



FSIS Perspective on Regulating Non-O157 STECs

Presented by

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FSIS Mission*



As the public health regulatory agency in USDA, FSIS is responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is:

- Safe
- Wholesome
- Correctly labeled and packaged

* Jurisdiction -- slaughter to processing, including pre-harvest control and retail sale; daily inspection occurs at slaughter/processing; surveillance occurs in commerce; primary statutes -- EPIA, FMIA, PPIA

FSIS Jurisdiction



What

- Amenable foods generally contain significant portions of meat, poultry, and processed eggs products (e.g., 3% NRTE or 2% RTE portions); FDA amenable foods are other than FSIS foods

How

- Mark of inspection is placed on all product as not adulterated or misbranded before release of product into commerce (FDA makes a determination regarding adulteration and misbranding generally after product is in commerce)

U.S. HEALTHY PEOPLE 2010; 2020



	1997	2006-2008	2010	HP2010; 2020*
Pathogen	Baseline Case Rate (infections from all foods per 100,000 population)**	Baseline Case Rate	FoodNet Case Rate	Target
<i>Campylobacter</i>	24.6	12.71	13.6	12.3; 8.5
<i>E. coli</i> O157:H7	2.1	1.2	0.9***	1.0; 0.6
<i>L. monocytogenes</i>	0.47	0.29	0.3	0.24; 0.2****
<i>Salmonella</i>	13.6	15.25	17.6	6.8; 11.4

- Chapter 10 - <http://www.healthypeople.gov/document/pdf/Volume1/10Food.pdf>, applies to all food sources, not just meat, poultry, and processed egg products
- *CDC MMWR – June 2010, 60(22): 749-755
- **Minor revisions were made in some case rates in November 2000
- ***First met in 2004 and then again in 2009 and 2010; CDC tracks non-O157 STEC and for 2010, the case rate was 1.0
- ****Changed to year 2005 by Presidential Executive Order

Pathogen-Specific Illness Estimates for FSIS Foods



	Measures	Objectives	Goal
Pathogen	Baseline 2005-2007	FY 2011	FY 2015
<i>Salmonella</i>	576,436	553,379	531,574
<i>E. coli</i> O157:H7	20,415	16,984	16,315
<i>Listeria monocytogenes</i>	1,236	1,043	1,002
All Illness	598,087	571,406	548,890

1: In July 2011, FSIS will begin a *Campylobacter* verification testing program. Illnesses associated with this pathogen will be incorporated into this table.

2: FSIS will adjust its performance standards to reflect new Healthy People 2020 goals. 5



Statute

Federal Meat Inspection Act (FMIA) of 1906*

-- Title 21 – Food and Drugs

--- Chapter 12 – Meat Inspection

---- Subchapter 1 – Inspection requirements; adulteration and misbranding

*PPIA and EPIA similarly worded



Statute (continued)

Subchapter I – Inspection requirements

-- §601.1 Definitions

--- “Commerce” – Between States, territory, DC

--- “Meat food product” – product capable of use as human food from carcass of any cattle, sheep, swine, or goats, or equines

---- Except in relatively small proportions or historically have not been considered by consumers as products of the meat food industry

--- “Prepared” – slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed



Statute (continued)

Subchapter I

-- §601.1 Definitions (continued)

--- **“Adulterated”** – Apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

---- *(m)(1) – if it ...contains any ...deleterious substance which may render it injurious to health*

- **in case the substance is not an added substance, product is not adulterated if the quantity of such substance does not ordinarily render it injurious to health**

---- *(m)(4) – if it has been prepared...under insanitary conditions...*



Current Thinking – Strength of Case-By-Case Adulterant Determinations

1. No link between establishment and illness
2. No direct association between establishment and illness but insanitary conditions seen
3. Circumstantial association between establishment and illness but evidence of problem with HACCP system
4. Definitive link between establishment and illness



Food Safety Hazard

1996*:

- HACCP regulations (9 CFR 417)

- *Food safety hazard* – Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption

- Every official establishment shall conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment must apply to control those hazards. The hazard analysis shall include food safety hazards than can occur before, during, and after entry into the establishment.

61 FR 38868, July 25, 1996



STEC BACKGROUND

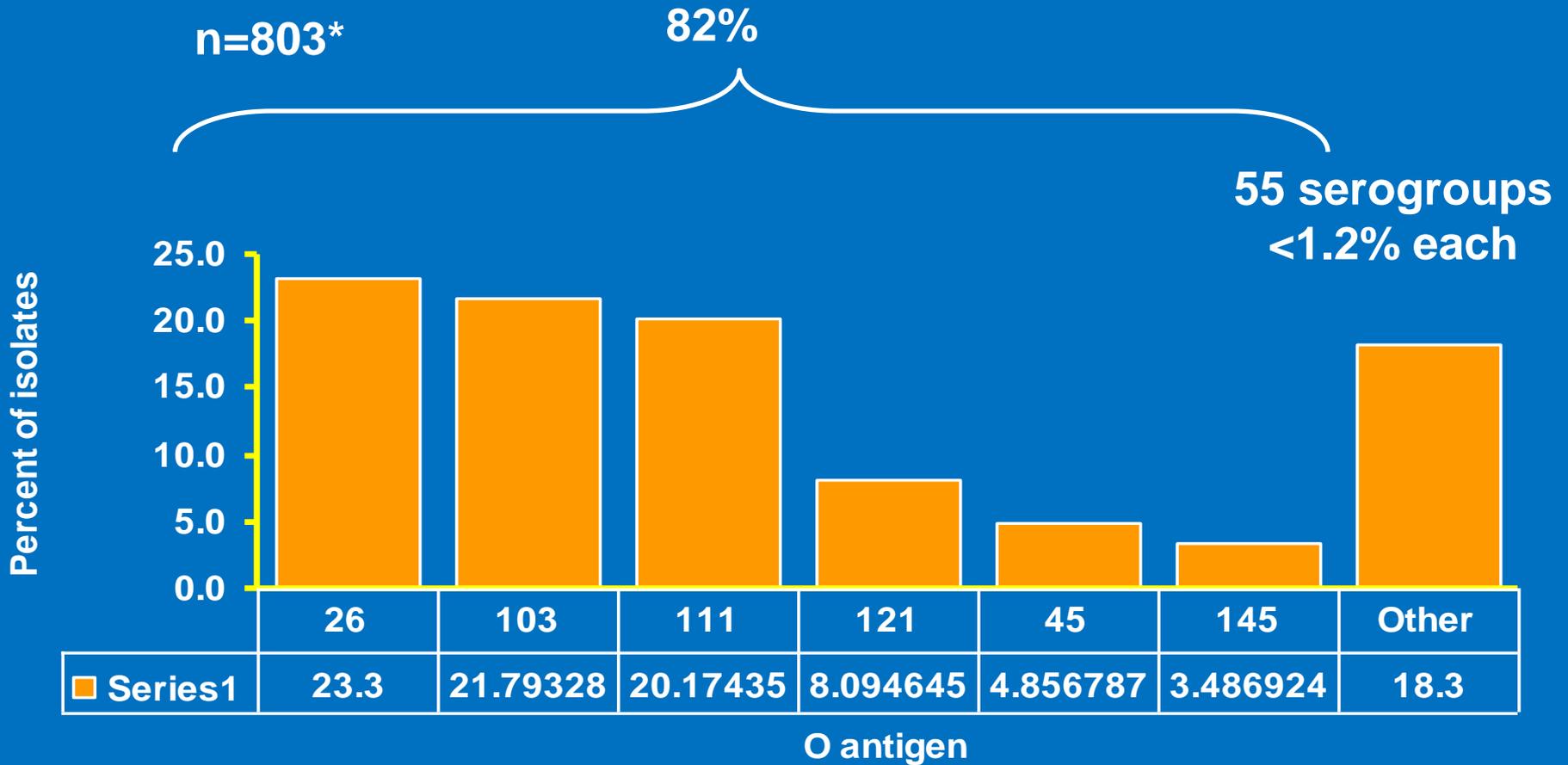
- *Escherichia coli* O157:H7 (*E. coli* O157:H7) causes life-threatening illness prepared customarily
 - Initially associated with illnesses from consumption of ground beef; now applied to trimmings (direct source materials for ground beef) and tenderized beef
 - FSIS declared this form of *E. coli* an adulterant in certain raw beef products in 1994 and clarified in 1999 and 2002

STEC BACKGROUND (continued)



- Shiga-toxin forming *E. coli* (STEC) other than O157 STEC cause illnesses each year; in 2010, more illnesses from all foods were reported for non-O157 STEC than from O157 STEC
 - Screening methodology for identification developed for the six most commonly reported causes of human illness in the U.S.
 - Looking to prevent rather than react to illnesses/deaths;

Human isolates of non-O157 STEC by O serogroup, FoodNet sites, 2000-2007



*An additional 86 isolates had missing O group information

STEC UPDATE



- FSIS has developed a regulatory strategy articulated in a draft FR Notice at OMB
- Public health protection is a responsibility of the regulated industry and should not await government intervention before responding (government steps in when action is not applied uniformly across a wide sector of the industry)
 - Reducing the likelihood of contamination in or on live cattle coming to slaughter is prudent regardless of the degree of reduction
 - Preventing contamination during slaughter is paramount
 - Cleaning up carcasses after contamination events is essential but is not the best means to ensure food safety
 - STEC and *Salmonella* contamination on beef products is a result of the same condition and circumstances – focus on more than individual contaminants is prudent



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