



FSIS Regulatory Perspective

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Objectives

- Explain FSIS's statutory basis for finding product adulterated
- Explain how FSIS has determined that raw product contaminated with certain pathogens is adulterated, including how FSIS has considered outbreaks
- Explain how FSIS has considered outbreaks as changes that require establishments to reassess their HACCP plans



Adulteration

Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) definition:

Product is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance . . . does not ordinarily render it injurious to health” (21 U.S.C. 453(g)(1), 601(m)(1).



E. coli O157:H7

Since the 1990s, FSIS has considered *E. coli* O157:H7 to be an adulterant in:

- Raw, non-intact beef products (e.g., ground beef, patties, and mechanically tenderized beef products)
- Raw intact components used to manufacture these products.(e.g., beef manufacturing trimmings)



E. coli O157:H7

A 1993 O157:H7 outbreak caused several deaths and more than 500 illnesses

Findings:

- Hamburgers associated with outbreaks
- Undercooked at restaurants
- Very few *E. coli* O157:H7 cells necessary to cause illness



E. coli O157:H7

- September 28, 1994, speech by then-FSIS Administrator Michael R. Taylor:
- “We consider raw ground beef that is contaminated with *E. coli* O157:H7 to be adulterated within the meaning of the [FMIA]. We are prepared to use the Act’s enforcement tools, as necessary, to exclude adulterated product from commerce. We plan to conduct targeted sampling and testing of raw ground beef at plants and in the marketplace for possible contamination.”



E. Coli O157:H7

Court supported FSIS's position:

Because beef products contaminated with *E. coli* O157:H7 are often cooked in a manner that may not prevent illness, this pathogen is a substance that renders "injurious to health" even products that many consumers consider to be properly cooked (*Texas Food Industry Association, et. al. v. Espy, et. al.*, Civ. No. A-94-CA-748 JN).



E. coli O157:H7

1999, Expanded List of Products:

- With the exception of intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product (64 FR 2803; Jan. 19, 1999)
- FSIS deemed adulterated *E. coli* O157:H7-contaminated raw non-intact beef products and intact cuts that are to be further processed into non-intact products before being distributed for consumption.



Non-O157 STEC

Certain non-O157 STEC are now
considered adulterants:

O26

O45

O103

O111

O121

O145



Non-O157 STEC

Support based on outbreak information (76 FR 58157):

Thermal resistance similar to O157:H7

Infectious doses of non-O157 STEC are low

- O26 from fermented beef sausage in Denmark
- O111 STEC in beef sausage in Australia
- O145 in ice cream in Belgium



Read-to-Eat product

If contaminated with microbial pathogen,
adulterated on same basis raw beef product is
adulterated with O157:H7 or non-O157 STEC:

It bears or contains a poisonous or deleterious
substance which may render it injurious to
health . . . (21 U.S.C. 453(g)(1), 601(m)(1)).



Outbreaks

Raw product associated with illness outbreak and contains pathogens not otherwise considered adulterants:

Product is adulterated if it is “... unsound, unhealthful, unwholesome, or otherwise unfit for human food” (21 U.S.C. 453(g)(3) or 601(m)(3)).



Outbreaks

August 28, 2010--Cargill Meat Solutions Corp., Wyalusing, PA, recalled approximately 8,500 pounds of ground beef products that may be contaminated with *E. coli* O26.

- FSIS was notified by the Maine Department of Agriculture, Food and Rural Resources of an *E. coli* O26 cluster of illnesses.
- 2 case-patients were identified in Maine and 1 case-patient in New York with a rare, indistinguishable PFGE pattern as determined by PFGE subtyping in PulseNet.
- FSIS determined that there was an association between the ground beef products subject to recall and the cluster of illnesses in Maine and New York.



Outbreaks

December 15, 2011—Hannaford grocery chain, Scarborough, MA, recalled undetermined amount of fresh ground beef that may have been contaminated with *Salmonella Typhimurium*.

CDC reported 14 ill people with an indistinguishable PFGE pattern; 11 of them reported consuming ground beef; 10 reported purchasing ground beef at Hannaford stores.

Working with CDC, public health partners in affected states, and the company, FSIS determined link between Hannaford and the outbreak illness.



Reassessments

9 CFR 417.4(a)(3): An official establishment is required to reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the establishment's hazard analysis or alter the establishment's HACCP plan.



Reassessments

Listeria monocytogenes (64 FR 28351; May 26, 1999):

Improved ability to associate *Listeria monocytogenes* with particular products and to detect outbreaks of listeriosis

Raised questions about establishments' approach to addressing the pathogen

Establishments required to reassess their HACCP plans for ready-to-eat products



Reassessments

In 2005, reassessments required for mechanically tenderized beef products (70 FR 30331; May 26, 2005)

Establishments required to:

- Take into account 3 relatively recent O157:H7 outbreaks associated with these products
- Determine whether HACCP plans adequately address biological hazards, particularly O157:H7



Summary of FSIS Approach

Raw beef product contaminated with O157:H7 or other STEC and ready-to-eat product contaminated with pathogens is adulterated because it contains a “poisonous or deleterious substance” that may not be destroyed under “ordinary” cooking practices

Raw product contaminated with a pathogen not considered an adulterant but associated with an outbreak is adulterated because it is unsound, unhealthful, unwholesome, or otherwise unfit for human food

Outbreaks may be new information that requires establishments to reassess their HACCP plans



Questions