

# **Federal Regulation of STECs and Other Pathogens: Past Present and Future**

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# Statutory Authority

- **Federal Meat Inspection Act – 21 U.S.C. 601 *et seq.***
- **Poultry Products Inspection Act – 21 U.S.C. 451 *et seq.***
- **Egg Products Inspection Act – 21 U.S.C. 1031 *et seq.***

# Federal Meat Inspection Act

- “... and the carcasses and Parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as ‘Inspected and passed’, ...” 21 U.S.C. 604. (Emphasis added)
- “All such products found by any such inspectors and by the operator of such establishment to be not adulterated shall be marked, stamped, tagged, or labeled as ‘Inspected and passed’.” 21 U.S.C. 606(b)(1). (Emphasis added)

# Adulteration Proviso

**. . . 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 . . . if the quantity of such substance . . . does not ordinarily render it injurious to health**

**21 USC 601(m)(1)**

# Proviso Escape Clauses

**Adulteration if “for any other reason unsound,  
unhealthful, unwholesome or otherwise unfit for  
human food**

**21 USC 601(m)(3)**

**or**

**“prepared, packed or held under insanitary  
conditions”**

**21 USC 601(m)(4)**

# Adulteration Policy

- *E. coli* O157:H7
- Non-O157:H7 STECs
- *Salmonella*
- *Sanitation*

# *American Public Health Assn. v. Butz*

“The presence of salmonellae on meat does not constitute adulteration within this definition [of ‘adulterated,’ provided in 21 U.S.C. § 601 (m)] ....As it said in its letter of August 18, 1971 ‘the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness.’ In other words, American housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.” *APHA v. Butz*, 511 F.2d 331, 334 (1974).

Lawsuit “alleged that [USDA] was wrongfully refusing to affix to meat and poultry products...labels containing handling and preparation instructions to protect the consumer against food poisoning caused by Salmonellae and other bacteria.”

Sought to enjoin USDA from “affixing the label ‘U.S. Passed & Inspected’... on meat and poultry unless it is accompanied by an [warning] that product may contain organisms capable of causing food poisoning”

DISSENT: “The court apparently takes the position that meat and poultry ‘ordinarily’ pose no threat of salmonellosis, because American consumers are aware of the problem...That, however, is a debatable proposition...”

# ***E. coli* O157:H7 in Ground Beef and Non-intact Beef**

**“To clarify an important legal point, 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. Finally, we plan to conduct targeted sampling and testing of raw ground beef at plants and in the marketplace for possible contamination.”**

***Michael Taylor, FSIS Administrator, in speech to American Meat Institute, September 28, 1994.***



# *Texas Food Industry Ass'n, et al. v. USDA*

“Plaintiffs’ primary argument ...is that *E. coli* contaminated ground beef is not adulterated because it is only injurious to health if improperly cooked. However, after reviewing the evidence, the Court disagrees. ...[U]nlike other pathogens, it is not ‘proper’ cooking but ‘thorough’ cooking that is necessary to protect consumers from *E. coli*... Therefore, *E. coli* is a substance that renders ‘injurious to health’ what many Americans believe to be properly cooked ground beef.” *TFIA v. USDA*, 870 F. Supp. 143, 148-49 (W. D. Tex. 1994).

Lawsuit sought injunction “to prevent USDA from conducting its *E. coli* sampling program” because:

- Agency failed to adhere to notice and comment procedure requirements of the APA
- Sampling program and adulterant decision are “arbitrary and capricious exercise of agency authority and it exceeds the USDA’s statutory authority under the FMIA.”

Court denied the industry motion for an injunction, ruling:

- No notice and comment required because it was an “interpretive” rule
- There are rational bases for the sampling program, and treating *E. coli* O157:H7 differently than other pathogens.

# FSIS Regulatory Shift

- FSIS began regulating by bureaucratic fiat
  - Notices
    - <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/fsis-notices> (Through September 24 67 new notices issued)
  - Directives
    - <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives> (4000 series through 13000 series)
- *Federal Register* publications other than proposed rules

# FSIS Regulatory Shift

“The public health risk presented by beef products contaminated with *E. coli* O157:H7 is not limited, however, to raw ground beef products. Given the low infectious dose of *E. coli* O157:H7 associated with foodborne disease outbreaks and the very severe consequences of an *E. coli* O157:H7 infection, the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 *must* depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed.”  
FSIS Policy Statement, 64 *Fed. Reg.* No. 11, 2803 (Jan. 19, 1999)

July 25, 1996: FSIS issues Pathogen Reduction/HACCP Final Rule mandating process controls in all meat plants

January 19, 1999: FSIS expands *E. coli* testing to include “non-intact meat and trimmings,” deeming (by implication) that *E. coli* O157:H7 on all “intact” meat is not an “adulterant”

October 7, 2002: FSIS explains : “intact cuts of beef that are to be further processed into non-intact product prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef because pathogens may be introduced below the surface. Manufacturing trimmings are an example...”

# **FSIS Notice 05-09**

**“[T]he mark of inspection is a reflection of a finding made by FSIS personnel that the establishment has followed the validated procedures in its HACCP plan, not that the pathogen has been eliminated or reduced to undetectable levels.”**

# Non-0157 STECs as an Adulterants

- **Final Determination and Request for Comments; Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products; 76 Fed. Reg. 58157 (Sept. 20, 2011). Industry Comments:**
  - The Draft Risk Profile did not support the determination
  - FSIS did not conduct a baseline survey of STEC on raw beef products to establish a need for the policy
  - A validated, commercially viable analytical method was needed

# ***E. coli* O157:H7 as an Adulterant in Beef Primals**

- **Push from certain elements within FSIS to consider intact primals and subprimals with *E. coli* on them to be adulterated.**
- **“Hot day,” insanitary condition theory**
- **A 2009 recall set the stage for the continuing the adulteration “creep” that began in 1994.**

# Resulting Liability Exposure

- Is “proper cooking” enough to avoid illness?
- Are USDA Safe Handling Labels a “Safe Harbor?”
- In 2014, as *E. coli* O157:H7 recalls continue to decline, will it really matter?

*Salmonella* as an Adulterant in  
Meat



# *Salmonella* as an Adulterant in Meat

“The difficulty in this case arises, in part, because *Salmonella*, present in a substantial proportion of meat and poultry products, is not an adulterant *per se*, meaning its presence does not require the USDA to refuse to stamp such meat "inspected and passed." This is because normal cooking practices for meat and poultry destroy the *Salmonella* organism, and therefore the presence of *Salmonella* in meat products does not render them "injurious to health" for purposes of § 601(m)(1). *Salmonella*-infected beef is thus routinely labeled "inspected and passed" by USDA inspectors and is legal to sell to the consumer.” *Supreme Beef v. USDA*, 275 F. 3d 432, 438-39 (5<sup>th</sup> Cir. 2001).

Supreme Beef sued to stop FSIS from withdrawing inspectors, “alleging that in creating *Salmonella* tests, FSIS had overstepped the authority given to it by the FMIA.” (113 F. Supp. 2d 1048, at 1051)

Court ruled in favor of Supreme Beef, finding that, under FMIA, a plant cannot be found “insanitary” based on failed *Salmonella* performance standards

“what the court takes issue with today is not the use of scientific methods in USDA inspections but the agency’s science-based testing of a processor’s product to evaluate the conditions of its plant.” (emphasis in original)

“science-based tests of a plant’s end product may be appropriate when the USDA is determining if a plant’s meat is adulterated under the several other [FMIA] definitions”

**“We’re spinning our wheels by developing other performance standards and enforcement strategies”**

**Dr. Bill James  
(former FSIS Chief Vet.)  
Meatingplace 12/11/13)**

# Multi-Drug Resistant *Salmonella* Investigations and Recalls

- *Salmonella Newport*
  - 23 cases in Colorado
  - Recall of 825,000 pounds of beef products
- *Salmonella* Typhimurium (DT104)
  - 14 cases in Colorado
  - Recall of 466,000 pounds of beef products

# Center for Science in the Public Interest Petition

- 2011 petition seeks declaration that Antibiotic Resistant (ABR) *Salmonella* in ground meat and ground poultry products are adulterants
- *ABR-Salmonella*
  - Hadar
  - Heidelberg
  - Newport
  - Typhimurium

# Center for Science in the Public Interest Petition

- Petition argues the ABR-Salmonella are adulterants
  - Petition argues the (m)(1) “may render it injurious to health” standard applies because “ABR *Salmonella* occurs due to the act of humans.” and
  - Petition argues the (m)(2)(A) standard applies because “it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance ... which may, in the judgment of the Secretary, make such article unfit for human food”

# *Salmonella* as an Adulterant

- *Salmonella* is the next big item in the agency's sights
- Recalls in ground beef and ground turkey
- Recently published change to *Salmonella* testing regimen for ground beef and trimmings
  - Sample size
  - Enumeration
  - Performance standards – *Supreme Beef* revisited

# *Salmonella* as an Adulterant

- Will there be a corollary effect on liability exposure?
- Can *Salmonella*, when present, be easily prevented?
- What defenses (in production and the court) are there?

# Conclusions

- **Adulteration and Performance Standards approaches on two different tracks**
- **Limitations to Adulteration Approach**
  - Blunt Instrument
  - Scientific Complexity
  - Practical Consideration
- **Limitations to Performance Standards**
  - Legally and Scientifically Suspect
  - Enforcement Limitations
  - Commitment of Resources



# Conclusions

## Need for:

- Solutions driven by Science
- More coherent and consistent policymaking process
- Comprehensive industry risk management
- Effective public communication under challenging circumstances
- Maximum efficiency in protecting public health

# Thank You

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