



United States Department of Agriculture

**OneUSDA** “Do right and feed everyone”



# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



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

# Food Safety and Inspection Service:

## **Presentation Overview:**

- STEC History and Policy
- Source Material and Control Measures
- Ongoing Verification of STEC Control Measures
- Common Misconceptions and Key Points
- Questions and Resources

Food Safety and Inspection Service:

## STEC History and Policy

In 1906, Congress made the Federal Meat Inspection Act (FMIA) law. The FMIA empowers FSIS to inspect meat in commerce.

FSIS Mission Statement:

*Protecting the public's health by ensuring the safety of meat, poultry, and processed egg products.*



## Food Safety and Inspection Service:

### STEC History and Policy

In 1993, an outbreak of *E. coli* O157:H7 occurred in the Pacific Northwest, causing 400 illnesses and four deaths. The public demanded change for safer ground beef products.

- In 1994, FSIS notified the public that raw ground beef products contaminated with *E. coli* O157:H7 are adulterated under the FMIA, unless processed to destroy the pathogen.
- In 1994, FSIS began sampling and testing ground beef for *E. coli* O157:H7.



## Food Safety and Inspection Service:

### STEC History and Policy

During that time, FSIS inspection was largely organoleptic (sight, touch, and smell). A call for a more "science-based" inspection system gave way to the 1996 landmark rule, Pathogen Reduction/HACCP Systems. The rule focuses on the prevention and reduction of microbial pathogens on raw products that can cause illness, and clarified the roles of government and industry.

- Industry is accountable for producing safe food.
- Government is responsible for setting appropriate food safety standards, maintaining vigorous inspection oversight to ensure those standards are met, and maintaining a strong regulatory enforcement program to deal with noncompliance.



# Food Safety and Inspection Service:

## STEC History and Policy

STEC is not considered an adulterant in all raw beef products.



- When STEC is present on the meat's exterior surfaces and the product remains intact (intended use), "*normal*" consumer cooking to a rare or medium internal state will destroy STEC, because the interior of the meat is considered free of STEC so thorough cooking is not necessary.



- When STEC is present on the meat's exterior surfaces 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), and "*normal*" consumer cooking to a rare or medium internal state will not destroy STEC.

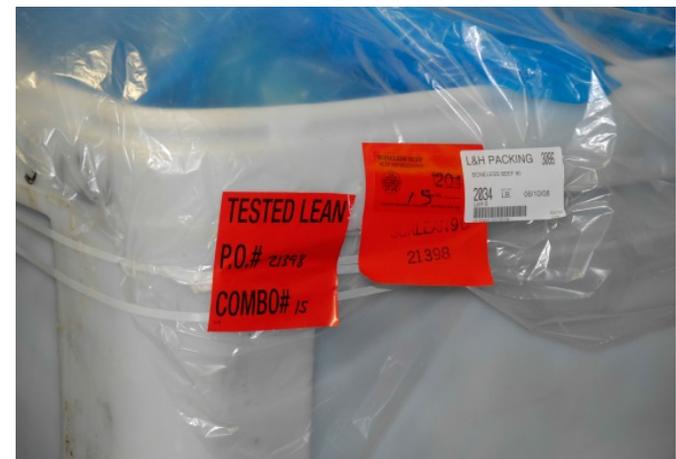
## Food Safety and Inspection Service:

### STEC History and Policy

In 2011 ([76 FR 58157](#)), FSIS expanded the list of serogroups to include 6 additional non O157 serogroups (O26, O45, O103, O111, O121, and O145). All 7 serogroups are collectively referred to as STEC. While there are many other serogroups, only these 7 are considered adulterants in raw non-intact beef and intact beef products intended for raw non-intact use.

In 2012, FSIS began sampling for all 7 STEC serogroups in beef manufactured trimmings.

FSIS generally accepts that HACCP systems effectively controlling *E. coli* O157:H7 effectively control STEC.



Food Safety and Inspection Service:

## STEC History and Policy

[9 CFR 417.2\(a\)\(2\)](#) requires each establishment to identify the intended use or consumers of the finished product.

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.



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.

## Food Safety and Inspection Service:

### STEC History and Policy

- Slaughter/Processing or “Self Supplier” establishments should have a system in place to communicate the product’s intended use to its customers.
- Receiving establishment or “Outside Supplier” that purchase beef from slaughter establishments should be aware of the slaughter establishment’s intended use, and implement additional controls for STEC when the product’ is not used as intended.



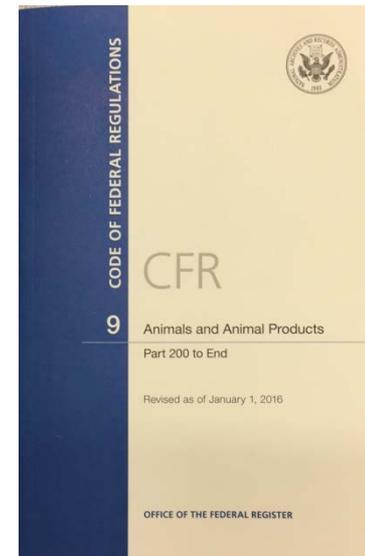
**Reminder:** Not all raw beef produced is intended for non-intact use  
Cryovaced primals and subprimals are commonly intended for intact use.

# Food Safety and Inspection Service:

## STEC History and Policy

### Regulatory Cascade and Framework

- [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, *“written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation.”*



## Food Safety and Inspection Service:

### STEC History and Policy

STEC contamination of non-intact beef products has historically occurred and caused human health illnesses.

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. ([76 FR 58157](#))

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  $\frac{3}{4}$  inch in any one dimension.

## Food Safety and Inspection Service:

### STEC History and Policy

- STEC can reside in the intestinal track, mouth, hide, and hooves of live cattle, and can be transferred to the carcass during the slaughter process.
- Slaughter establishments typically employ a variety of 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.



## Food Safety and Inspection Service:

### Source Material and Control Measures – Self-Supplier

The product's intended use may affect the STEC controls applied by the slaughter establishment. Not all products produced by a slaughter establishment are intended for non-intact use (e.g., cryovaced primals and subprimals)

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 controls for STEC and conduct ongoing verification of those controls, as there is not assurance to the efficacy of the slaughter establishment's STEC controls for these products.

Remember, the adulterant status of STEC is different for different products

**Intact beef products  
intended for intact use**

VS

**Non-Intact beef and beef  
intended for non-intact use**



## Food Safety and Inspection Service:

### Source Material and Control Measures – Self-Supplier

#### Slaughter/Processing or “Self Supplier”

In establishments that conduct both slaughtering and processing, knowledge of the STEC controls are self-contained within the establishment’s 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.



Food Safety and Inspection Service:

## Source Material and Control Measures – Self-Supplier

### Slaughter/Processing or “Self Supplier”

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.



## Food Safety and Inspection Service:

### Source Material and Control Measures – Outside Supplier

#### Receiving establishment or “Outside Supplier”

For processing establishments that receive beef that was not slaughtered onsite, for further processing, knowledge of the STEC controls are not initially self-contained within the receiving establishment’s HACCP system. The establishment either needs to:

1. Receive detailed information that the supplier is meeting necessary **purchase specifications**, or
2. Implement **in-house controls**.



## Food Safety and Inspection Service:

### Source Material and Control Measures – Outside Supplier

#### Purchase Specification Prerequisite program

**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 establishment's product used, and be updated routinely at a frequency sufficient to be credible;

**Certificate of Analysis (COA)** or similar information from the supplier to demonstrate that STEC has been reduced to below detectable levels in each lot received, on a lot-by-lot basis.

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.

## Food Safety and Inspection Service:

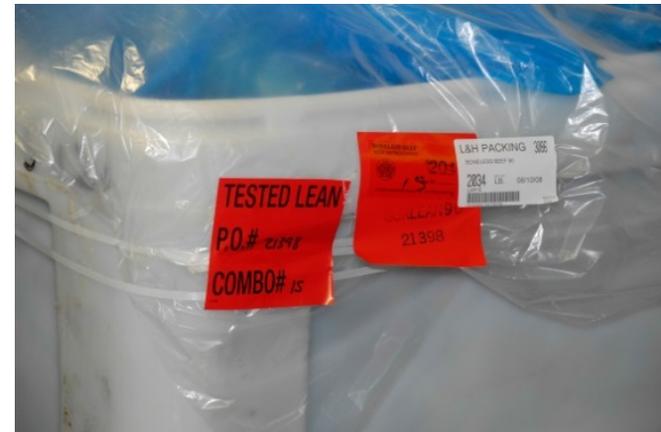
### Source Material and Control Measures – Outside Supplier

#### STEC control applied by receiving establishment

When the receiving establishment is unable to demonstrate STEC has been reduced to a non-detectable level on the source materials received, the establishment must implement in-house controls, on a lot by lot basis.

Those in-house controls typically include:

- Testing incoming product; or
- Testing finished product; or
- Treating or washing the product when removed from cryovac bags and trimming the outer surface before producing the non-intact product; or
- Using validated antimicrobial interventions or other lethality treatments on raw beef product.



## Food Safety and Inspection Service:

### Source Material and Control Measures – Review

Slaughter/Processing or “Self Supplier” - Demonstrate STEC is below detectable levels using a multi-hurdle approach from slaughter through processing

Receiving establishment or “Outside Supplier” - Demonstrate STEC is below detectable levels by:

- Receiving records from the supplier (Purchase Specifications), or
- Developing in-house controls.

Are there establishments where both apply?

- *Yes, it is not uncommon for establishments to conduct both slaughter/processing and also receive beef from outside sources. It is critical for these establishments to consider all sources of beef used to create non-intact beef – not just one source or the other.*

Food Safety and Inspection Service:

## Ongoing Verification of STEC Control Measures

Whether a self-supplier, outside supplier or both, HACCP requires ongoing verification of the HACCP system to ensure the system is functioning as intended.

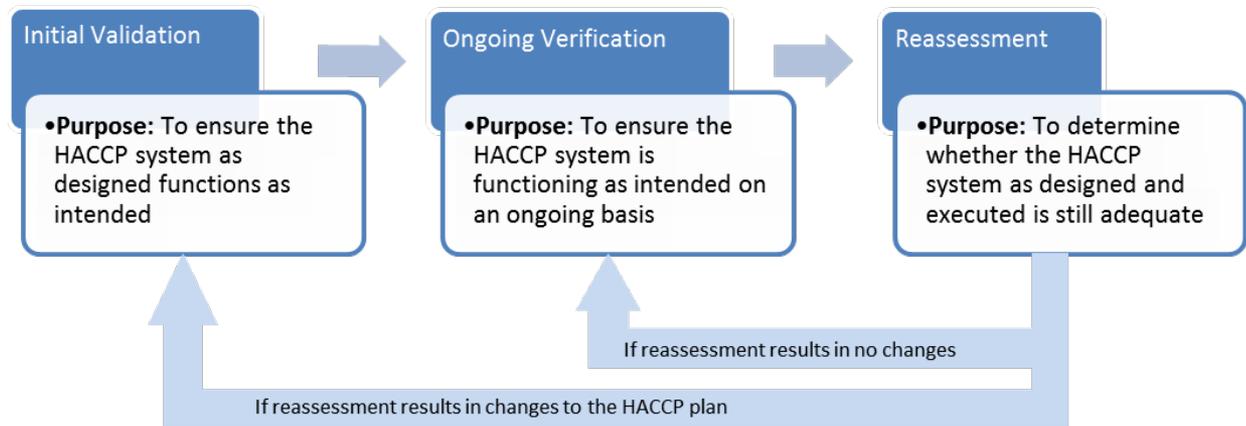


For raw non-intact beef establishments “functioning as intended” includes ensuring product is not adulterated (*i.e.*, STEC is eliminated or reduced to below a detectable levels).

# Food Safety and Inspection Service:

## Ongoing Verification of STEC Control Measures

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 all be considered when developing ongoing verification procedures and frequencies.



Initial Validation – “...as designed...”

Ongoing Verification – “...is functioning...”

## Food Safety and Inspection Service:

### Ongoing Verification of STEC Control Measures

**Testing is not required, ongoing verification is required** – Since microbial contamination is not visible, establishments often perform testing to verify the HACCP system is functioning as intended to eliminate or reduce STEC to below detectable levels. Each establishment must develop its own method of ongoing verification. There is no one-size fits all approach.

When testing is used for ongoing verification, FSIS recommends the following minimum sampling frequencies for raw non-intact products:

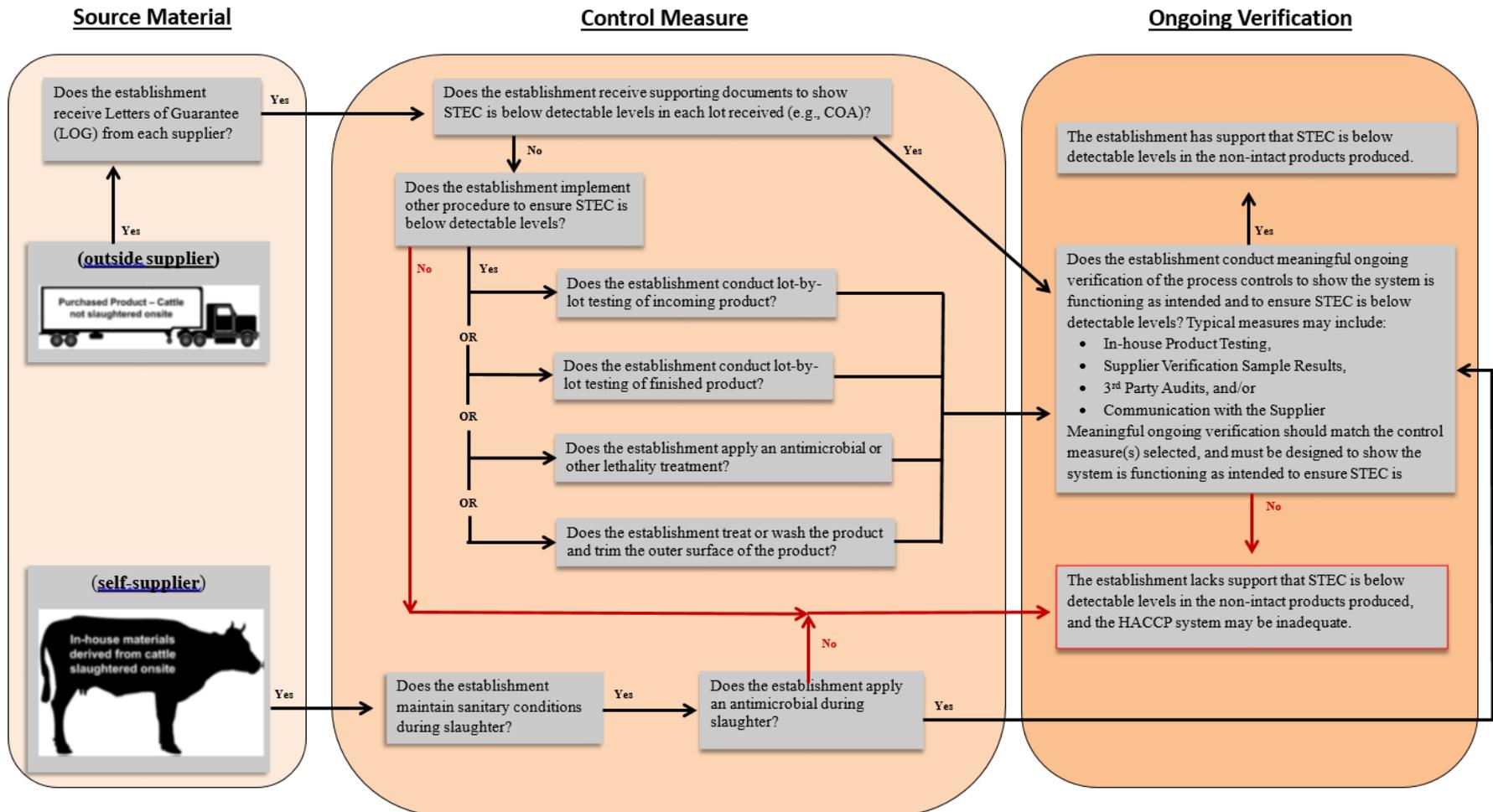
- >250,000 lb weekly - once per month (12 times annually)
- 5,000-250,000 lb weekly - once every 2<sup>nd</sup> month (6 times annually)
- <5,000 lb weekly - once every 3<sup>rd</sup> month (4 times annually)



Studies have shown that cattle shed STEC more during the warmer months. Establishments using the above frequencies should increase sampling (factor of 2) from April through October.

# Food Safety and Inspection Service:

## Source Material, Control Measure, Ongoing Verification



## Food Safety and Inspection Service:

### Common Misconceptions and Key Points

***To control STEC, my establishment uses the Letter of Guarantee (LOG) from the supplier indicating they apply a validated intervention.***

*This is problematic. Though the supplier does apply an intervention, there is no actual support that STEC is below detectable levels in the raw materials received. In fact, the intended use sections of many LOGs specify certain products (most commonly, individually cryovaced primals/subprimals) are not intended for grinding and the supplier did not verify STEC was below detectable levels in those products.*

***To control STEC, my establishment collects 6 STEC samples a year.***

*This is problematic without an actual STEC control measure. The recommendation of quarterly or monthly sampling in the Beef Processing Compliance Guideline is for ongoing verification, not as a sole control measure.*

***To control STEC, my establishment applies validated cooking instruction to the label.***

*This is problematic because “normal” cooking to a rare or medium state does not eliminate STEC in the interior. The label is a measure to inform the consumer of the need to cook the product thoroughly; labeling is not control or CCP for STEC*

## Food Safety and Inspection Service:

### Common Misconceptions and Key Points

- ✓ The adulterant status of STEC is different for intact vs non-intact products (*i.e.*, intended use).
- ✓ It is inappropriate to assume STEC has already been reduced to below detectable levels in beef products simply because it carries the mark of inspection.
- ✓ Not all raw beef produced is intended for non-intact use. Cryovaced primals and subprimals are commonly intended for intact use.
- ✓ Addressing STEC in raw non-intact beef requires consideration of the source material used, STEC controls applied, and ongoing verification to ensure the system is functioning as intended.
- ✓ Establishments that are both “self-suppliers” and use “outside suppliers” must consider all source materials used and all products produced.

# Food Safety and Inspection Service:

## Resources

### **Beef Pre-Harvest and Slaughter Controls**

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

### **Beef Processing**

- [FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing \*Escherichia coli\* \(STEC\) in Raw Beef \(including Veal\) Processing Operations](#) (2017)

### **HACCP Validation and Sampling**

- [FSIS Compliance Guideline HACCP Systems Validation](#) (Apr 2015)
- [Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing \*Escherichia coli\* \(STEC\) Organisms or Virulence Markers](#) (Aug 2014)

# Food Safety and Inspection Service:

## Questions

