



Cover

▲ Part II: Controlling Shiga Toxin-Producing *Escherichia coli* (STEC)

Food Safety and Inspection Service

Small Plant News



Volume 7 | Issue No. 9

Part II: Controlling Shiga Toxin-Producing *Escherichia coli* (STEC)

By **ROBERT BOYLE, DVM**, Outreach and Partnership Division and **ROMINA A. HENNIG, DVM** of the Animal and Plant Health Inspection Service (APHIS)



In Part I of this series, we discussed the Shiga toxin-producing *Escherichia coli* (*E. coli*), STEC, and the importance of making decisions in your hazard analysis based on the potential risk of product being contaminated with STEC. We also pointed out the difference in potential risks between using in-house and purchased source materials. In Part II, we will continue discussing the risks between using in-house and purchased source materials, but we will also look at STEC controls, discuss ongoing verification, and examine the risk of vulnerability.

Purchased Source Materials

If you are a receiving plant, then it is your responsibility to properly manage the use of raw beef product from multiple sources since the level of control that each supplier exercised over its raw beef production process

[Continued on Page 2...](#)

Controlling STEC Part II

...Continued from Page 1

may vary. This is an important consideration when you design your process, controls, and food safety verification procedures.

The figure below shows the different measures you can employ to address STEC in your food safety systems based on the source of materials. It may be found in the recently published FSIS Directive 10,010.2, "Verification Activities For Shiga Toxin-Producing *Escherichia Coli* (STEC) in Raw Beef Products."

The directive provides inspection program personnel (IPP) with instructions for verification activities, other than FSIS sampling, related to *E. coli* O157:H7 and non-O157 STEC, it may be accessed from FSIS' Web site at www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/10000-series.

STEC Controls

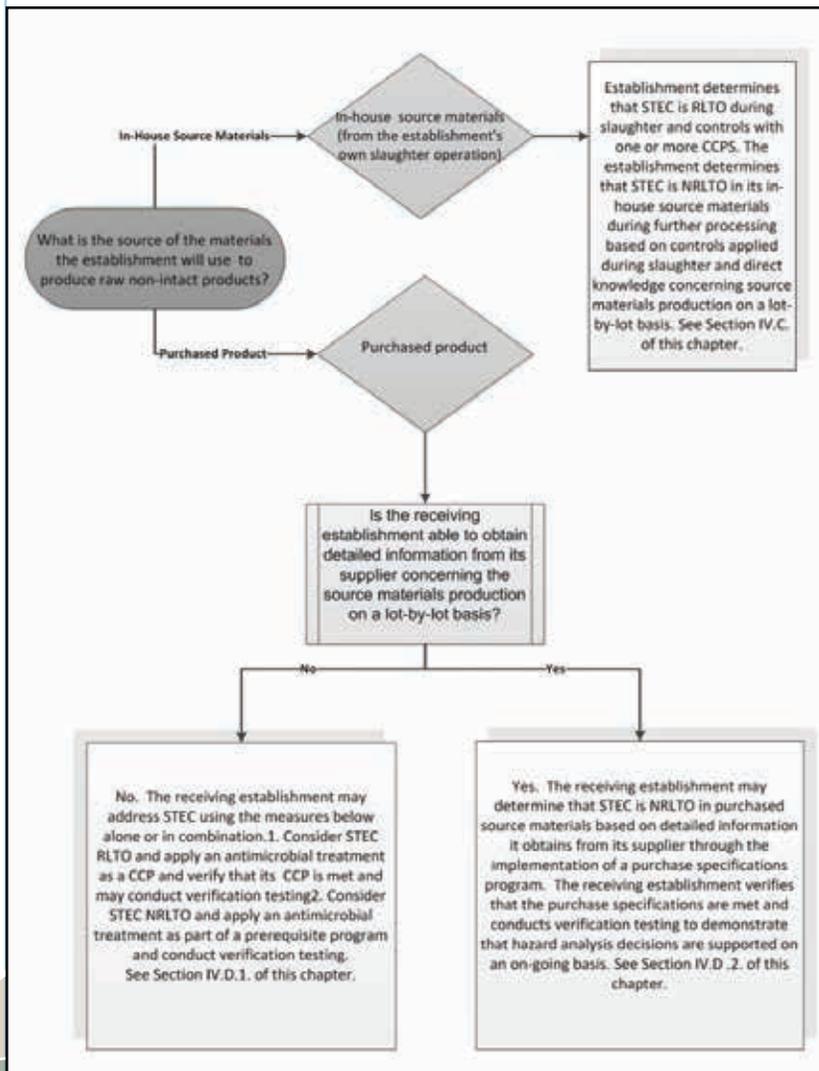
Processing plants must seek out information about their supplier's process and/or apply controls and other procedures to support the decisions made in its hazard analysis.

As we know, each plant and its processes are different, and there are a variety of Hazard Analysis Critical Control Point (HACCP) plans that can effectively address STEC. Some are more effective than others.

If, for example, your plant considers STEC to be reasonably likely to occur (RLTO), then a storage temperature critical control point (CCP) will not adequately address the hazard as required by regulations. Chilling during storage only **inhibits growth** and **does not kill organisms**. In fact, freezing may not kill STEC.

Although temperature control is a good process step to maintain food safety, temperature control on its own cannot reduce the level of STEC on beef to a below detectable level or zero. Therefore, a temperature control CCP alone cannot support hazard analysis concerning an adulterant such as STEC.

Since the temperature control CCP alone is inadequate, your plant may choose to add a CCP for the application of an organic acid antimicrobial treatment, for example, on the product.



Remember: Intervention strategies used in the production of raw products should include scientific support that includes microbiological data that specifies the expected level of pathogen reduction for the same hazard identified in the hazard analysis, as stated in the final "FSIS Compliance Guideline HACCP Systems Validation" published on May 8, 2015.

Continued on Page 3...

Controlling STEC Part II

...Continued from Page 2

If the scientific support includes such data and matches your plant's process, then you should gather in-plant validation data demonstrating that you can implement the critical operational parameters of the intervention on an ongoing basis.

The compliance guide is a valuable source of information that will assist you in meeting the initial validation requirements in 9 CFR 417.4 and is available on FSIS' Web site at www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.

In some States, HACCP coordinators may offer assistance with effectively addressing STEC in your HACCP plan. Contact information for HACCP coordinators is available on FSIS' Web site at www.fsis.usda.gov/wps/portal/informational/contactus/state-haccp-contacts-and-coordinators.

Ongoing Verification

You should conduct ongoing verification activities to ensure that your food safety system is working as intended. Your plant may have scientific support that an intervention can eliminate STEC from beef, and you may be using it exactly as described in the supporting documentation. However, because of incoming loads of microorganisms, cross-contamination, and poor sanitary dressing procedures, interventions can be overwhelmed to the point where they are ineffective. The interventions may not be completely effective against STEC if there is a significant amount of contamination.

Frequent verification is necessary to ensure that your interventions are functioning as intended and that sanitary dressing procedures are continually effective. Additionally, frequent verification is needed to show that your prerequisite programs are successfully preventing the hazard, and that the decisions in your hazard analysis are continually supported.

Risk of Vulnerability

Ongoing verification that the food safety system is working as intended is a very important aspect of how your plant demonstrates that you have adequately addressed STEC. If you're a receiving plant that relies solely on a supplying plant's Certificate of Analysis without performing any of your own verification testing, and you are operating without an intervention, then this creates vulnerability to a potential food safety risk. Each intervention and testing opportunity provides enhanced confidence that contamination is minimized or reduced to below detectable levels or zero.

In addition, you cannot assume that a USDA mark of inspection on a received product confirms that STEC has been prevented, eliminated, or reduced to below detectable levels in the product. Each processing plant is expected to ensure, through its own food safety system and supporting documentation, that the hazard is adequately addressed.

The USDA mark of inspection means that FSIS has verified that the plant has followed its HACCP process, it does not reflect whether or not the product is free of STEC. Therefore, a plant is not adequately supporting its hazard analysis if it determines that STEC is not reasonably likely to occur (NRLTO) in the incoming product solely because the product bears the USDA mark of inspection.

Again, FSIS does not mandate that an official processing plant have a CCP to address *E. coli* O157:H7 during the fabrication process. In other words, a CCP is not required when your plant has enough support and verification to show on an ongoing basis that your food safety system is preventing or reducing levels of STEC to below detectable levels. However, you need to use sound decision-making and be able to support those decisions for an adequate design of your food safety system.

Your plant's food safety system needs to be dynamic, not static, which means that you must continuously assess the effectiveness of your system and determine if it's adequate or must be changed. This can be done by you evaluating your ongoing verification data for trends over time.

FSIS recognizes that extensive, high-frequency sampling might be cost prohibitive for small and very small plants. However, it would be difficult for you to support that your food safety system is working as intended, and that your hazard analysis decisions are supported on an ongoing basis, without doing any product testing.

Continued on Page 4...

Controlling STEC Part II

...Continued from Page 3

For information on the design of sampling programs, refer to “Guidance for Small and Very Small Plants on Sampling Beef Products for *Escherichia coli* O157:H7” found on FSIS’ Web site at www.fsis.usda.gov/wps/wcm/connect/9f40a351-16c9-4953-9d4c-c2ba51913fa8/Draft_Guidance_SVSP_sampling_for_ecoli.pdf?MOD=AJPERES.

It is important to note that the sampling frequencies provided in the guidance assume that source materials have been previously tested. If the source materials have not been tested, and your plant uses the guidance as support for your sampling program, then you should consider testing at a higher sampling frequency than what is found in the draft guidance.

To summarize, during the hazard analysis process, some factors for plants to consider that might increase the risk from STEC are:

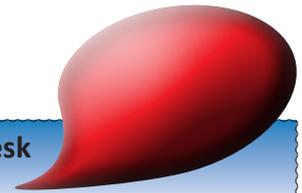
- Formulation of raw beef product from multiple sources;
- Lack of knowledge about the supplying plant’s production process;
- Lack of data from microbial sampling of incoming product and processed product; and
- Failure of the plant to assess continually the adequacy of its food safety system.

Attention to factors that affect your hazard analysis is not only a requirement, but is also a key part in the process to ensure the production of safe, wholesome food. Ensuring food safety is not only a public health priority; it is good business.

For more information, or if you have any questions, contact the Small Plant Help Desk at (877) 374-7435 Monday through Friday between the hours of 8:00 a.m. and 5:00 p.m. ET, or via E-mail at InfoSource@fsis.usda.gov.

Small Plant Editorial Staff

- ▲ Editor in Chief:
Daniel P. Puzo
- ▲ Editor:
Keith Payne
- ▲ Managing Editor:
Jane Johnson, DVM
- ▲ Creative Director:
Gordon E. Wilson
- ▲ Design:
Duane Robinson
- ▲ Office of Outreach, Employee Education and Training
Assistant Administrator
Michael G. Watts



FSIS Small Plant Help Desk
1-877-374-7435
InfoSource@fsis.usda.gov

Please feel free to submit any suggestions for topics you would like to see covered in the *Small Plant News* to *Small Plant News*, USDA/FSIS, 1400 Independence Ave., SW, Mailstop 3778, Patriots Plaza III, Rm. 9-265A, Washington, DC 20250, or via email to SmallPlantNews@fsis.usda.gov.

Small Plant News, USDA/FSIS, 1400 Independence Ave., SW, Mailstop 3778

Patriots Plaza III, Rm. 9-265A, Washington, DC 20250. (800) 336-3747; E-mail: SmallPlantNews@fsis.usda.gov

USDA is an equal opportunity provider, employer, and lender.