

# Compliance Guidelines for Shiga toxin *Escherichia coli* (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (“Beef Trim”)

August 2014

## **I. Purpose of the Labeling Guidance**

This document provides guidance on the use of labels bearing an FSIS sketch approved Shiga toxin-producing *Escherichia coli* (STEC) sampled and tested claim on beef trim. Such special labeling claims are voluntary. An establishment may use such claims when it demonstrates that they are truthful and not misleading (9 CFR 317.8(a)). FSIS must approve such claims before the establishment may use them on labels (9 CFR 412.1). The labeling guidance provided in this document applies to beef slaughter/fabrication establishments, although it’s likely to be most useful to those that manufacture 50,000 pounds or more of trimmings daily and conduct lot by lot testing.

## **II. Background**

On October 14, 2008, FSIS issued draft guidance entitled “Label Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings (‘Trim’) Concerning *E. coli* O157:H7,” and requested comments on the document. FSIS also held a public meeting to discuss the guidance and other topics concerning *E. coli* O157:H7. A second version of this document, published in May 2012, was revised in response to the comments on the draft guidance. The current version was updated to reflect the Agency’s recent policy developments regarding non-O157 STEC. Since FSIS issued this compliance guideline for comments in May 2012, FSIS began testing beef manufacturing trimmings for six non-O157 STEC (O26, O45, O103, O111, O121, and O145) in addition to *E. coli* O157:H7. FSIS also declared these six non-O157 STEC adulterants in raw, non-intact beef products and product components. (<http://www.fsis.usda.gov/wps/wcm/connect/6aa26172-2d27-4534-99d4-8c528b285fd2/2010-0023.pdf?MOD=AJPERES>).

Additionally, FSIS updated the Compliance Guideline for *E. coli* O157:H7 Sampled-and-Tested Claims for Boneless Beef Manufacturing Trim to recognize that establishments may want to submit a request for a labeling claim stating that product has been tested for the six additional STEC adulterants. FSIS clarified that it would need to see the same type of information to approve sampled and tested claims for the other adulterant STEC as it would need to see for sampled and tested claims concerning *E. coli* O157:H7.

FSIS has developed the following guidance for establishments that wish to use a label claim asserting that beef trim has been sampled, tested, and found negative for *E. coli* O157:H7, adulterant non-O157 STEC or a general claim for all STEC. This label claim is intended to provide receiving establishments with information regarding the sampling and testing of beef trim for STEC organisms conducted by supplier establishments. FSIS may approve claims of this type if supported by adequate information.

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A label claim that beef trim comes from a production lot that has been sampled, tested, and found to be negative for STEC will be helpful for receiving establishments because Certificates of Analysis (COAs), which also provide sampling and testing information, frequently do not properly transfer with beef trim product through the distribution chain. This guidance document addresses label claims that are **not intended** to be displayed to consumers. FSIS may approve STEC sampled and tested claims on trim that goes to retail stores, for example to a retailer who purchases the trim for grinding. However, FSIS will not approve such a label claim for display to consumers because it may be misleading to consumers by suggesting that the end product is free of the pathogens or may not need to be cooked thoroughly.

A negative test for STEC **does not** guarantee that all of the beef trim from the sampled production lot is free of the pathogens. Such assurance cannot be provided by sampling and testing. Rather, sampling and testing for STEC is intended to provide evidence regarding the effectiveness of Hazard Analysis and Critical Control Points (HACCP) measures related to the prevention, elimination, and reduction of the pathogens. A sampled and tested claim is meaningless – and therefore misleading – if the establishment asserting the claim has not incorporated into its HACCP system measures designed to control for STEC, and if the sampling and testing methodologies used are not designed to verify the effectiveness of those measures. Therefore, for FSIS to determine that a label claim that beef trim has been sampled, tested, and found negative for STEC is truthful and not misleading, the establishment requesting to make the claim would need to submit evidence demonstrating that its HACCP measures related to STEC are effective in reducing the pathogens to non-detectable levels, and that the results of the establishment’s sampling and testing demonstrate that those HACCP measures are effective.

To demonstrate that a labeling claim would be truthful and not misleading, FSIS would accept documentation showing that an establishment uses the FSIS sampling and testing methods or equivalent methods. The FSIS sampling method for beef trim is described in [FSIS Directive 10,010.1](#). Additionally, relevant sampling program guidance, including a discussion of High Event Period criteria, is provided in the document “[Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing \*Escherichia coli\* \(STEC\) Organisms or Virulence Markers](#).” The method of analysis should be equivalent to that of the current method that the FSIS laboratories use as cited in the [Microbiological Laboratory Guidebook \(MLG\)](#).

A list of STEC testing methods that have been validated by recognized international organizations can be found at the following link: [Foodborne Pathogen Test Kits Validated by Independent Organizations](#).

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STEC testing methods that have not yet been validated by these organizations but have received FSIS Letters of No Objection can be found at the following link: [STEC No Objection Letters](#)

While these sources of information indicate that the methodology has been validated for use in some context, it is important to confirm that the method of choice is fit for the intended purpose of the analysis and provides useful information for the food safety program used by the establishment. It is important for establishments to ensure that their private laboratory complies with the specific method that was validated, including the enrichment broth, incubation conditions, and test portion used to ensure that the pathogen screening test is effective. Private laboratories should have documented quality control programs that ensure the integrity of testing results. The establishment and laboratory should demonstrate confidence in test results and not re-sample or re-test pathogen-positive and non-compliant products.

The sections below describe the types of information that FSIS would expect to see on labels that bear STEC sampled and tested claims to prevent the labels from being false or misleading. They also describe the specific types of documentation that interested persons would need to submit to FSIS to obtain sketch approval for the use of such claims. Labels that include such special claims need to be submitted in accordance with 9 CFR § 412.2 for evaluation and sketch approval by the Labeling and Program Delivery Staff (LPDS) before use. FSIS inspection program personnel (IPP) periodically will verify that the establishments that make such claims are performing the sampling and testing that are described in the supporting documentation. FSIS intends to provide instructions to IPP for verifying that product meets these claims in establishments that use such labeling claims. FSIS intends to issue these instructions before it approves such claims.

### **III. Information to Appear on a Label Bearing a Sampled and Tested Claim**

A sampled and tested label claim should include all applicable features required by 9 CFR 317.2. FSIS likely would find that a sampled and tested claim for beef trim is not misleading if it is supported by the following information

1. A statement that the product in the labeled container is comprised of only beef trim derived from a production lot that has been sampled, tested and found negative for STEC;
2. A statement specifying that the sample collection method used was either the FSIS method or an equivalent method;
3. A statement specifying that the testing method used was either the FSIS method or an equivalent method;

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4. A statement that sampling and testing was conducted independently from FSIS testing;
5. A statement identifying the production lot from which the sampled and tested trim was derived (e.g., lot identification number or lot code);
6. If the production lot identified by the sampled and tested claim was created by combining product from two or more source production lots of trim (for example to create a particular formulation of lean to fat content), a statement that (a) explains this fact; (b) explains whether all source lots of trim bear STEC sampled and tested labels; and (c) explains whether the lot of trim identified by the sampled and tested label was sampled and tested in its final formulation;
7. If the labeled product (whether the label is applied to a container, a box, etc.) contains beef trim from a split lot (i.e., the labeled product contains only a portion of the production lot identified by the label or only a portion of any source production lot used to create the identified production lot), a statement that the labeled product contains part of a split lot; and
8. A statement of limited use indicating that the label may not be displayed at retail.

The following are examples of labeling claims that would be deemed acceptable under various circumstances, provided the establishment submits adequate documentation to support the claim. Other wording also may be appropriate.

1. Beef trim from a production lot independently sampled and tested negative for *E. Coli* O157:H7 using FSIS sampling and testing methods. Production lot No. 12345. This label may not be displayed at retail.
2. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS-equivalent sampling and testing methods. Derived from production lot No. 12345. Part of a split lot. This label may not be displayed at retail.
3. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS sampling and testing methods. Production lot No. 12345. Contains product from multiple source lots. Source lots not labeled as sampled and tested. Lot No. 12345 was

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sampled and tested. This label may not be displayed at retail.

4. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS sampling and testing methods. Production lot No. 12345. Contains product from multiple source lots. Source lots labeled as sampled and tested negative. Lot No. 12345 not sampled and tested negative. This label may not be displayed at retail.
5. Beef trim from a production lot independently sampled and tested negative for *E. coli* O157:H7 using FSIS sampling and testing methods. Derived from production lot No. 12345. Part of a split lot. Contains product from multiple source lots. Source lots and Lot No. 12345 sampled and tested negative. This label may not be displayed at retail.

### **IV. Documentation to be Included with the Label Submittal**

In order to ensure that a claim stating beef trim has been sampled, tested, and found negative for STEC is not misleading, an establishment should submit information that would allow FSIS to determine that the sampling results verify the effectiveness of the establishment’s HACCP system in controlling the pathogen. The list that follows describes the types of documentation, all of which needs to be submitted to LPDS with the label application, which would enable FSIS to make this determination.

1. Documentation demonstrating that lots of beef trim used to produce the product labeled with a sampled and tested claim originated from carcasses slaughtered at an official establishment using at least one validated intervention for STEC at a Critical Control Point (CCP) in the slaughter establishment’s HACCP plan;
2. Documentation demonstrating on-going communication (e.g. communication SOP, email records, phone logs) between establishments that use or commingle products that bear STEC sampled and tested claims and establishments that produced those products to ensure any changes to the HACCP plan are made known;
3. Documentation demonstrating that the sample collection method used is the same as or equivalent to the FSIS sample collection method described in FSIS Directive 10,010.1, and that the sampling is incorporated into the establishment’s HACCP plan;

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4. Documentation demonstrating that the testing method used is the same as or equivalent to the FSIS testing method described in the FSIS Microbiology Laboratory Guidebook, and that the testing is incorporated into the establishment’s HACCP plan.  
This documentation should provide assurance that the testing method protocol has been appropriately validated, is fit for the intended purpose of the analysis, and provides useful information for the food safety program. The establishment also should maintain documentation that ensures that the private laboratory complies with the specific method protocol that was validated, including the enrichment broth, incubation conditions, and test portions used to ensure that the pathogen screening test is effective, and that the laboratory has a documented quality program that ensures the integrity of the testing result;
5. Documentation demonstrating that if any sample tests positive or presumptive positive for STEC, the production lot represented by that sample is diverted from raw ground beef operations (e.g., the positive production lots are diverted to cooking or other full lethality treatment that will destroy the pathogen) and demonstrating how the establishment will ensure that such production lots have received an appropriate disposition either at an official establishment, landfill operation, or renderer;

Note: If product screens positive for STEC and is not confirmed to be negative, FSIS considers the product to be positive for the pathogen.

6. Documentation demonstrating that there is no re-sampling (collecting another sample) of any production lots that test positive or presumptive positive for STEC;
7. When either multiple operations within one establishment, or multiple establishments, are involved in creating the materials that will constitute a single production lot of sampled and tested trim, documentation that provides:
  - a. An explanation of how and when all involved operations or establishments communicate information pertaining to sanitary dressing performance and trim testing results;
  - b. An explanation of how that documentation will be made available to FSIS personnel for review at each establishment;

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- c. An explanation of how the communicated information is used to investigate and adjust the HACCP system to ensure that the system is adequate to control STEC; and
  - d. A discussion of how the combination of materials from separate operations or establishments may affect the microbiological independence of production lots;
8. Documentation demonstrating that the establishment maintains a written protocol describing the criteria used to distinguish an acceptable number of sporadic positives from a trend towards a systemic failure to control for STEC (i.e., high event period). These criteria should justify how the establishment discerns whether one production lot is microbiologically independent of another when the same source material is used to produce individual production lots. (Same source material is trim produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift).) The protocol also should describe the decision-making criteria for product disposition when the establishment experiences a high event period<sup>1</sup>; **and**
9. A description of how the establishment will use the FSIS approved sampled and tested label to identify the specific production lot tested (e.g., lot code or lot identification number).

### **V. Procedures for Submitting Labels for Approval**

Establishments interested in utilizing an STEC sampled and tested labeling claim on their beef trim products need to submit label applications in accordance with the information provided on the FSIS [Label Application Guidance](#) web page.

Questions about this guidance may be submitted to the Labeling and Program Delivery Staff (LPDS) through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **STEC Labeling Claims**

Question Field: Enter question with as much detail as possible.

Product Field: Select **Labeling** from the drop-down menu.

Category Field: Select **Labeling Regulations, Policies and Claims – Special Claims** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

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<sup>1</sup> Additional guidance on designing high event period criteria is provided in the document “[Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing \*Escherichia coli\* \(STEC\) Organisms or Virulence Markers.](#)”

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When all fields are complete, press Continue.