



## FSIS Notice 05-09



# Measures to Address *E. coli* O157:H7 at Establishments that Receive, Grind, or Otherwise Process Raw Beef Products



# FSIS Notice 05-09

## I. PURPOSE

*To identify inadequate measures employed by establishments to address E. coli O157:H7.*

- *increased rate E. coli O157:H7 in product*
- *Recalls*
- *Food borne illnesses*



# FSIS Notice 05-09

## *Key Points Covered*

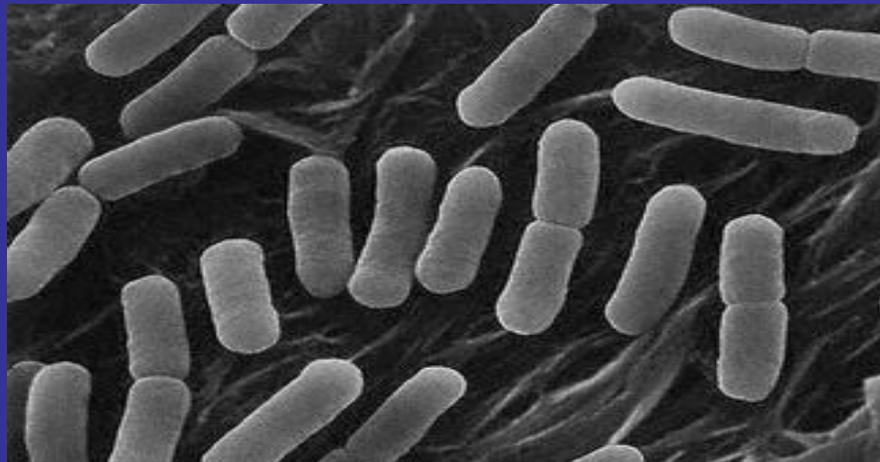
- Provide EIAO with specific criteria that they are to consider when they assess whether these establishments have adequate support for how, based on their hazard analysis, they address *E. coli* O157:H7 in their HACCP systems.



# FSIS Notice 05-09

## *Key Points Covered*

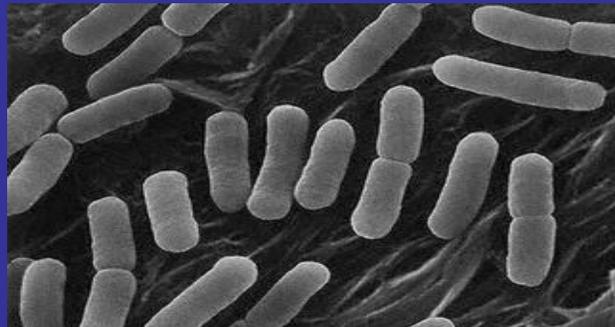
- Provides CSI with instructions on how to conduct verification activities at establishments that use CCPs to prevent, eliminate, or reduce *E. coli* O157:H7 in raw beef products or that use their Sanitation SOPs or another prerequisite program to prevent occurrence of this pathogen.



# FSIS Notice 05-09

## II. INADEQUATE MEASURES TO ADDRESS *E. coli* O157:H7

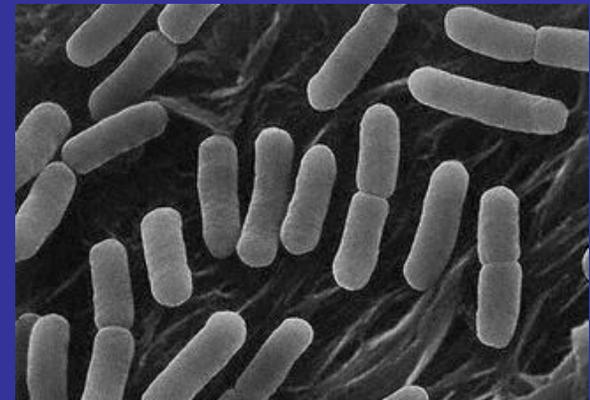
- Mark of inspection  $\neq$  no *E. coli* O157:H7 in product
- *The mark of inspection is a reflection of a finding made by FSIS personnel that the establishment has followed the validated procedures in its HACCP plan, not that the pathogen has been eliminated or reduced to undetectable levels.*



# FSIS Notice 05-09

## II. INADEQUATE MEASURES TO ADDRESS *E. coli* O157:H7

- Only support in HA is that product bears the mark of inspection
- *Correlate* with the District Office through the Frontline Supervisor *to determine if the HACCP plan is inadequate (9 CFR 417.6(a)).*
  - *EIAO perform FSA*
  - *NOIE*

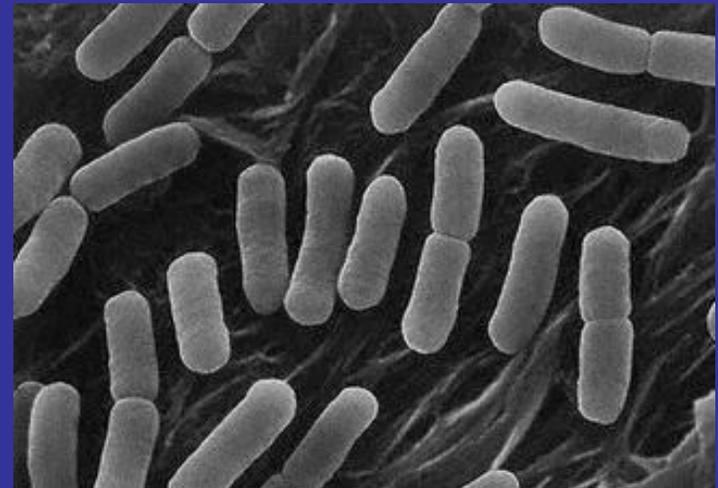


# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

*Key point:* no one, absolute way to control or prevent *E. coli* O157:H7

- IPP verifying 9 CFR 417.5(a) using
  - CCPs in HACCP plan,
  - Sanitation SOP,
  - another prerequisite program, or
  - a combination of these





# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

FMIA §601 (I) The term “prepared” means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Any official establishment preparing finished raw beef products must consider the potential food safety hazard of *E. coli* O157:H7



# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

### *Key point:*

*- 9 CFR 417.5(a)(1) requires supporting and ongoing documentation that establishes that the pathogen hazard is not reasonably likely to occur in its operation because of the design and execution of its prerequisite program.*

*- prerequisite programs may include the use of purchase specifications.*



# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

### *Purchase specifications in a prerequisite program*

FSIS expects the *receiving* establishment to have:

1. Supplier document (e.g., letter of guarantee) outlines CCPs that address *E. coli* O157:H7 and that describes those interventions;
2. COAs (i.e., actual test results) and the sampling method used (e.g., N=60) by the supplier; and
3. Records (e.g., the receiving establishment's own testing results, ongoing communication with suppliers, or third party audits) that demonstrate that the receiving establishment is executing its program in a consistent and effective manner.

# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

### *Relationships in a receiving establishment*

1. Direct relationship – detailed information shared



2. Casual relationship – general supplier letter but no microbial data

3. Indirect relationship - brokers or importers





# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

### Additional provisions in food safety program

1. Seek direct contact with supplier establishment to determine whether the suppliers have validated interventions and procedures and inquire about the sampling methods the supplier uses.
2. Obtain evidence from the broker or importer for each incoming shipment of raw beef materials that the materials were tested (e.g., N60), and that the test results were negative for *E. coli* O157:H7



# FSIS Notice 05-09

## III. MEASURES TO ADDRESS *E. coli* O157:H7

Other mechanisms for controlling the presence of *E. coli* O157:H7 such as:

- a. testing incoming product;
- b. treating or washing the product when removed from Cryovac bags and trimming the outer surface before processing non-intact product;
- c. testing finished product; or
- d. using antimicrobials or other lethality treatments on raw beef product.



# FSIS Notice 05-09

## IV. EIAO VERIFICATION ACTIVITIES

- Follow methodology in FSIS Directive 5100.1 to assess decisions/support for measures taken to address *E. coli* O157:H7.
- Evaluate validation of the HACCP system.
  - *practical data or information reflecting actual experience in implementing the HACCP plan*
  - *validation data demonstrates that *E. coli* O157:H7 has been eliminated or reduced to a non-detectable level*
  - *identification or development of data demonstrating process control to get the anticipated effect under actual in-plant operational conditions*





# FSIS Notice 05-09

## IV. EIAO VERIFICATION ACTIVITIES

- Assess Sanitation SOP or prerequisite program that is employed to prevent *E. coli* O157:H7 in raw beef products
  - determine whether the hazard analysis has the supporting documentation
    - review and assess scientific support and decision-making documents associated with the development and use of its prerequisite program as required in 9 CFR 417.5(a)(1)
  - determine whether the ongoing documentation shows the presence of the pathogen hazard is not likely to occur in the process
    - supported by the evidence from the system in operation
    - systems approach to process control - minimize variability

# FSIS Notice 05-09



## IV. EIAO VERIFICATION ACTIVITIES

Ask and gather information on the following:

1. Relationship the receiver has with its supplier
2. Documents (e.g., supplier letter) from each supplier that describe the supplier's procedures
3. COAs (i.e., actual test results) and a description of the sampling method used (e.g., N=60)
4. System for maintaining written procedures and records (e.g., its own testing, ongoing communication with suppliers, or third party audits)
5. If receives raw beef product from brokers or importers and how this raw beef product is handled?



# FSIS Notice 05-09

## IV. EIAO VERIFICATION ACTIVITIES

- Consider all the factors when documenting FSAs findings as set out in FSIS Directive 5100.1.
- Negative answers to the questions *do not automatically* mean that the establishment's system is inadequate.
- If only some of the criteria (supplier letter, COA, records) are in the prerequisite programs; EIAOs must consider the establishment's use of any validated CCPs to control *E. coli* O157:H7.



# FSIS Notice 05-09

## V. CSI VERIFICATION ACTIVITIES

- HACCP Plan has a CCP to control *E. coli* O157:H7
  - *Verify 9 CFR 417.4(a) - validated that the CCP achieves the anticipated effect in-plant*
  - *If questions, IIC is to contact the DO through FLS*
  - *DO is to determine whether it is necessary to send an EIAO to the establishment.*



# FSIS Notice 05-09

## V. CSI VERIFICATION ACTIVITIES

- Prerequisite program used to prevent *E. coli* O157:H7 in raw beef products

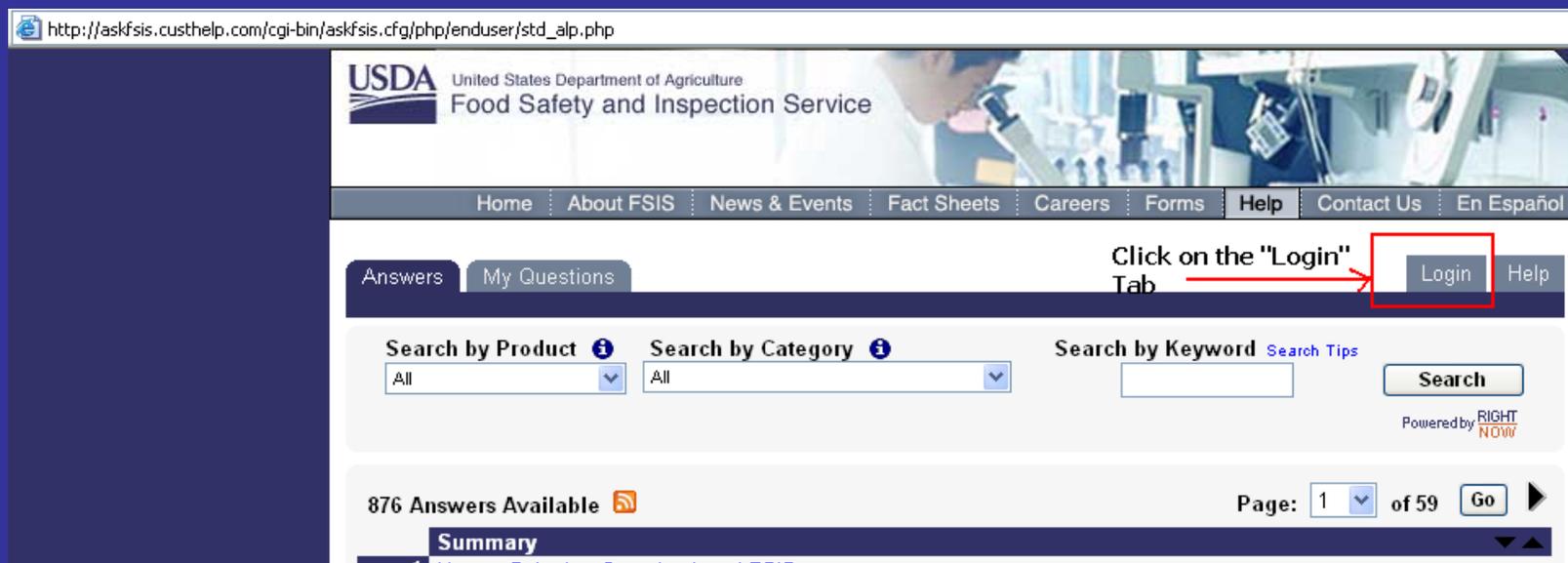


- *the establishment's prerequisite program is being executed as designed*
- *If questions, IIC is to contact the DO through FLS*
- *DO is to determine whether it is necessary to send an EIAO to the establishment.*





- Refer questions to:
  - askFSIS at <http://askfsis.custhelp.com> or



- Call PDD(technical) or RIMD(sampling) at  
1-800-233-3935