

## *E. coli* O157:H7 FSIS Actions

Directive 10,010.1 Rev. 1

In-Plant

Control

Transit

### Sample Results

- Negative
- “Potential positive”
- “Presumptive positive”
- “Confirmed positive” or “positive”

### Presumptive Positive

- Inspection program personnel
  - Notify plant of the presumptive positive
  - Inform plant that it should begin to gather supplier information, whether the source is domestic or foreign

### Confirmed Positive

- A sample is confirmed to contain the bacterial isolate of *E. coli* O157:H7 when biochemical, serological, or genetic testing results in a finding of *E. coli*
  - Serotype O157:H7,
  - O157:H7NM (nonmotile), or
  - O157:H7-indeterminate

### Actions After a Positive – In-Plant

- District Office is notified of a positive through the FSIS Biological Information Transfer and E-Mail System (BITES)
- FSIS determines whether a product retention, detention, or recall is necessary

### Actions After a Positive – In-Plant

- FSIS:
  - Enters the information into the FSIS System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS)
  - Notifies the supplier
  - Analyzes the situation to determine if enforcement action is appropriate

### Components Produced at Same Plant

- If a positive raw ground beef product was made from raw ground beef components produced at the same plant
  - FSIS inspection program personnel conduct a HACCP 02 procedure for the source materials used in the ground product
  - FSIS may sample and test the raw ground beef components at the plant

## Actions After a Positive – In-Plant

### Inspection program personnel

- Issue a Noncompliance Record (NR), using the “verification” trend indicator
- Perform a HACCP 02 procedure for the specific production that tested positive
  - As soon as possible after the plant implements its corrective action

## Actions After a Positive – In-Plant

### ■ Plant must

- Maintain control of positive product
- Implement corrective action
- Properly dispose of positive product
- Maintain records of proper disposition of positive product

## Options for Disposition

- Options for disposition of positive product
  - Further processing at the same plant or another plant
  - Disposal at landfill or renderer

## Plant Responsibilities

- Plant must maintain control of product while in transit
- Plant must maintain records of proper disposition

## Plant Noncompliance

- FSIS documents noncompliance if plant
  - Does not have records indicating proper disposition

## If HACCP 02 Shows Noncompliance

- If inspection personnel identify noncompliance during the HACCP 02 procedure
  - Issue an NR and collect one follow-up sample

## If HACCP 02 Identifies No Problems

- If inspection program personnel identify no significant problems through the HACCP 02 procedure
  - Collect one follow-up verification sample, as soon as possible after the plant takes corrective action

## Plant’s HACCP System – Concerns

- If inspection program personnel have concerns about whether the plant’s HACCP system is adequate to ensure food safety
  - They do not collect a follow-up verification sample
  - They notify their front-line supervisor

## In-Plant

- Frontline supervisor may
  - Bring in an Enforcement Investigations and Analysis Officer (EIAO) to conduct a comprehensive assessment of the plant’s food safety systems

#### In-Plant

- If the EIAO determines that the plant's corrective actions are appropriate and effective
  - Inspection program personnel collect a follow-up verification sample

#### In-Plant

- If the EIAO determines that the plant's corrective actions are inappropriate or ineffective, the EIAO recommends:
  - Enforcement action
    - Notice of Intended Enforcement (NOIE),
    - Withholding, or
    - Suspension

#### In-Plant

- If the District Office defers a decision to suspend the plant or takes a suspension action and then puts it into abeyance
  - FSIS will conduct follow-up sampling to verify that the corrective action is appropriate and effective
  - District Office will determine number of follow-up samples to be taken

#### Components from Suppliers

- If a plant supplies the components used to produce raw ground beef that tests positive at a second plant or retail facility
  - FSIS inspection program personnel conduct a HACCP 02 procedure at the supplying plant
  - FSIS may test raw ground beef components at the supplying plant

#### Collecting Samples from Components Inspection program personnel

- Collect only samples from components intended for use in raw, non-intact product
- If the intended use is unclear, treat the product as though it were intended for use in raw non-intact product

#### Receiving Positive Components

Inspection program personnel conduct a HACCP 01 or 02 procedure in that plant and verify that the plant:

- Documents the receipt of presumptive positive or positive product
- Maintains control of the product, and
- Has addressed *E. coli* O157:H7 in its hazard analysis and HACCP plan

#### Receiving Positive Components

- If FSIS finds noncompliance, it takes appropriate action

#### Product Moving Off-site

- Presumptive Positive for *E. coli* O157:H7
  - FSIS permits product to move off-site under appropriate controls for disposition at official establishments, landfill operations, or renderers

- ❑ If establishment's confirmation testing finds sample **negative** for pathogen, product may be shipped under normal procedures

#### Move Under Company Control

- Product that is
  - ❑ Confirmed positive
  - ❑ Presumptive positive and no additional testing confirmed product negative
  - ❑ Destined for an official establishment for further processing that will destroy pathogen

#### Adulterated or Misbranded after Transport

Product found to be adulterated or misbranded after it has been transported from an official establishment

- ❑ Transportation back to the establishment that originally produced the product or to another official establishment must be authorized

#### US Retained Tag

- Placed on products suspected of being adulterated
  - ❑ During reinspection of product

#### Move Under Company Control

- Presumptive Positive for *E.coli* O157:H7
  - ❑ FSIS permits product to move under company control to facilitate proper disposition
    - Company seals
    - Under USDA seal or accompanied by FSIS form 7350-1
  - ❑ FSIS to modify regulations to reflect this policy

#### Plant Noncompliance

- FSIS documents noncompliance if plant
  - ❑ Does not maintain proper control of positive product while in transit

#### Review – Flow Diagrams

- Three flow diagrams cover
  - ❑ Enforcement
  - ❑ Concerns about a plant's HACCP system
  - ❑ Actions in plants which produce components