

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

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# FSIS NOTICE

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11-19

4/30/19

**INFORMATION REGARDING INSTRUCTIONAL LABELING STATEMENTS FOR RAW BEEF PRODUCTS SHIPPED TO INTERMEDIARY OFFICIAL ESTABLISHMENTS PRIOR TO DELIVERY TO AN OFFICIAL ESTABLISHMENT FOR FULL LETHALITY TREATMENT TO ADDRESS SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI***

**NOTE:** An instructional statement concerning Shiga Toxin-Producing *Escherichia coli* (STEC) is a statement that addresses how the raw product is to be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level (e.g., “for cooking only” or “for full lethality treatment”).

## I. PURPOSE

A. This notice reissues the instructions in FSIS Notice 06-18 to inspection program personnel (IPP) for verifying an establishment’s use of instructional labeling statements concerning STEC when raw beef products are shipped to one or more official establishments before delivery to the official establishment for cooking or other full lethality treatment (e.g., irradiation or high pressure pasteurization).

B. IPP are to continue to follow the instructions in [FSIS Directive 10,010.2](#), *Verification Activities for Shiga Toxin-Producing Escherichia coli in Raw Beef Products*, for products labeled with an instructional statement and shipped directly to an official establishment for cooking or other full lethality treatment.

C. This notice only applies to product that has not been tested or has tested negative for STEC. IPP are to follow verification procedures in Chapter III Sections I and IV of [FSIS Directive 10,010.2](#) for product that is presumptive or confirmed positive for STEC and labeled with an instructional statement.

## II. BACKGROUND

Products labeled with instructional statements may be produced and labeled at one establishment and undergo further processing (e.g., repackaging, grinding) at an intermediate, non-cooking official establishment prior to being sent to another official establishment for cooking or other full lethality treatment. If the product is to undergo further processing at an intermediary establishment, the intermediary establishment is to address the potential for cross-contamination in its HACCP system. ID warehouses and brokers are not official establishments, and cannot re-box or further process product labeled with instructional or disclaimer statements. ID warehouses may store product only ([9 CFR 412.1\(e\)](#)).

## III. VERIFICATION ACTIVITIES AT PRODUCING ESTABLISHMENTS

A. When conducting a HACCP verification task, IPP at an establishment that applies instructional statements are to follow the instructions in [FSIS Directive 10,010.2](#), Chapter IV, to verify the producing establishment maintains and implements sanitation procedures to prevent cross-contamination and

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maintains records adequate to demonstrate the product was sent to an official establishment for a full lethality process.

B. When IPP identify noncompliance, they are to document the noncompliance on a noncompliance record (NR) as described in [FSIS Directive 5000.1](#), Chapter V, using the HACCP verification task and the appropriate regulatory citation (usually 9 CFR 417.5).

C. IPP are to be aware that product for export, and product sent to a state-inspected establishment or a retail firm may not bear an instructional statement.

#### **IV. VERIFICATION ACTIVITIES AT INTERMEDIARY ESTABLISHMENTS**

A. A producing establishment may ship product to one or more intermediary establishments before the product is delivered to the official establishment that applies the full lethality treatment.

B. Intermediary establishments that receive product labeled with an instructional statement and further process the product may reapply (i.e., “carry forward”) the instructional statement without label approval. IPP at intermediary establishments that carry forward labeling of product with an instructional statement are to:

1. Follow the instructions in [FSIS Directive 10,010.2](#), Chapter IV to verify the establishment is appropriately using the instructional statement. The HACCP system for establishments that carry forward the instructional statement do not need to include a validated intervention for STEC as the product is intended for cooking or other full lethality treatment;
2. Verify the establishment’s hazard analysis ([9 CFR 417.2](#)) and decision-making documents ([9 CFR 417.5](#)) meet the criteria in [FSIS Directive 10,010.2](#), Chapter IV when performing the HACCP verification task;
3. Verify the establishment tracks and facilitates communication between the supplying establishments and receiving establishments to ensure records are available showing each lot of product was sent to an establishment for cooking or other full lethality treatment; and
4. IPP are to document noncompliance on an NR as described in [FSIS Directive 5000.1](#), Chapter V, using the HACCP verification task and the appropriate regulatory citation (usually 9 CFR 417.5) when they find that the intermediate establishment has not met the criteria above.

#### **V. ID WAREHOUSES AND BROKERS**

A. IPP are to verify that product with an instructional statement is not broken down into smaller units or repackaged at an ID warehouse. If IPP observe breaking bulk or repackaging of product bearing instructional or disclaimer statements at an ID warehouse, they are to contact the District Office and detain the product, as instructed in Section VI of [FSIS Directive 10,010.2](#).

B. IPP are to notify the Labeling and Program Delivery Staff in the Office of Policy and Program Development if a label sketch approval is found for instructional statements at an ID warehouse.

#### **VI. QUESTIONS**

Refer questions regarding this notice to the Office of Policy and Program Development 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 **Notice 11-19**.  
Question Field: Enter question with as much detail as possible.  
Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling – E. coli O157:H7** from the drop-down menu.  
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

**NOTE:** Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink that reads "Sabrina J. Wagner". The signature is written in a cursive style.

Assistant Administrator  
Office of Policy and Program Development