

**DRAFT - Label Policy Guidance for  
N-60 Testing Claims for Boneless Beef Manufacturing Trimmings (“Trim”)  
Concerning *E. coli* O157:H7**

**I. Purpose of the Guidance**

This document provides guidance to the industry on the use of labels bearing an FSIS approved N-60 *E. coli* O157:H7 testing claims on beef trim. Such special label claims are voluntary. An establishment may use such claims when it demonstrates such *E. coli* O157:H7 testing claims are truthful and not misleading. FSIS needs to approve such claims before the establishment can use them on labeling. This guidance is presented in draft form to provide current thinking. The industry is invited to comment on this guidance.

**II. Background**

Labels on meat and poultry products are to convey clear, truthful and not misleading information about the products to which the labels are applied. When establishments make specific claims on labels, the claims should convey information that accurately describes the conditions under which the product was produced, certain characteristics of the product or its ingredients, or other data that are relevant to the claim.

FSIS allows the use of labels that contain special claims (e.g. instructional and disclaimer statements for *E. coli* O157:H7) under certain conditions. In order to provide receiving establishments, particularly small and very small plants with information about the HACCP system and testing done at the supplier establishment, the Labeling and Program Delivery Division (LPDD) has developed the following N-60 testing claim guidance. This labeling claim is intended to provide the receiving establishment with this information in lieu of Certificates of Analysis (COAs) that may not properly transfer with product through distributors. This claim asserts that the raw beef component has been produced under an integrated control program between the slaughter/dressing operation and the trim production operation and tested for the presence of *E. coli* O157:H7 using a particular sample method (e.g., N-60 sampling). Labels bearing this claim would not be approved for products sold at retail or directly to consumers.

If FSIS institutes this program, the Agency would likely expect that specific conditions would be met before labeling bearing N-60 testing claims concerning *E. coli* O157:H7 on beef trim can be applied. The sections below describe the information that would need to be included on labels bearing these claims and the documentation that needs to be included with a submittal to FSIS before approval and use of such labels. As with all special claims, these labels would need to be submitted for evaluation and approval by the LPDD before use. FSIS inspection program personnel would be provided instructions for verifying the N-

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60 labeling claim in establishments that use such labels.

**III. Information to appear on the N-60 testing claim label**

If FSIS institutes this program, labels bearing testing claims would need to include all features required by 9 CFR 317.2 and the following criteria to support the use of the claim:

1. The label would need to include that the testing is the establishment’s testing (e.g., “Derived only from ABC Company’s N-60 Tested and Passed Beef Trim”);
2. The label would need to include a statement on whether the testing claim is specific to the labeled container or to multiple containers of a particular weight/number in the sampled production lot (e.g., a statement is included on the label such as “N-60 negative for 2,000 lbs” or “N-60 negative for 100 (40 pound) boxes”);
3. The label would need to include the statement of limited use “Not for consumer labeled product;” and,
4. If the beef trim was N-60 tested and then various containers of the tested trim are mixed together for a particular formulation, the N-60 label would need to state that the final product was tested before it was combined with other tested trim, and that the final product was not tested. If the final formulated product was N-60 tested, then the label could say so and could state that the contents were N-60 tested twice under N-60 sampling, or other appropriate qualification.

**IV. Documentation to be included with the label submittal**

Under the contemplated program, the label application would need to include the following, as well as a statement that all such documentation is incorporated into the establishment’s HACCP plan, subject to verification by FSIS inspection program personnel:

1. Documentation demonstrating that all beef trim used to produce the product 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;

Note: FSIS requires documented on-going communication between establishments that use or commingle products that bear N-60

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claims to ensure any changes to the HACCP plan are made known.

2. Documentation that all beef trim labeled with an N-60 testing claim is tested for *E. coli* O157:H7 (either via a screen method that includes this specific pathogen or a method specific to this pathogen) using the FSIS method or an equivalent method for *E. coli* O157:H7 analysis, and that the testing is incorporated into the establishment’s HACCP plan;
3. Documentation that the sample collection methodology indicates that at least 60 randomly selected samples consisting of at least 325 grams of product are composited and tested (NOTE: The Agency’s tentative view is that it would not object if a laboratory used a wet pooling process whereby the individual N-60 samples are enriched, and an aliquot is removed from each of the enrichments for a pooled sample analysis; in such cases, individually enriched samples may subsequently be tested following a pooled sample positive in order to discern which of the N-60 samples contributed to the positive finding; this situation is not considered “retesting”);  
;
4. Documentation that if any N-60 tested lot is positive for *E. coli* O157:H7, the lot represented by such N-60 sample is diverted from raw ground beef operations (i.e., the positive lots are diverted to cooking or other further processing that will destroy the pathogen). The documentation would need to explain how the establishment will ensure that such lots have been properly disposed to eliminate the adulterant;
5. Documentation showing evidence that there would be no re-sampling (collecting another N-60 sample) of any production lots that test positive for *E.coli* O157:H7;
6. If multiple operations within one establishment or multiple establishments are involved in creating the production lot of N-60 tested trim (e.g., a slaughter/processing combination establishment produces the trim, or the trim is derived from another establishment from which the trim also bears an FSIS approved N-60 labeling claim), documentation that describes how and when communication between or among the establishments would be recorded regarding slaughter/dressing performance and trim testing results, how that documentation would be made available to the IICs for review at each establishment, how that information would be used to investigate and adjust the HACCP system ensure that the HACCP system is adequate to control *E. coli* O157:H7, and how this information would affect microbiological independence of production lots;

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7. A written protocol addressing the criteria used by the establishment requesting the FSIS approved N-60 testing claim label to identify an acceptable number of sporadic positives from a trend towards a systemic failure to control for *E. coli* O157:H7 (i.e., “high event day”); these criteria would need to justify how to discern when one production lot is/isn’t microbiologically independent of another when same source material are used in individual production lots. The protocol also would need to describe the decision making for product disposition; and,
8. A description of how the FSIS approved N-60 label will identify the specific production lot tested (e.g., lot code or lot identification number).

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

If this program is instituted, interested persons would be able to submit label applications in accordance with the information that the Agency would provide on the FSIS web site at:

[http://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 contact the LPDD at 202-205-0623 or at 1-800-233-3935, and then following the menu prompts, press 1, then press 3, and then press 1 again.