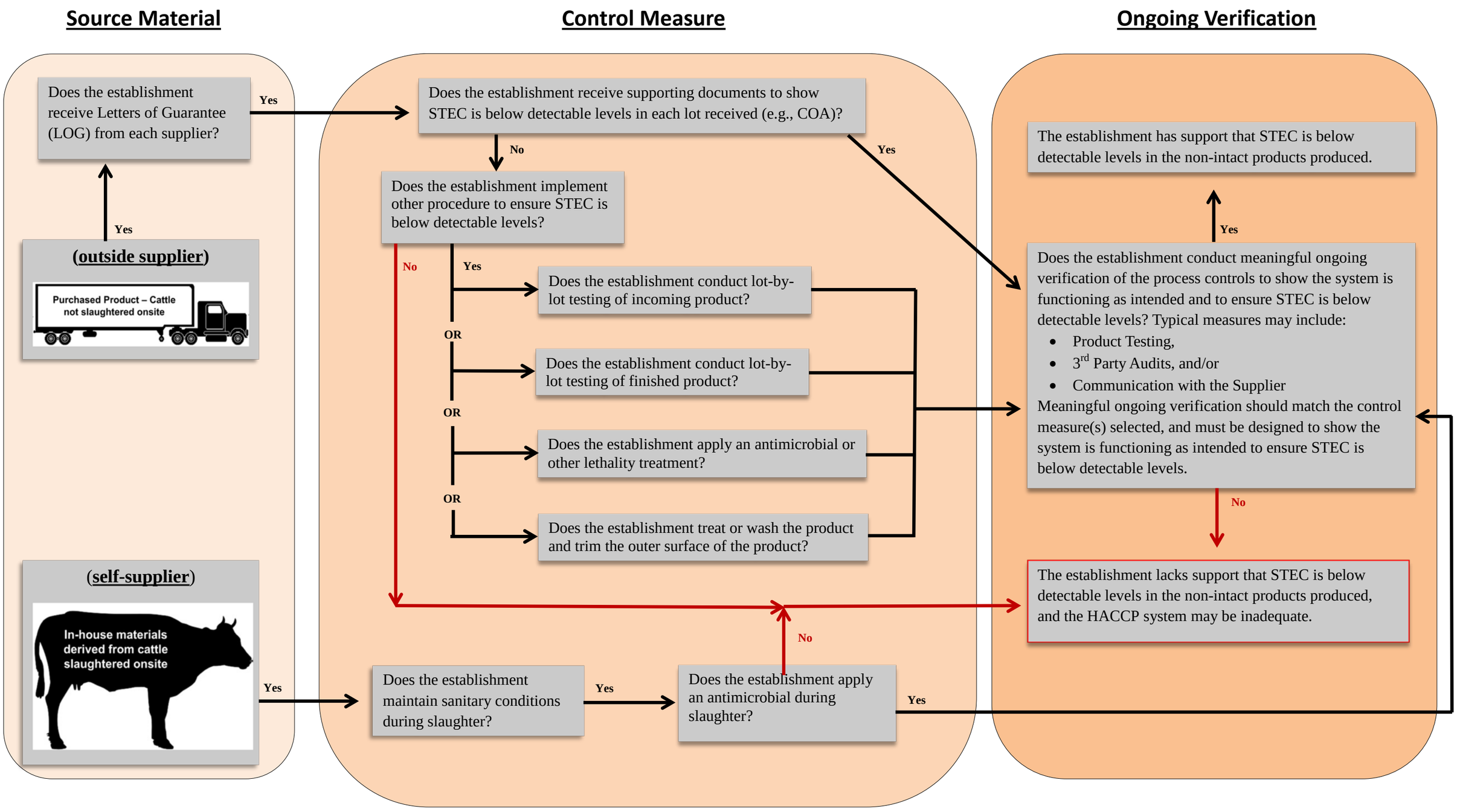
Analysis - In this example, the establishment uses a systematic approach to address STEC in the Slaughter HACCP plan by using measures to prevent carcass contamination, conduct zero tolerance examinations of carcasses for contamination, and reduce STEC with an antimicrobial treatment. Proper cold chain management following slaughter would support that STEC outgrowth would be prevented. The ongoing verification sampling would 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.

Scenario #4: *Tested product without lot-by-lot COA*
A small establishment receives 2,000 lb. of coarse ground beef daily to produce various ground beef products and beef patties. The program requires an LOG from each supplier that describes the controls in place for STEC, including one or more validated treatments and product sampling. The receiving establishment is not able to receive a traditional “lot-by-lot” COA, but does maintain the LOG and shipping invoices or other similar support documents, stating that each lot of product was produced from 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 below detectable levels in the product received. The receiving establishment conducts ongoing verification sampling of the finished product at the “every two months” frequency (total of 9 samples annually) to verify the purchase specifications. The establishment has a CCP in place to prevent growth by maintaining proper product temperature during processing and storage.

Analysis - The receiving establishment is able to obtain a LOG, but is unable to obtain a traditional "lot-by-lot" COA. However, the receiving establishment is able to gain knowledge of the supplier's slaughter process, STEC controls, and is able to gain an understanding of the supplier's test-and-hold procedures and maintains such supporting documentation (e.g., statement on the invoice or other document on file). The receiving establishment is able to show that the product received was derived from tested negative source materials, and it has received specific information concerning each lot of incoming product that is equivalent to a lot-by-lot COA. This information provides the receiving establishment with necessary support that STEC is reduced to below detectable levels in the products received. The ongoing verification sampling results (9 samples annually) provide adequate ongoing verification to show the program is functioning as intended and continues to reduce STEC to below detectable levels in the raw non-intact beef products. In addition, the establishment has a CCP in place to effectively address cold chain maintenance of the product. The above HACCP system is adequate.

Attachment 1 – STEC Decision-Making Flow Chart Guide

This flow chart can be used as the framework to understand how the source materials, control measures, 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, changes from the flow diagram 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, so long 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, the 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.



Attachment 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 to 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

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 common to industry. FSIS does not approve or recommend any one particular antimicrobial treatment over another. Under the HACCP regulations, establishment are required to select the antimicrobial treatment or treatments that best fits 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 Koohmaraie, 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
- Wheeler, T. L., Kalchayanand, N., and Bosilevac, J.M. (2014) Pre- and post-harvest interventions to reduce pathogen contamination in the U.S. beef industry. Meat Science. 98: 372-382.
- 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.

Hide-on carcass wash:

- Schmidt, J. W., R. Want, N. Kalchayanand, T. Wheeler, and M. Koohmaraie. 2012. Efficacy of hypobromous acid as a hide-on carcass antimicrobial intervention. *J. Food Prot.* *7*5(5):955-958.
- Bosilevac, J. M., X. Nou, M. S. Osborn, D. M. Allen, and M. Koohmaraie. 2005. Development and evaluation of an on-line hide decontamination procedure for use in a commercial beef processing plant. *J. Food Prot.* 68:265–272.
- Arthur, T. M., J. M. Bosilevac, D. M. Brichta-Harhay, N. Kalchayanand, S.D. Shackelford, T.L. Wheeler, and M. Koohmaraie. 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.
- Hardin, M.D., G. R. Acuff, G.R., L. M. Lucia, J. S. Oman, and J. W. Savell. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. *J. Food Prot*. 58: 368-374.
- Delmore, R.J., J. N. Sofos, G. R. Schmidt, K. E. Belk, W. R. Lloyd, G. C. Smith. 2000. Interventions to Reduce Microbiological Contamination of Beef Variety Meats. *J. Food Prot.* 63: 44-50.
- Bosilevac, J. M., X. Nou, G. A. Barkocy-Gallagher, T. M. Arthur, and M. Koohmaraie. 2006. Treatments using hot water instead of lactic acid reduce levels of aerobic bacteria and Enterobacteriaceae and reduce the prevalence of *Escherichia coli* O157: H7 on preevisceration beef carcasses. *J. Food Prot. 69*(8), 1808-1813.
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