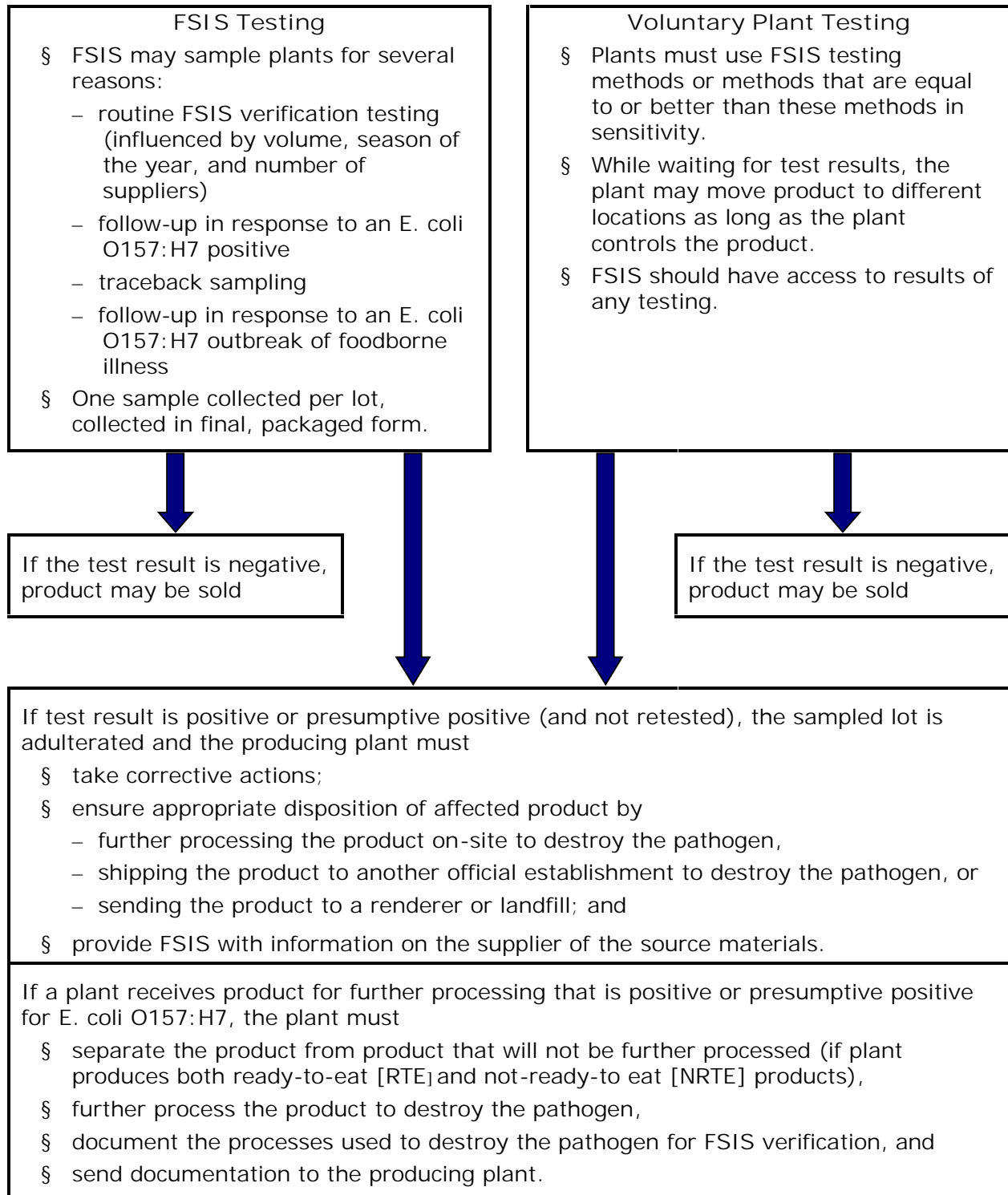


## Testing of Product for E. coli O157:H7

All official establishments producing raw ground beef products, raw ground beef components, or raw beef patty components are subject to FSIS sampling for E. coli O157:H7. Establishments may conduct their own voluntary sampling as well.



## Use of Instructional or Disclaimer Statements Concerning E. coli O157:H7

### Instructional Statements:

A statement that addresses how the product should be prepared or handled so that the pathogen is eliminated or reduced to an undetectable level. These statements are not required by FSIS. For example, an instructional statement may read "for cooking only."

### Disclaimer Statements:

A statement about the type of controls or verification activities addressing the pathogen that were not used in the production of the product. These statements are not required by FSIS. For example, a disclaimer statement may read "product has not been tested for E. coli O157:H7."

### Establishments that Place Instructional or Disclaimer Statements on Their Labels:

- § Must obtain sketch approval from FSIS Labeling and Consumer Protection Staff and maintain a sketch approval in their records.
- § Cannot use these statements as a CCP or intervention for E. coli O157:H7.
- § Must reflect this information in their decision-making documents and hazard analysis.
- § Should have controls in place to separate product intended for cooking from product not intended for cooking.
- § "For cooking only" instructional statements, should have controls in place to ensure that the product is shipped only to establishments that will cook it.

### Establishments that Receive Products with Instructional or Disclaimer Statements on Their Labels:

- § Must address the use of the incoming product with disclaimer statements in their HACCP plan as if the product is contaminated with E. coli O157:H7.
- § Must follow the instructional statements on incoming product.

NOTE: Product labeled "for cooking only" may go to an establishment that cooks product intended for additional further processing. An establishment is complying with the labeling instructions if it cooks the product at a sufficient temperature and for a sufficient time period to eliminate or reduce E. coli O157:H7 to an undetectable level.

## Purchase Specifications

One way establishments producing raw ground beef product control E. coli O157:H7 in ground beef is using purchase specifications to ensure they receive source materials that have undergone interventions that eliminate or reduce E. coli O157:H7 to an undetectable level. These purchase specifications should be detailed in one of the establishment's prerequisite programs (for example, HACCP plan, sanitation SOP, or other prerequisite program).

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### Prerequisite Programs

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- § Establishments should require documentation from their suppliers showing that the purchase specifications are being met, and they should verify this at some frequency.
- § Establishments should know how their suppliers are preventing or reducing E. coli O157:H7 and whether they conduct verification testing.
- § Suppliers should notify the receiving establishment if their interventions have not been effective or have not been applied correctly.
- § FSIS recommends that establishments with purchase specifications include testing as part of their verification activities.
- § If establishments receive product that tests positive for E. coli O157:H7, they should conduct corrective actions. These actions include contacting the supplier to determine what controls failed or no longer buying from that supplier.

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### Documentation Requirements

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- § Should include information on relevant prerequisite programs in the supplying establishments' supporting documentation.
- § Should specify the interventions used by the supplying establishment.
- § Should state that the intervention used by the supplying establishment is effective as proven by negative test results.
- § Should accompany each shipment of product and should not be photocopies of the same information with each shipment.
- § Should specify whether suppliers have CCPs that address E.coli O157:H7.

## Validation of Critical Control Points

If product is positive for E. coli O157:H7 and ...

- § the plant's HACCP plan includes a CCP for E. coli O157:H7, the plant must take corrective actions.
- § the plant's HACCP plan does not include a CCP for E. coli O157:H7, the plant must reassess its HACCP plan and take corrective actions.

Establishments that receive raw ground beef must

- § ensure that the supplier meets purchase specifications,
- § verify that purchase specifications prevent E. coli O157:H7 from entering the plant in the product received,
- § continually verify that suppliers' validated CCPs are effective,
- § maintain supporting documentation on suppliers' verification activities, and
- § validate CCPs in their own HACCP plan (do not have to validate CCPs in suppliers' HACCP plans).

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### Peer-Reviewed Validation Studies

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To validate a CCP using a peer-reviewed study, plants must demonstrate that they are able to repeatedly meet the parameters in the study and verify that the pathogen is not detected. All interventions used in the study must be applied at the establishment in order for the study to be used as a validation. A challenge study (using introduced pathogens) is another way to validate a process, but it must be conducted in a laboratory outside the plant.

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### Indicator Organisms

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Indicator organisms that are not pathogens are useful in studying the general effectiveness of plant interventions and making determinations about process control. Currently, there are no true non-pathogenic organisms that mimic E. coli O157:H7.

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### Finished Product Testing

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In most cases, a CCP based on finished product testing to determine product disposition would be inappropriate. A CCP for disposition that relies on product testing is appropriate when

- § a plant conducts its own slaughter, fabrication, and grinding and does not use product from other plants;
- § a plant includes CCPs at slaughter and fabrication, and its finished product testing is at a level sufficient to find the pathogen at very low frequency; and
- § a grinder and its suppliers have internal controls for E. coli O157:H7, and both conduct rigorous verification testing of product at multiple points.

## BIFSCO Best Practices for Blade Tenderization

The Beef Industry Food Safety Council (BIFSCO) created a “best practices” document for producers of whole muscle cuts (for example, chucks, ribs, tenderloins, strip loins, top sirloin butts, rounds) to reduce the likelihood of E. coli O157:H7 contamination. Although the operating practices at individual companies may vary, producers of whole muscle cuts are urged to consider these best practices as guidelines for their own internal practices and documentation.

BIFSCO specified best practices for the following areas:

- § raw material control
- § supplier evaluations
- § temperature control
- § process controls
- § lotting
- § HACCP system
- § sanitation and facilities
- § interventions/inhibitors
- § microbiological testing
- § packaging and labeling
- § integrated approach to control

The best practices document can be found at  
[http://www.bifSCO.org/uDocs/03\\_29\\_06%20Non-Intact%20Best%20Practices.pdf](http://www.bifSCO.org/uDocs/03_29_06%20Non-Intact%20Best%20Practices.pdf).