

# Lessons Learned from Past Enforcement Cases



# Objective

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Upon completion of this module, you will be able to describe what the agency has learned from some recent enforcement cases and the significance of each.

# Heightened Awareness

## Food Safety Issues

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- Several recent cases that have raised concerns regarding the safety of product.



# Coverage about Food Safety Issues

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- Media
- Television
- Radio

# Increased External Interest in FSIS

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- Industry Groups
- Constituent Groups
- Congressional Staffs and Committees
- General Accounting Office
- Office of Inspector General

# Recent Concerns

## E.coli O157:H7

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- Recent recalls and food safety assessments also point to the fact that measures employed by a number of establishments to address E.coli O157:H7 are inadequate.

# E. Coli O157:H7 Cases

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- Several establishments over the past few years involved in recalls



# *E. Coli* O157:H7 Cases

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- Failure to support hazard analysis decisions
  - 417.2 and 417.5; failure to control O157:H7 to a non-detectable level
  - Ground Beef Patties
  - Non-intact steaks

# *E. Coli* O157:H7 Cases

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- Concerns raised regarding supplier testing
  - Supplier not conducting N-60 testing.
  - Receiving plant conducting testing but not N-60.
  - Supplier testing only quarterly.
  - Supplier testing product that does not necessarily correlate with product received.
  - Supplier not furnishing a COA with each shipment.
  - Supplier conducting testing but there is no information that the receiving plant is receiving testing results from the supplier.

# *E. Coli* O157:H7 Cases

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- No information reflecting discussions held with plant officials or with the FLS or in-plant team regarding issues that impact the enforcement recommendation.
- Example - there have been discussions with plant officials which support that the plant has never received supplier testing results. Yet, these discussions are not captured in the record. No notes of discussions held with the plant, or MOIs.

# *E. Coli* O157:H7 Cases

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- No ongoing verification assessing the effectiveness of the pre-requisite program used to support the decision that *E. coli* O157:H7 is not a hazard that is reasonably likely to occur.
- Product that is for cooking only being shipped through a broker and no information showing that controls are in place to ensure that reached a cooking facility.

# *E. Coli* O157:H7 Cases

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- Is the supplying establishment ensuring that product is not contaminated with a detectable level of *E.coli* O157:H7 at the time it introduces product into commerce?
- Is the supplier adhering to good manufacturing practices and employing effective sanitary dressing procedures to control the pathogen?

# *E. Coli* O157:H7 Cases

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- Establishments wrongly using as support for the decision made that *E.coli* O157:H7 is not a hazard that is reasonably likely to occur the fact that the product bears the FSIS mark of inspection.
- Product being supplied through a “broker” who is unable to provide information that the suppliers have validated interventions and procedures.

# Lessons Learned *E. coli* O157:H7

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- Is frequent verification occurring to provide assurance that the pathogen is being adequately controlled?
- Many plants receive only an annual letter of guarantee or third party audit to support their controls in place for *E.coli* O157:H7.
  - Not considered by FSIS to be adequate to ensure an establishment's HACCP program is functioning effectively

# Low Acid Canned Food (LACF)

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- 9 CFR 318.300 Subpart G
- Inadequate heat transfer
- Faulty retorts



# *Salmonella* Cases

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- Stuffed raw, frozen, breaded and pre-browned Chicken Cordon Bleu and Kiev
  - Public Health Alert
  - *Salmonella* cluster of illnesses
  - 21 U.S.C. 453(g)(3) – unhealthful and therefore unfit
  - FSA conducted – NOIE followed by Suspension - failure to adequately address *Salmonella* 417.2 and 417.5

# *Salmonella* Cases

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- Stuffed raw, frozen, breaded and pre-browned Chicken Cordon Bleu and Kiev
  - *Salmonella* cluster of illnesses
  - 21 U.S.C. 453(g)(3) – unhealthful therefore unfit
  - Recall
  - FSA Conducted – NRs issued

# *Salmonella* Cases

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- Ground Beef Establishment
  - Two separate clusters of illnesses associated with products
  - Drug Resistant *Salmonella* Newport and S. DT104
  - Class I Recall for S. DT104 in Ground Beef
  - IIT Conducted – *Salmonella* samples all negative / NRs issued

# New HAV Procedure

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- We want inspectors take a closer look at the plant's hazard analysis and to identify items that raise a “red flag” for closer review.

# New HAV procedure

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- Recognizes that employees on the front line, who are at the plant each day, can play a key role in identifying issues of concern.



# New HAV Procedure

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- Lessons learned have taught us the importance of placing more focus on verifying that an establishment meets the regulatory requirements associated with its hazard analysis.



# New HAV Procedure

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- Calls for inspection personnel to play closer role in helping FSIS to determine if the establishment's hazard analysis addresses relevant food safety hazards for the process, product, and intended use, and whether there is support for the food safety practices being utilized.

# Questions?

