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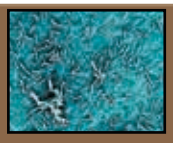

Cover

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

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

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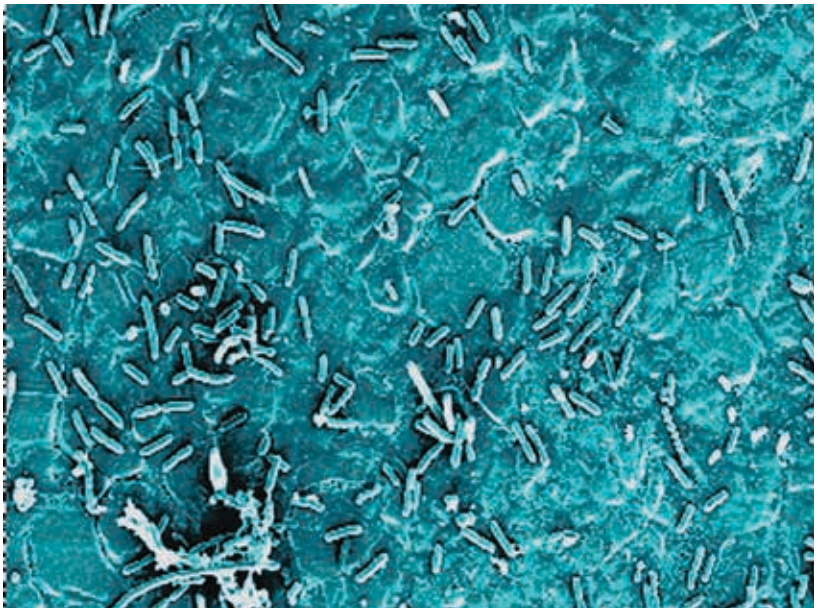

The prevention of biological hazards is a priority when developing a Hazard Analysis and Critical Control Point (HACCP) system. In particular, dangerous Shiga toxin-producing *Escherichia coli* (*E. coli*), or STEC, are known to cause severe disease and sometimes death in vulnerable people. It's important to point out that adulterant STEC have a very low infectious dose. In the right environment it is possible for as few as 10 to 100 microorganisms to cause severe illness.

Although most beef servings are not contaminated with STEC, the potential risk that comes with even a small amount of contamination is significant and dangerous. As

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a result, USDA's Food Safety and Inspection Service (FSIS) emphasizes the importance of a plant's ability to verify that adequate control measures are in place to continuously address STEC.

Most foodborne pathogens are not considered adulterants because ordinary cooking and preparation of these products is generally sufficient to destroy the pathogens. STEC are unique, however, in that they can survive in raw, non-intact beef that many consumers consider properly cooked.

Non-intact beef is considered to be beef product subjected to processes that cause pathogen penetration from the exterior surface into the product's interior. Examples include ground beef, hamburger, beef patties, mechanically tenderized products, vacuum-tumbled products, and other products that have been processed in a manner to make them non-intact. Processes that make product non-intact include chopping, grinding, mincing, flaking, injecting with solutions, vacuum marinating, corning, mechanically tenderizing, needling, cubing, frenching, pounding, or reconstructing into formed products. Source materials, intended for use in any raw non-intact product, include beef manufacturing trimmings, bench trim, and other raw ground beef components (e.g., head meat, cheek meat, heart meat, weasand meat).

FSIS' temperature recommendation for consumers to cook raw, non-intact beef and achieve a safe product is 160 degrees Fahrenheit. The agency is well aware that some consumers ordinarily, or typically. do not cook raw, non-intact beef to an internal temperature of 160 degrees. In fact, some consumers consider ground raw, non-intact beef to be properly cooked at less than 160 degrees or at culinary preferences of rare, medium-rare, or medium.

When cooked in such a manner, raw, non-intact beef contaminated with STECs may cause serious physical problems, including death. Thus, raw, non-intact beef and raw intact beef intended for use in raw non-intact products that are contaminated with *E. coli* 0157:H7 or any of the six pathogenic non-O157:H7 STEC: (O26, O45, O13, O111, O121, and O145) contain a poisonous or deleterious substance and are adulterated within the meaning of the Federal Meat Inspection Act (FMIA) 21 U.S.C. 601(M)(1).

It is illegal for meat contaminated with any of these adulterant STECs to enter into commerce.

CREATING THE PLAN

Your HACCP plan must include the hazard analysis, any supporting documentation, the prerequisite programs used to support decisions in the hazard analysis, and all HACCP records.

Title 9 of the Code of Federal Regulations (9 CFR), sections 417.4(a)(1) and 417.4(a)(2), requires you to validate your HACCP system, meaning that you must demonstrate that your system is designed to control potential hazards adequately and produce safe, unadulterated product, and to verify, on an on-going basis, that your food safety system is working as intended.

In addition, you must support all of your hazard analysis decisions as required by 9 CFR 417.5(a)(1). Put another way, according to the final "FSIS Compliance Guideline HACCP Systems Validation" published on May 8, 2015, validation of a HACCP system involves two separate elements (1) showing that there is a scientific basis for the design of your program, and (2) showing that your plan will actually work as designed when implemented. Under 9 CFR 417.4(a)(1) your establishment is required to assemble two types of supporting documentation to demonstrate these elements are met:

1. The scientific or technical support for the HACCP system design - that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards; and

2. The in-plant validation data (execution) - that is the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected

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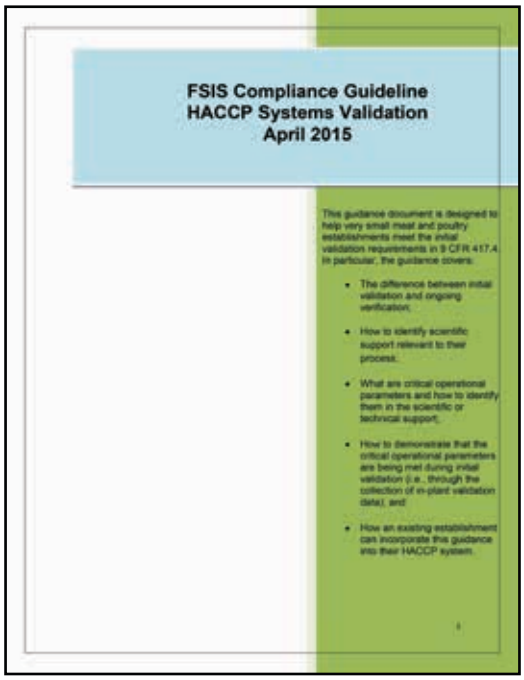
within a particular establishment to achieve the intended food safety objective.



The final version of the "FSIS Compliance Guideline HACCP Systems Validation" is available on FSIS' Web site at *www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index*

As part of the hazard analysis process, you're required to determine if these biological hazards are reasonably likely to occur. If your plant produces raw beef products, then your hazard analysis should assess the risk of STEC. The assessment should occur regardless of whether the material is from your establishment's own slaughter process or from another supplying plant.

It is important to note that FSIS does not mandate that an official processing plant have a critical control point (CCP) to address STEC during the fabrication process. Even so, there must be evidence of the evaluation of this hazard and support for the decision that it is not reasonably likely to occur if that is, indeed, the case.

ADDRESSING ADULTERANTS

There are many ways for a HACCP system to address adulterant STEC. For example, if you have a slaughter operation, you may address the pathogen through one or more critical control points (CCPs) in your HACCP plan. A multi-hurdle approach in a prerequisite program may include a Sanitation Standard Operating Procedures (SSOP) antimicrobial intervention program, sanitary dressing, zero tolerance fecal, and the results of microbial monitoring data.

For incoming product, a CCP for received raw intact beef may apply an antimicrobial intervention in response to the determination that the hazard is reasonably likely to occur. In each instance, under 9 CFR 417.2(a)(1), if you are producing raw meat or poultry products, you must support that potential hazards have been addressed in your product.

For the production of raw products, the scientific support should contain microbiological data specifying the expected level of pathogen control or prevention achieved by the intervention strategy so that you can determine whether the intervention is adequate for its product and process. Using documentation that does not contain microbiological data on the specific level of reduction achieved could represent vulnerability in your plant's HACCP system design and create problems.

The scientific support for raw meat products should also be sufficiently related to the process, product and hazard identified in your hazard analysis. It is particularly important that the scientific support for intervention strategies used in the production of raw products include microbiological data that specifies the expected level of pathogen reduction for the same hazard identified in the hazard analysis.

For additional guidance, consult the "FSIS Compliance Guideline HACCP Systems Validation," Appendix 3 for how to identify critical operational parameters from the scientific support. Also, Appendix 4 contains examples of critical operational parameters that have been identified for different types of processes and scientific support. Examples of the types of in-plant documentation expected are also provided for assistance.

POTENTIAL RISKS

The decisions made in your hazard analysis should be based on the potential risk of product contamination with STEC. The hazard analysis should also take into consideration your plant's processing procedures and your ability to

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verify continuously that these procedures are being performed in a way that is effective at preventing, eliminating, or reducing the hazard. In the case of STECs, FSIS considers them to be adulterants, and the only acceptable level is below detectable levels or zero.

The source of raw materials will have a significant impact on your hazard analysis. There are typically two sources of raw materials used in raw non-intact beef products. One is in-house source materials from your own slaughter operation and the other is purchased source materials from a separate supplying plant. The knowledge you have of the production of source materials from your own slaughter operation will be different from that of purchased product, thus this will impact your decisions in the hazard analysis.

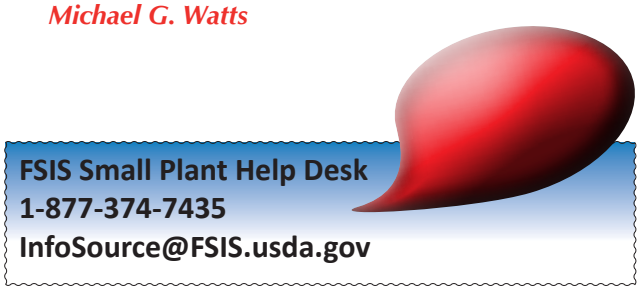
IN-HOUSE SOURCE MATERIALS

Most of the reductions in the levels of STECs occur in slaughter plants. For in-house source materials, the plant has direct knowledge regarding the production of source materials, including sanitary dressing practices, zero tolerance findings, microbial data, antimicrobial treatment reductive capabilities and records of critical operating parameters.

The hazard analysis decision-making process for a plant that uses purchased product as its source material is more complicated than for a plant that uses in-house source material. The relationship you have with your supplier will determine the level of knowledge the plant has concerning the production of the source materials, and this will impact hazard analysis decisions.

In Part II of this article, Vol. 7, No 9, we will continue discussing the risks between using in-house and purchased source materials, provide information on STEC controls, ongoing verification, and risking vulnerability.

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.*



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.

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