



# Measures to Address Shiga toxin-producing *Escherichia coli* (STEC) in Raw Non-intact Beef Products

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Office of Policy and Program Development  
FSIS, USDA  
Washington, DC



# Objectives

- ❑ Reason for today's discussion
  - ❑ Two askFSIS Q&As
- ❑ Review of HACCP principles
- ❑ Measures to address STEC in raw non-intact products
  - ❑ In-house vs. Purchased Product
- ❑ Review two askFSIS Q&As



# Impetus for Today's Talk

## Two posted askFSIS Q&As

- Control of STEC Organisms in Raw Non-intact Beef Processing Establishments
- Processing Establishment's need for a CCP for Raw Beef Fabrication



# Review HACCP Regulations



# Background

## HACCP Regulations

- 417.2(a) requires establishments to
  - Identify any food safety hazards that might occur in the production process
    - Includes hazards before, during, and after entry into est.



# Background

## HACCP Regulations

- 417.1 defines a Critical Control Point (CCP)
  - A point, step, or procedure in a food *process* at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
- FSIS considers an acceptable reduction for STEC to be a reduction to an undetectable level at any point in the distribution chain because it is an adulterant.



# Background

## HACCP Regulations

- 417.4(a)(1) requires that establishments initially validate the adequacy of their food safety system
- 417.4(a)(2) requires that establishments verify on an on-going basis that their food safety system is working as intended
- 417.5(a)(1) requires establishments to support decisions in their hazard analysis



# Measures to Address STEC in Raw Non-intact Beef Products



# Two Sources for Source Materials

1. In-house  
Own slaughter Operation
2. Purchased product



# In-house vs. Purchased Product

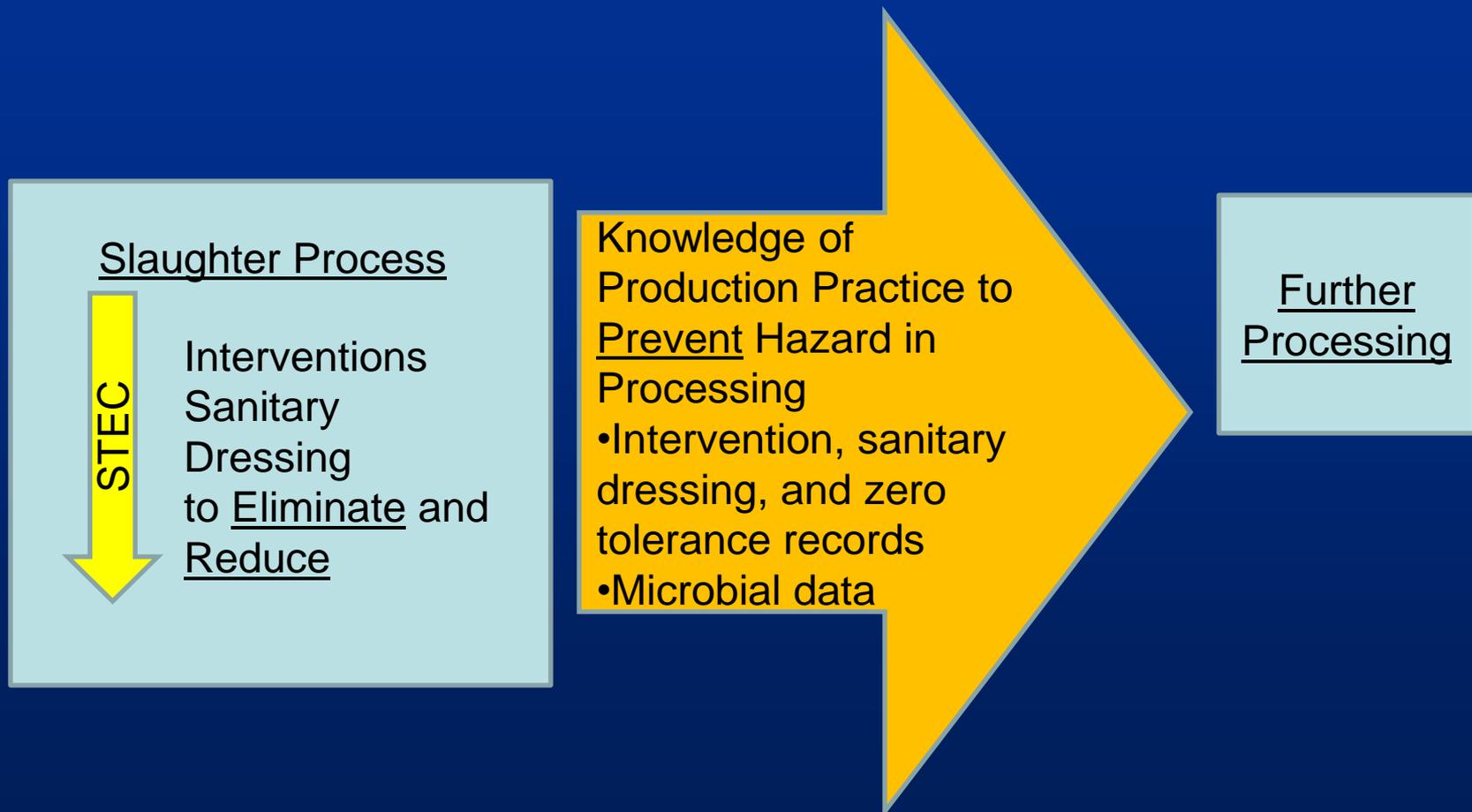
- Knowledge of production of source materials different
- Decisions in hazard analysis are affected



# In-house Product

- Most common decision is NRLTO due to control measures (e.g., interventions and sanitary dressing) in slaughter process
- Establishment has knowledge regarding the source materials' production
  - Records of critical operating parameters
  - Sanitary dressing practices
  - Zero tolerance
  - Microbial data
- The reductions are happening in slaughter establishments

# In-house Product





# Purchased Product

- Receiving establishment has options to address hazard and support HA decisions
  - Not reasonably likely to occur (NRLTO) due to purchase specifications
    - Require information (through LOG) on supplying establishment's interventions and COAs or other up-to-date information that source materials have been tested and found negative
    - Receiving establishment's ongoing verification that purchase specifications are met and testing that supports that HA decisions are supported on an ongoing basis



# Purchased Product

Knowledge of Production  
Practices Employed  
Needed to Prevent Hazard  
in Processing

- Purchase specifications  
requiring LOGs on  
interventions and COAs

## Further Processing

- Verification that  
purchase specs are met  
and testing to show  
program is effective and  
HA decisions are  
supported



# Purchased Product

- RLTO and apply an antimicrobial intervention CCP
  - Ongoing verification of parameters and test results
- NRLTO because of the application of an antimicrobial intervention as part of a prerequisite program
  - Ongoing verification of parameters and test results



# Purchased Product

Little to no information to  
prevent hazard

## Further Processing

- Antimicrobial Intervention to Reduce or Eliminate through CCP and testing to show intervention effective
- OR
- Antimicrobial Intervention to Prevent Hazard through prerequisite program and testing to show intervention effective



# Purchased Product

- Why RLTO and controlling only with a storage CCP and no other information doesn't work
  - The hazard analysis identifies a RLTO hazard and doesn't have any other measures to address STEC.
    - Reduction of STEC to an acceptable level is non-detectable because it is an adulterant
    - Chilling doesn't kill organisms. Temperature control only inhibits growth.
    - Although temperature control is a good process control step to inhibit microorganism growth, temperature control alone is inadequate to support hazard analysis decisions concerning STEC



# Purchased Product



Little to no  
information to  
prevent hazard

## Further Processing

- CCP for chilling only
  - Chilling does not eliminate STEC to undetectable level. Temperature control only inhibits growth and does not kill STEC.



Inadequate measure alone for adulterant where reduction to undetectable level is required.

Therefore, hazard analysis decision for STEC not supported but temperature control is adequate for other non-adulterants.



# Verification

- Establishments are required to conduct on-going verification activities to ensure that their HACCP plan is functioning as intended.
  - We know from previous experience that an establishment's intervention(s) can be overwhelmed
    - Poor sanitary dressing procedures
    - Increased incoming load
    - Many interventions are only documented to reduce STEC levels by 1-2 logs.



# Verification

- Since STEC is generally present at very low levels, frequent verification is necessary to ensure that
  - Intervention(s) is functioning as intended
  - Sanitary dressing is effective
  - Decisions in the hazard analysis are supported on an ongoing basis
  - Sampling



# Take-home Message

- The level of control required for adulterants is different than non-adulterants
- Slaughter establishments have direct knowledge of their process.
- Further processors either seek out information about their supplier's process or apply controls or other procedures
- Temperature control alone is inadequate to support hazard analysis decisions for STEC



## askFSIS Q&As

- Review on own to determine if further clarification needed



# Control of STEC Organisms in Raw Non-intact Beef Processing Establishments

## Scenario:

A small establishment receives raw beef primal and subprimals from several suppliers and brokers. The establishment manufactures these raw beef source materials into intact and non-intact (bench trim, ground beef, needle tenderized steaks, and marinated vacuum tumbled) raw beef finished products. The establishment determined that there is a biological hazard that is reasonably likely to occur and designed its HACCP system with a critical control point for monitoring temperature of the product in cold storage to control the outgrowth of any Shiga toxin-producing *Escherichia coli* (STEC) organisms.



- **Scenario (cont')**: The establishment does finished product testing of its ground beef following the [Draft Guidance for Small and Very Small Establishments on Sampling Beef Products for Escherichia coli O157:H7](#) for production of less than or equal to 1,000 pounds daily. The establishment collects samples six times a year (taking 1 in each of the colder quarters and 2 each in the warmer quarters). The establishment does not test incoming source materials and is not able to obtain certificates of analysis (COA) due to the indirect relationship with its suppliers.
- Does the Agency consider a temperature control CCP (i.e., no validated antimicrobial interventions) an acceptable measure to reduce STEC organisms in a raw beef-processing establishment to non-detectable levels?



- No. Temperature control can inhibit the growth of STEC organisms, but even freezing would not be able to reduce (kill) STEC organisms. Because the presence of STEC organisms adulterates non-intact raw beef products, the Agency expects a *processing* establishment to control the presence and outgrowth of STEC organisms. Through robust testing, an establishment may verify that its controls for STEC organisms are reducing the pathogen to non-detectable levels. STEC organisms can be highly virulent and have a low infectious dose; they are able to cause foodborne illness in young children, the elderly, and immune-compromised individuals who eat these non-intact products.



FSIS recognizes that extensive, high-frequency sampling might be cost-prohibitive for small and very small establishments. FSIS believes, however, that testing of product produced by these establishments is necessary. In its recommendation to small and very small establishments on sampling for STEC, the Agency assumes that an establishment has tested all source trim product. If the establishment has not tested all source trim, then the sampling frequency for finished ground beef product will need to be much higher than the sampling frequency provided in the Agency's draft guidance.

Under 9 CFR 417.2(a)(1) an establishment is to consider both the potential presence of the pathogen and the outgrowth of the pathogen. The measures in place that an establishment uses shall prevent or control the multiplication of microbes that may be present on meat and poultry products and kill and reduce the numbers of any microbes that might be on the surface of meat and poultry products to non-detectable level.



# Processing Establishment's need for a CCP for Raw Beef Fabrication

Does FSIS mandate that an official *processing* establishment have a critical control point (CCP) to address *E. coli* O157:H7 in the beef fabrication *process* of their raw ground or raw not-ground beef HACCP plan if the establishment has a purchase specification program that requires the supplying slaughter establishment to have intervention in place to control *E. coli* O157:H7 and each lot of raw beef product comes with a Certificate of Analysis (COA)?



No, FSIS does not mandate that a *processing* establishment have a critical control point to address *E. coli* O157:H7 during the fabrication *process*. 9 CFR 417.2(a)(1) requires that every official establishment determine the food safety hazards reasonably likely to occur in its production *process* and identify the preventive measures it can apply to control those hazards. Furthermore, 9 CFR 417.5(a)(1) requires that an establishment support its decision in the hazard analysis developed under 9 CFR 417.2(a)(1). Establishments need to have sound decision-making and to be able to support those decisions for an adequate design of its food safety system. As defined in 9 CFR 417.1, a CCP is point, step, or procedure in a food *process* at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. A CCP is not a step at which a control is always required to eliminate the identified food safety hazard. FSIS considers an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level at any point in the distribution chain.



- Because of the sporadic nature of this pathogen and the limitations of finished product testing (e.g., N-60 testing), contamination of production lots at a level of 5% or greater is highly likely to be detectable. However, contamination of most production lots is believed to be considerably less than 1%. Thus, an establishment that relies upon a prior negative testing result as the sole verification that the pathogen was reduced to non-detectable levels creates a substantive vulnerability. Each intervention and testing opportunity provides enhanced confidence that contamination is minimized or reduced to non-detectable levels.
- In other words, a receiving establishment that only relies on the supplying establishment's certificate of analysis (COA) without any verification testing and without an intervention leaves itself open to a potential food safety risk. The receiving plant must be able to base its decision on direct knowledge of the level of control exerted by the supplier with on-going evidence-based information to support that the supplier's *process* is controlled and maintained within acceptable limits.



- Likewise, an establishment cannot assume that product with an official mark of inspection has been *processed* to conclusively result in this particular pathogen being prevented, eliminated, or reduced to a non-detectable level at the supplying establishment. Under 9 CFR 417.2(a), an establishment's hazard analysis is required to include the food safety hazards that can occur before, during, and after entry into the establishment. The mark of inspection means that FSIS has verified that the establishment has followed the HACCP *process* that it (the establishment) has determined is necessary to produce a safe product. It does not say anything about the specific content of a particular product. Therefore, an establishment may not rely on the official mark as a guarantee that all the food safety hazards were eliminated at the supplying establishment. Hence, establishments at each point in the distribution chain must address whether or not hazards are reasonably likely to occur. An establishment must be able to demonstrate that its food safety system, when executed as designed, is able to produce a safe meat food product.



- A receiving establishment needs to have a validated HACCP plan that is functioning as intended, including maintaining control of its *process* through proper monitoring of sanitation and the temperature of the product, in order for its food safety system to consistently be capable of producing a safe, wholesome, properly labeled product in a sanitary environment. An establishment's food safety system needs to be dynamic, not static. Thus, an establishment needs to continually assess the effectiveness of its system and to make adjustments to it when the establishment finds that its *process* is, or is trending, out of control. Formulating raw beef product from multiple sources, which may vary in the level of control that each supplying establishment exercised over their raw beef production *process*, may affect each receiving plant's food safety system differently, and thus this fact must be considered by the official *processing* establishment in designing its *process*, its controls, and its food safety verification procedures. It is the establishment, not FSIS, that determines and supports how to best address *E. coli* O157:H7 in the beef fabrication *process* of its raw ground or raw not-ground beef HACCP plan.



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**Questions?**