



Draft Labeling Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings Concerning *E. coli* O157:H7

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Draft Labeling Policy Guidance for N-60 Testing Claims

- Labels on meat and poultry products are to convey truthful and not misleading information
- Special label claims are voluntary
- Food safety issue (not traditional labeling issue)



Background

- Labeling and Program Delivery Division (LPDD) received requests for label approval for labels bearing N-60 *E. coli* O157:H7 testing claims
- Draft labeling guidance was developed to provide industry with information on the use of labels bearing an FSIS approved *E. coli* O157:H7 testing claim on beef trim
- An establishment may use such claims when it demonstrates such *E. coli* O157:H7 testing claims are truthful and not misleading
- Although product bearing the label claim can be sold to a retailer the claim cannot appear on retail-ready packaging (e.g., would appear on beef trim produced at a slaughter/dressing establishment sold to a retailer)



Background

(continued)

- N-60 label claims are intended to provide information to a receiving establishment about the supplier's HACCP system and testing done at the supplier's establishment in lieu of a certificate of analysis that may not properly transfer with product through distributors
- The 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)



Background

(continued)

- Specific conditions should be met before labeling bearing N-60 testing claims concerning *E. coli* O157:H7 on beef trim can be applied
- Labels would need to be submitted for approval prior to use (includes a technical review of information)
- Label submittals would need to include a label bearing certain information and documentation before FSIS approval and use of such labels
- FSIS inspection program personnel would need to be provided instructions for verifying the N-60 labeling claim in establishments that use such labels



N-60 Claim Label Information

- A statement conveying that the testing is the establishment's testing (e.g., "Derived only from ABC Company's N-60 Tested and Passed Beef Trim")



N-60 Claim Label Information (continued)

- 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”)
- The label would need to include the statement of limited use e.g., “Not for consumer labeled product”



N-60 Claim Label Information (continued)

- If the beef trim was N-60 tested and then various containers of the tested trim are mixed together for a particular formulation, N-60 label would need to state that the final product was tested before it was combined with other tested trim but 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



N-60 Label Claim Documentation

- 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 system



N-60 Label Claim Documentation (continued)

- 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
 - Statement that the testing is incorporated into the establishment's HACCP system



N-60 Label Claim Documentation (continued)

- Sample collection methodology indicates that at least:
 - 60 randomly selected samples are analyzed
 - at least 325 grams of product are composited and tested or, if enriched, an aliquot from the enriched composite can be analyzed



N-60 Label Claim Documentation (continued)

- 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)
 - Description of how the establishment will ensure that such lots have been properly disposed to eliminate the adulterant



N-60 Label Claim Documentation (continued)

- 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



N-60 Label Claim Documentation (continued)

- 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),



N-60 Label Claim Documentation (continued)

- ✓ 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 to ensure that the system is adequate to control *E. coli* O157:H7



N-60 Label Claim Documentation (continued)

- 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”);



N-60 Label Claim Documentation (continued)

- ✓ 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 must describe the decision making for product disposition
- ✓ 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)
- ✓ how this information would affect microbiological independence of production lots



N-60 Label Claim Documentation (continued)

- description of how the FSIS approved N-60 label will identify the specific production lot tested (e.g., lot code or lot identification number)



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- FSIS is providing this draft guidance for review and comment. All stakeholders are encouraged to submit their comments to:
FSISGuidanceDocumentComments@fsis.usda.gov
Comments will be accepted until November 17, 2008.
- If this program is instituted, interested persons may submit label applications in accordance with the information that the Agency would provide on the FSIS web site
http://www.fsis.usda.gov/Regulations_&_Policies/Label_Application_Guidance/index.asp