

## *E. coli* O157:H7

Directive 10,010.1 Rev.1

### Instructional and Disclaimer Statements

#### Labeling Statements for

- Raw ground beef product
- Raw ground beef
- Raw beef patty components
- Directive 10,010.1 Rev. 1 gives guidance for when plants may use
  - Instructional Statements
  - Disclaimer Statements

#### Labeling Statements

- Placed on products for use at other official establishments
  - Official establishments ensure products bearing instructional statements receive adequate lethality treatment
  - Products bearing disclaimer statements must be destined for establishments that address *E.coli* O157:H7 in their HACCP plans

#### Instructional Statements

- An Instructional Statement concerning *E. coli* O157:H7 is
  - A statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level.

#### Instructional Statements

- Examples of Instructional Statements:
  - “For full lethality treatment”
  - “For cooking only”
- Must be approved by the FSIS Labeling and Consumer Protection Staff (LCPS)

#### Disclaimer Statements

- A Disclaimer Statement concerning *E. coli* O157:H7 is
  - A statement regarding the type of verification activities that were not used in producing the product.
  - An example is
    - “product has not been tested for *E. coli* O157:H7”

#### Disclaimer Statements

- Disclaimer statements must be approved by the LCPS staff
- Products with disclaimer statements can only go to
  - A plant that addresses *E. coli* O157:H7 in its HACCP plan.

#### Disclaimer Statements

- Directive 10,010.1 Rev. 1 provides:
  - Very specific verification procedures that inspection program personnel conduct
  - At plants that place these labels on products and

- At plants which receive products bearing these labels

Establishment producing product and placing these statements on the label

- Verify that establishment received sketch approval from LCPS and it is maintained in required labeling records by conducting an 04B04 procedure
  - Noncompliance Record (NR) issued if not approved or maintained

Verification Activities - IPP

- Conduct HACCP 01 and 02 procedures
  - Verify
    - Statement does not serve as control or CCP to address *E.coli* O157:H7
    - Statement is not used to justify determination that *E.coli* O157:H7 hazard not reasonably likely to occur
    - Use of the instructional statement is reflected in establishment's decision making documents
    - HACCP plans for products bearing disclaimer statement includes validated intervention for *E.coli* O157:H7

Noncompliance

- Establishment's use of instructional statements do not meet criteria outlined in FSIS Directive 5000.1, Revision 1
- HACCP plan for product with disclaimer statement does not include intervention for *E.coli* O157:H7

Establishment Receiving Product or Components

- Verify establishments that receive incoming products
  - Have addressed use of incoming product with disclaimer statement in HACCP plan as if product may be contaminated with *E. coli* O157:H7
  - Are following instructional statements on incoming products

Noncompliance

- Establishment's not meeting the criteria in the Directive

Product Retained

- Establishment:
  - Is not following instructional statement or
  - Is receiving product with disclaimer statement and its hazard analysis or decision making does not address use of incoming product as if it were contaminated with *E.coli* O157:H7

Product Retained

- Process may not be adequate to eliminate or reduce *E.coli* O157:H7 and
- Product is not intended for further processing that would destroy the pathogen

Retained Product

- Inspection Program Personnel
  - Document noncompliance on NR
  - Notify District Office