

# **Compliance Guideline for *E. coli* O157:H7 Sampled and Tested Claims for Boneless Beef Manufacturing Trimmings (“Trim”)**

**May 2012**

## **I. Comment Submission**

This Compliance Guideline is being issued in accordance with the procedures for guidance documents in the Office of Management and Budget’s (OMB) “Final Bulletin for Agency Good Guidance Practices” (GGP). More information can be found on the FSIS Web page:

[www.fsis.usda.gov/Significant\\_Guidance/index.asp](http://www.fsis.usda.gov/Significant_Guidance/index.asp).

This Compliance Guideline represents FSIS’s thinking on labeling claims that boneless beef manufacturing trimmings (trim) have been sampled, tested, and found to be negative for *E. coli* O157:H7 (“sampled and tested claims”). These claims should be considered usable as of this issuance if approved by FSIS. FSIS will update these guidelines in response to any comments that it receives and as needed to reflect the most current information available to FSIS and stakeholders. The comment period will be 60 days.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>.

Follow the online instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

• Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2011-0009. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

# **Compliance Guideline for *E. coli* O157:H7 Sampled and Tested Claims for Boneless Beef Manufacturing Trimmings (“Trim”)**

## **II. Purpose of the Guidance**

This document provides guidance on the use of labels bearing an FSIS sketch approved *E. coli* O157:H7 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 317.4(a)).

## **III. 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. This version of the guidance has been revised in response to the comments on the draft guidance. Most notably, FSIS has modified the description of the information that it recommends an *E. coli* O157:H7 sampled and tested labeling claim should include and of the documentation that establishments should submit in support of an application for sketch label approval of such claims. This version of the guidance document also provides an explanation regarding the relationship between *E. coli* O157:H7 sampled and tested claims and HACCP measures related to the pathogen.

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. This label claim is intended to provide receiving establishments with information regarding the sampling and testing of beef trim for *E. coli* O157:H7 conducted by supplier establishments. FSIS may approve claims of this type if supported by adequate information.

A label claim that beef trim comes from a production lot that has been sampled, tested, and found to be negative for *E. coli* O157:H7 will be helpful to 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 *E. coli* O157:H7 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 pathogen or may not need to be cooked thoroughly.

A negative test for *E. coli* O157:H7 does not guarantee that all of the beef trim from the sampled production lot is free of the pathogen. Such assurance cannot be provided by sampling and testing. Rather, sampling and testing for *E. coli*

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O157:H7 is intended to provide evidence regarding the effectiveness of HACCP measures related to the prevention, elimination, and reduction of the pathogen. 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 *E. coli* O157:H7, 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 *E. coli* O157:H7 is truthful and not misleading, the establishment requesting to make the claim would need to submit evidence that demonstrates that the establishment’s HACCP measures related to *E. coli* O157:H7 are effective in reducing the pathogen 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 Chapter II, Section IV, Parts A and B of [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” at the following website:  
([www.fsis.usda.gov/PDF/Compliance\\_Guide\\_Est\\_Sampling\\_STEC\\_0512.pdf](http://www.fsis.usda.gov/PDF/Compliance_Guide_Est_Sampling_STEC_0512.pdf))  
The FSIS testing method for *E. coli* O157:H7 is described in method number 5 and 5A of the [FSIS Microbiology Laboratory Guidebook](#).

Equivalency of alternative sampling and testing methods may be demonstrated via a rigorously designed validation study. The document, “FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods” ([www.fsis.usda.gov/PDF/Validation\\_Studies\\_Pathogen\\_Detection\\_Methods.pdf](http://www.fsis.usda.gov/PDF/Validation_Studies_Pathogen_Detection_Methods.pdf)) provides relevant validation study guidance.

The sections below describe the types of information that FSIS would expect to see on labels that bear *E. coli* O157:H7 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 § 317.4 for evaluation and sketch approval by the Labeling and Program Delivery Division (LPDD) 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

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establishments that use such labeling claims. FSIS intends to issue these instructions before it approves such claims.

### **IV. 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 would likely 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 beef trim derived from a production lot that has been sampled, tested and found negative for *E. coli* O157:H7;
2. A statement specifying that the sampling 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;
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 bore *E. coli* O157:H7 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.

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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 *E. coli* O157:H7 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 *E. coli* O157:H7 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 sampled and tested. This label may not be displayed at retail.
4. 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. 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.

### **V. 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 *E. coli* O157:H7 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 type of documentation that 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 *E. coli* O157:H7 at a CCP in the slaughter establishment’s HACCP plan;

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2. Documentation demonstrating on-going communication between establishments that use or commingle products that bear *E. coli* O157:H7 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 sampling method described in Chapter II, Section IV, Parts A and B of FSIS Directive 10,010.1, and that the sampling is incorporated into the establishment’s HACCP plan;
4. Documentation demonstrating that the testing method used is the same as or equivalent to the FSIS testing method described in method number 5 and 5A of the FSIS Microbiology Laboratory Guidebook, and that the testing is incorporated into the establishment’s HACCP plan;
5. Documentation demonstrating that if any sample tests positive for *E. coli* O157:H7, the production lot represented by that sample is diverted from raw ground beef operations (i.e., the positive production lots are diverted to cooking or other further processing that will destroy the pathogen) and demonstrating how the establishment will ensure that such production lots have been properly disposed to eliminate the adulterant or destroy the product;

**Note:** If product screens positive for *E. coli* O157:H7 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 for *E. coli* O157:H7;
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 *E. coli* O157:H7; 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 *E. coli* O157:H7 (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. The protocol should also describe the decisionmaking 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).

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

Establishments interested in utilizing an *E. coli* O157:H7 sampled and tested labeling claim on their beef trim products need to submit label applications in accordance with the information provided on the FSIS Web site at:

[www.fsis.usda.gov/Regulations\\_&Policies/Label\\_Application\\_Guidance/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/Label_Application_Guidance/index.asp)

If you have questions, please submit them through askFSIS at <http://askfsis.custhelp.com> or contact the LPDD by telephone at 1-800-233-3935, and then following the menu prompts, press 1, then press 3, and then press 1 again.

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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.”  
[http://www.fsis.usda.gov/PDF/Compliance\\_Guide\\_Est\\_Sampling\\_STEC\\_0512.pdf](http://www.fsis.usda.gov/PDF/Compliance_Guide_Est_Sampling_STEC_0512.pdf)