

Ground Beef Inspections and *E. Coli* O157:H7: Placing the Needs of the American Beef Industry Above Concerns for the Public Safety

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Millions of Americans suffer from foodborne illnesses each year.¹ While mild cases often get shrugged off after spending a night in the bathroom, a small number of people suffer drastic consequences for liking their burgers medium rare.² Consumers take for granted, and

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1. Estimates range that anywhere from a few million to nearly eighty million illnesses are a result of foodborne pathogens each year. *See, e.g.*, Caroline Smith DeWaal, *Food Safety Inspections: A Call for Rational Reorganization*, 54 FOOD & DRUG L.J. 453, 453 (1999) (thirty-three million illnesses); Kerri E. Machado, *Unfit for Human Consumption: Why American Beef is Making Us Sick*, 13 ALB. L.J. SCI. & TECH. 801, 811 (2003) (five million illnesses); Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563, 565 (2004) (seventy-six million illnesses). Estimates vary wildly due to varying mandatory reporting requirements among the states as well as the public's failure to report mild cases of food poisoning. *See generally* Josefa M. Rangel et al., *Epidemiology of Escherichia coli O157:H7 Outbreaks, United States, 1982–2002*, 11 EMERGING INFECTIOUS DISEASES 603, 608 (2005).

2. Foodborne illnesses can be transmitted through a variety of sources. Recent publicized outbreaks include unpasteurized juice, spinach, and strawberries. *See, e.g.*, CTRS. FOR DISEASE CONTROL, DEP'T OF HEALTH & HUMAN SERVS., *Ongoing Multistate Outbreak of Escherichia coli Serotype O157:H7 Infections Associated with Consumption of Fresh Spinach—United States, September 2006*, 55 MORBIDITY & MORTALITY WKLY. REP. 1045 (2006) (spinach); Press Release, U.S. Food & Drug Admin., FDA, State of Maryland, and Baugher Enterprise Warn Consumers to Avoid Baugher's Apple Cider (Nov. 5, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm232986.htm> (juice); Teresa Carson, *E. Coli Outbreak in Oregon Linked to Strawberries*, REUTERS (Aug. 8, 2011), <http://www.reuters.com/article/2011/08/08/us-strawberry-ecoli-oregon-idUSTRE7776IQ20110808> (strawberries). This Note will focus on beef products, as they are the most common cause of both outbreaks and sporadic cases of *E. coli* O157:H7. Ctrs. For Disease Control, Dep't of Health & Human Servs., *Multistate Outbreak of Escherichia coli O157:H7 Infections*

are reassured by, the presence of a “USDA inspected” sticker on their meat products.³

The American beef industry is the largest agricultural enterprise in the United States, producing over twenty-five billion pounds of beef products and contributing more than sixty-six billion dollars annually to the national economy.⁴ The industry’s power extends deep into the political world as well.⁵ Lobbyists for the beef industry in Washington, D.C. spend millions of dollars to block legislation that would increase regulation.⁶ If passed, such legislation could reduce production and the industry’s economic bottom line.

The current regulations for ground beef inspections place the majority of the responsibility on the beef industry to ensure that their products remain safe for consumption. Each processor is responsible for designing sanitation guidelines to limit contamination from occurring in the first place.⁷ Additionally, each processor must institute an inspection program to ensure that any products that have become contaminated are identified and removed.⁸ But because fast

Associated With Eating Ground Beef—United States, June–July 2002, 51 MORBIDITY & MORTALITY WKLY. REP. 637, 638 (2002).

3. All meat products determined to be unadulterated, and thus cleared for human consumption, must be labeled as “inspected and passed” before they are distributed. *See* 21 U.S.C. §§ 606(a), 607 (2006).

4. Cattlemen’s Beef Bd. & Nat’l Cattlemen’s Beef Ass’n, *Beef Market at a Glance*, EXPLORE BEEF, available at http://www.explorebeef.org/CMDocs/ExploreBeef/FactSheet_BeefMarketAtAGlance.pdf. Retail sales of beef products reached over fifteen billion dollars in 2008 (last updated May 2009). *Id.* at 2. *See also U.S. Beef and Cattle Industry: Background Statistics and Information*, ECON. RESEARCH SERV., <http://www.ers.usda.gov/news/BSECoverage.htm> (last modified May 25, 2011).

5. *See Machado*, *supra* note 1, at 826–29 (naming several Republican political appointees with extensive ties to the beef industry who instigated various beef industry-friendly policies).

6. *See* THE CTR. FOR PUB. INTEGRITY, SAFETY LAST: THE POLITICS OF E. COLI AND OTHER FOOD-BORNE KILLERS 76 (1998), <http://www.publicintegrity.org/assets/pdf/SAFETYLAST.pdf> (listing the top recipients in the Senate and House of Representatives of campaign contributions from the meat industry). For a listing of contributions made to federal candidates by political action committees within the livestock industry, broken down by election cycle, see Ctr. for Responsive Politics, *Livestock: PAC Contributions to Federal Candidates*, OPENSECRETS.ORG, <http://www.opensecrets.org/pacs/industry.php?txt=A06&cycle=2010> (last visited Oct. 16, 2011).

7. *See infra* note 41.

8. *See infra* Part III.

line speeds in production facilities remain the industry's top priority,⁹ the industry is unlikely to institute inspection procedures that would slow down their ability to maximize profits.¹⁰

Part I of this Note reviews the history of federal regulation of the beef industry, discusses the particular dangers of *Escherichia coli* O157:H7 (“*E. coli* O157:H7”) as a foodborne pathogen, outlines the inspection systems implemented in response to outbreaks of *E. coli* O157:H7 outbreaks, and explains current recall practices for potentially contaminated products. Part II analyzes the shortcomings of the current regulatory framework for ground beef inspections and the ability of the beef industry to “pass the buck” when contaminated beef products make their way out to the public. Part III proposes legislation that would grant the government the ability to mandate recalls of contaminated products and to fine those companies who do not properly inspect their products or maintain sanitary processing facilities.

I. HISTORY

A. THE FEDERAL MEAT INSPECTION ACT

Congress first granted the United States Department of Agriculture (USDA) the authority to conduct ante- and postmortem inspections of livestock slaughtered for meat in 1890 as a response to European concerns about the safety of American beef products.¹¹

9. A single worker at the evisceration stage of the slaughtering process, during which the internal organs of the cattle are removed, may handle as many as sixty cattle an hour. ERIC SCHLOSSER, FAST FOOD NATION 203 (2001). The larger processing facilities have the ability to produce up to 800,000 pounds of ground beef products in a single day. *Id.* at 204.

10. In the early 1990s, when the USDA attempted to instigate a stricter inspection system that integrated microbial testing, it had to allow an increase in line speeds before it was able to persuade several slaughterhouses to implement the new system. Machado, *supra* note 1, at 817–18. The USDA then phased out this short-lived program and returned to its original inspection practices. *Id.* at 819. It did not, however, reduce line speeds back to the original slower speeds. *Id.*

11. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6,774, 6,775 (Feb. 3, 1995) (providing a brief history of meat inspection programs in the United States). In the 1880s, imports of American pork and other livestock products were restricted by European countries due to fears of trichinosis in pork and other animal diseases in livestock. MICHAEL OLLINGER & VALERIE MUELLER, USDA ECON. RESEARCH SERV., MANAGING FOR SAFER FOOD: THE ECONOMICS OF SANITATION AND PROCESS CONTROLS IN

Federal regulation of the beef industry truly began, however, in response to the public outcry that followed the 1906 publication of Upton Sinclair's *The Jungle*, which detailed the filthy conditions of the meatpacking industry.¹² The Federal Meat Inspection Act (FMIA),¹³ passed within a year of *The Jungle*'s publication, established sanitary standards for slaughter and processing facilities, mandated ante- and postmortem inspection of all animals, and required slaughtering and processing plant owners to allow government inspectors access to their facilities.¹⁴

Seeking to prevent the distribution of "adulterated"¹⁵ products containing fecal matter, disease, or other forms of contaminants to the public, the USDA placed thousands of inspectors in the field to conduct animal-by-animal inspections.¹⁶ An inspector could order the

MEAT AND POULTRY PLANTS 3 (2003), available at <http://www.ers.usda.gov/publications/aer817/aer817c.pdf>.

12. See Brenda Lawson, *Foodborne Illness: The Cause and Effect of E. coli O157:H7 Contamination of Our Food Supply*, 4 MICH. ST. U. J. MED. & L. 71, 79 (1999). *The Jungle* is a fictional work based on the Chicago meatpacking industry's terrible working conditions that took place around the turn of the twentieth century. See UPTON SINCLAIR, *THE JUNGLE* (Maura Spiegel ed., 2003) (1906); see also Lawson, *supra*.

13. Federal Meat Inspection Act of 1907, Pub. L. No. 59-242, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. §§ 601-683 (2006)).

14. 21 U.S.C. §§ 603-604, 606, 608 (2006). The corresponding regulation for the poultry industry was not passed until the 1950s when poultry consumption substantially increased. Poultry Products Inspection Act of 1957, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified as amended at 21 U.S.C. §§ 451-472 (2006)).

15. The term "adulterated" is applied to:

[A]ny carcass, part thereof, meat or meat food product under one or more of the following circumstances: (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health, . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . .

21 U.S.C. § 601(m)(1)-(4) (2006).

16. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. at 6,775. The Food Safety and Inspection Service (FSIS) is the agency within the USDA that is currently responsible for inspecting and regulating all meat and poultry moving within interstate and foreign commerce. See generally Organization, Functions, and Delegations of Authority, 48 Fed. Reg. 15,284, 15,285 (Apr. 8, 1983) (outlining the organization and primary functions of the FSIS). Created by the Secretary of Agriculture as the Food Safety and Quality Service in 1977, it was renamed as part of a realignment of the USDA in 1981. *Id.*

removal of any animal or carcass deemed unfit for consumption,¹⁷ and if the processor failed to do so, then the inspector could take steps to have that facility's inspection privileges revoked.¹⁸ Loss of inspection privileges effectively shuts down a meat processing facility because they cannot operate until the inspector returns to the facility.¹⁹

B. *E. COLI* O157:H7

E. coli is a common bacteria present in the gastrointestinal tracts of animals and humans.²⁰ When an animal is slaughtered, the contents of the intestinal tract can come in contact with muscle tissue, thereby transferring the bacteria.²¹ Should that meat then be ground down, then *E. coli* would be blended into the final product.²² *E. coli*

17. See Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 WILLAMETTE L. REV. 411, 458 (1997). Inspections were generally conducted by organoleptic methods whereby inspectors used sight, touch, and smell to detect disease or to otherwise determine that an animal and/or its meat was unfit for human consumption. See Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. at 6,775 (detailing the history of beef inspection in the United States and the methods employed).

18. See Lassiter, *supra* note 17, at 451.

19. See *id.*

20. See SCHLOSSER, *supra* note 9, at 199; CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, BAD BUG BOOK: FOODBORNE PATHOGENIC MICROORGANISMS AND NATURAL TOXINS HANDBOOK, available at <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm071284.htm> [hereinafter BAD BUG BOOK].

21. See Delilah Dill Schuller, Comment, *Pathogen Reduction Through "HACCP" Systems: Is Overhaul of the Meat Inspection System All It's Cut Out To Be?*, 8 SAN JOAQUIN AGRIC. L. REV. 77, 81 (1998).

22. See *id.* Although the majority of *E. coli* O157:H7 outbreaks implicating contaminated beef are a result of undercooked ground beef products, there have also been product recalls involving whole muscle cuts of beef as a consequence of mechanical enhancement. Ashley R. Rosenberg, *The Survivability, Growth, and Heat Susceptibility of E. coli O157:H7 in Enhanced Beef Brine Solutions Containing Potassium Lactate and Lactic Acid Producing Bacteria 14* (May 2009) (unpublished M.S. thesis, Texas Tech University), available at http://etd.lib.ttu.edu/theses/available/etd-04032009-140740/unrestricted/Rosenberg_Ashley_Thesis.pdf ("Beef steaks are considered a low risk to consumers for *E. coli* O157:H7 infection due to the constitution of whole muscle cuts. The inside of muscle is considered sterile and free of bacteria. The surface of the steak is the only area with the potential to be contaminated . . .").

O157:H7,²³ one of many different strains of *E. coli*, has proven to be particularly deadly.²⁴

Although other strains of *E. coli* can cause gastrointestinal illness,²⁵ the toxins produced by *E. coli* O157:H7 can cause hemorrhagic colitis²⁶ and can lead to hemolytic uremic syndrome (HUS).²⁷ HUS occurs in two to seven percent of *E. coli* O157:H7 infections and primarily affects children.²⁸ In addition to the more severe health complications that may arise from inadvertent consumption of *E. coli* O157:H7, the bacteria is particularly dangerous because of its hearty nature and its ability to infect with very few organisms.²⁹

23. The combination of letters and numbers refers to markers on the surface of the bacteria which distinguish *E. coli* O157:H7 from other strains of *E. coli*. Denis Stearns, *Preempting Food Safety: An Examination of USDA Rulemaking and Its E. Coli O157:H7 Policy in Light of Estate of Kriefall ex rel. Kriefall v. Excel Corporation*, 1 J. FOOD L. & POL'Y 375, 381–82 (2005).

24. See Schuller, *supra* note 21, at 18. The O157:H7 strain of *E. coli* is deadlier than others due to its ability to produce Shiga-like toxins, which can cause extensive damage to the intestine and may enter the bloodstream and damage the kidneys as well. BAD BUG BOOK, *supra* note 20; Machado, *supra* note 1, at 811; see also Thomas G. Boyce et al., *Escherichia Coli O157:H7 and the Hemolytic-Uremic Syndrome*, 333 NEW ENG. J. MED. 364, 365–66 (1995) (describing the clinical manifestations of *E. coli* O157:H7 infections).

25. Mild cases of *E. coli* infections are often misattributed to the “stomach flu” and are never reported, likely because they can pass in a few hours. See SCHLOSSER, *supra* note 9, at 202; see also Paul S. Mead et al., *Food Related Illnesses and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607, 611 (1999) (table providing estimates of illnesses, hospitalizations, and deaths caused by known foodborne pathogens, including several different types of *E. coli*).

26. See Stearns, *supra* note 23, at 384. Hemorrhagic colitis is typically “characterized by severe abdominal cramps, bloody stool, but sometimes little or no fever.” *Id.*; see also Machado, *supra* note 1, at 811.

27. See Machado, *supra* note 1, at 811. “HUS [hemolytic uremic syndrome] can cause kidney failure, anemia, internal bleeding, destruction of vital organs, neurological damage, seizures and strokes.” *Id.* HUS is the cause of the majority of acute illnesses and deaths resulting from *E. coli* O157:H7 infections. Stearns, *supra* note 23, at 385.

28. Stearns, *supra* note 23, at 385. Among children suffering from HUS, approximately half will require dialysis. *Id.* at 385. The mortality rate for children who develop HUS is five to ten percent. *Id.* at 386 n.57; see also Chinyu Su & Lawrence J. Brandt, *Escherichia coli O157:H7 Infection in Humans*, 123 ANNALS INTERN. MED. 698, 700–01 (1995) (discussing the prevalence of HUS in children resulting from *E. coli* O157:H7 infections).

29. See SCHLOSSER, *supra* note 9, at 201. *E. coli* O157:H7 can survive on kitchen surfaces for days and in moister environments for weeks, and has the ability to withstand temperatures up to 160 degrees Fahrenheit. *Id.*; see also S.A. Wilks et al., *The Survival of Escherichia coli O157 on a Range of Metal Surfaces*, 105 INT'L J. OF FOOD MICROBIOLOGY 445, 451 (2005) (noting that *E. coli* O157 was able to survive for more than 28 days on stainless steel surfaces in both refrigerated and room temperature environments). Furthermore, whereas it can take the

Although *E. coli* O157:H7 was first identified as a pathogen in 1982,³⁰ it took an outbreak³¹ of over 500 infections of HUS and four deaths from late 1992 into early 1993 for Congress to significantly overhaul the federal food safety regulations.³² In 1994, the USDA began by labeling *E. coli* O157:H7 as an adulterant under FMIA,³³ making it the only bacteria labeled as such to date.³⁴ The beef industry quickly objected to this new classification on the grounds that *E. coli* was not injurious to health unless the product containing the bacteria was improperly cooked.³⁵ This challenge proved

consumption of up to a million organisms of some foodborne pathogens to cause an infection, *E. coli* O157:H7 can cause an infection with very few organisms. *See id.* (as few as five organisms); Stearns, *supra* note 23, at 387 (as few as twenty organisms).

30. Su & Brandt, *supra* note 28, at 698 (describing the initial discovery of the bacteria and subsequent epidemiology). This identification was a result of an investigation following an outbreak of gastrointestinal illness from hamburger consumption at a fast food restaurant. *Id.*; *see also* Lee W. Riley et al., *Hemorrhagic Colitis Associated with a Rare Escherichia coli Serotype*, 308 NEW ENG. J. MED. 681 (1983).

31. This outbreak is typically referred to as the “Jack-in-the-Box outbreak.” *See, e.g.*, Lawson, *supra* note 12, at 74 (“[I]t was the December 1992 Jack-in-the-Box outbreak that first caught public attention.”); Stearns, *supra* note 23, at 390 (“The Jack in the Box outbreak was notable in many respects.”). Although victims became ill after consuming hamburgers at various Jack in the Box locations, the hamburger patties were later determined to have become contaminated during processing. *See* Beth P. Bell et al., *A Multistate Outbreak of Escherichia coli O157:H7-Associated Bloody Diarrhea and Hemolytic Uremic Syndrome from Hamburgers: The Washington Experience*, 272 J. AM. MED. ASS’N 1349, 1352 (1994) (noting that a large portion of patties produced on one day were determined to be contaminated by a single strain of *E. coli* O157:H7).

32. *See* Stearns, *supra* note 23, at 390–91 (explaining the policies announced by the USDA shortly after the outbreak).

33. *Id.* at 392. The FSIS did not publish this classification in the Federal Register. *Id.* Rather, the FSIS Administrator simply announced in a speech before the American Meat Institute (AMI) that beef containing *E. coli* O157:H7 would be considered adulterated under the FMIA. *Id.*

34. Lawson, *supra* note 12, at 81. The FSIS announced a new testing program for ground beef where samples testing positive for *E. coli* O157:H7 would be labeled “adulterated” under the FMIA. Stearns, *supra* note 23, at 393. This left unanswered the question of whether intact beef containing *E. coli* O157:H7 would be “adulterated” as well. *Id.*

35. *See* Carole Sugarman, *What’s in the Beef? USDA to Start Sampling Ground Meat to Monitor Contamination*, WASH. POST, Nov. 1, 1994, at Z16 (noting that the AMI argued that the testing program would give consumers a “false assurance that they no longer have to thoroughly cook ground beef”). The meat industry also objected to the process through which the USDA announced and implemented enforcement of this new classification arguing that the Agency acted outside its statutory authority by failing to follow the APA-required notice-and-comment procedure. *See* Texas Indus. Food Ass’n v. Espy, 870 F. Supp. 143, 145–46 (W.D. Tex. 1994).

unsuccessful,³⁶ and *E. coli* O157:H7 remains an adulterant.³⁷ The USDA then undertook the first major modernization of the inspection system since the passage of FMIA in 1906.³⁸

C. SHIFT TO HACCP INSPECTION SYSTEMS

The USDA began by requiring the use of Hazard Analysis and Critical Control Points (HACCP) systems, which incorporate scientific analysis into determining whether food products are contaminated.³⁹ These regulations shifted the approach from

36. See 870 F. Supp. 143. The court rejected this argument, observing that “a product is ‘adulterated’ if ‘it . . . contains any . . . substance which may render it injurious to health.’ . . .” *Id.* at 148 (quoting 21 U.S.C. § 601(m)(1)) (emphasis in original). The court noted that:

[E]vidence . . . indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. Coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. Coli* is a substance that renders “injurious to health” what many Americans believe to be properly cooked ground beef.

Id. at 149.

37. The USDA recently expanded its definition of “adulterant” to include six additional *E. coli* serogroups. Food Safety & Inspection Serv., U.S. Dep’t of Agric., *USDA Takes New Steps to Fight E. Coli, Protect the Food Supply* (Sept. 13, 2011), available at <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2011/09/0400.xml>. Beginning March 5, 2012, FSIS will begin testing for *E. coli* serogroups O26, O103, O45, O111, O121, and O145, in addition to O157:H7, as these serogroups can also cause serious illness and death. *Id.*

38. Two earlier legislative efforts, the Wholesome Meat Act of 1967, Pub. L. No. 90-201, 81 Stat. 584 (codified at 21 U.S.C. § 601 (2006)), and the Wholesome Poultry Products Act of 1968, Pub. L. No. 90-492, 82 Stat. 791 (codified at 21 U.S.C. § 451 (2006)), were enacted as amendments to FMIA and PPIA, but served primarily to create uniformity in the regulation of meat and poultry products. See Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6,774, 6,776 (Feb. 3, 1995).

39. HACCP was first developed by the Pillsbury Company as a means of assuring food safety in zero gravity for the U.S. space program. Theodore C. Cronk, *The Historic Evolution of HACCP: Better Questions, Safer Foods*, 49 FOOD & DRUG L.J. 485, 485 (1994). The USDA announced four objectives in applying the HACCP program to meat inspection:

(1) require that each [slaughtering] establishment develop and implement written sanitation standard operating procedures . . . ; (2) require regular microbial testing by slaughter establishments to verify the adequacy of the establishments’ process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points).

“command-and-control,” in which the government inspector is responsible for production decisions, to one where the primary responsibility is on the slaughtering and processing facilities to ensure that their products remained unadulterated.⁴⁰ Under HACCP programs, a meat processing facility must identify the food production that are most vulnerable to contamination, and then must design safety procedures at these critical points.⁴¹ In addition, processors are required to develop sanitation standard operating procedures (SOPs) to complement the HACCP requirements.⁴²

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (July 25, 1996).

40. See Stearns, *supra* note 23, at 394. The government’s role in food safety would shift “from inspection to verification.” Cronk, *supra* note 39, at 489.

41. The Final Rule instituting the use of HACCP systems, promulgated by the FSIS in 1996, outlined the seven general principles underlying the system:

- (1) A hazard analysis of each process during meat production must be conducted to identify and list the food safety hazards likely to occur, and to determine the preventative measures necessary to control such hazards.
- (2) The critical control points (CCPs) of each process, at which control can be applied and the potential food safety hazard can be prevented, eliminated, or reduced to an acceptable level, must be identified.
- (3) Critical limits for the preventative measures related to the CCPs must be identified. These critical limits are often based on process parameters including temperature, time, moisture level, or survival of target pathogens.
- (4) Monitoring requirements for the CCPs must be established. While the FSIS prefers continuous monitoring, the frequencies at which the CCPS are monitored are up to the individual processors.
- (5) Corrective actions must be established for when monitoring indicates that there are deviations from the critical limits at any of the CCPs.
- (6) A recordkeeping procedure must be developed and maintained for the entire HACCP system.
- (7) HACCP systems must be regularly verified. This includes both an initial validation that the system works properly and periodic verification once the system is operational.

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,814-38,817 (codified at 9 C.F.R. §§ 417.1-8 (2009)). While individual processors are responsible for developing and instituting HACCP systems in their facilities, the FSIS will be involved to a limited extent in the verification process. *Id.*

42. See 9 C.F.R. § 416 (2009). The Sanitation SOPs are intended to prevent insanitary practices that could “create an environment conducive to contamination of products.” Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,814, 38,829 (codified at 9 C.F.R. § 416). The Sanitation SOPs include “daily preoperational and operational sanitation procedures that the establishment would implement to prevent direct

HACCP systems reduce the role of FSIS inspectors.⁴³ Rather than ensure a safe meat supply, inspectors primarily review processors' documentation of HACCP compliance⁴⁴ and have no active role in the inspection of carcasses.⁴⁵ Although the beef industry continues to grow, the number of FSIS inspectors has decreased,⁴⁶ further diminishing their ability to ensure that the beef products entering the consumer marketplace are safe.⁴⁷

Each HACCP procedure consists of a recordkeeping component and a review and observation component.⁴⁸ FSIS inspectors can use either of these components to verify the facility's compliance with the HACCP regulations, opting to either assess the facility's paperwork or to observe facility workers on the facility floor.⁴⁹ Slaughter facilities are also required to test for generic *E. coli* at

product contamination or adulteration." *Id.* at 38,830. In addition to Sanitation SOPs covering all equipment and surfaces that could directly contact products, each facility must also maintain Sanitation Performance Standards (SPS). FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS DIRECTIVE 5000.1 REVISION 3, 4 (2008), available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5000.1Rev3.pdf> [hereinafter FSIS DIRECTIVE 5000.1]. "The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems." *Id.*; see also 9 C.F.R. § 4.16(2)-(6).

43. See CTR. FOR PUB. INTEGRITY, *supra* note 6, at 63. Among FSIS inspectors, the HACCP system received the nickname "Have a Cup of Coffee and Pray." *Id.*

44. In a survey of FSIS inspectors working in facilities operating under the HACCP guidelines, 379 inspectors responded that "they spend five times as much time checking company records under HACCP as they did under the former system and about one-third of the time spent under the former system actually inspecting the meat and poultry products to protect consumers." FELICIA NESTOR & WENONAH HAUTER, PUBLIC CITIZEN, THE JUNGLE 2000: IS AMERICA'S MEAT FIT TO EAT? 5-6 (Sept. 2000), available at http://www.whistleblower.org/storage/documents/the_jungle.pdf.

45. As one meat inspector described it, "we're paper pushers now . . . We have to spend so much of our time trying to check [the plant's] documentation that we really don't have time to look at the product anymore. We're checking papers, not products." CTR. FOR PUB. INTEGRITY, *supra* note 6, at 68 (quoting a federal meat inspector and president of a local meat inspectors' union).

46. From 1981 to 2007, the number of full-time FSIS employees decreased from 9,932 to 9,184. *Federal Meat Inspectors Spread Thin as Recalls Rise*, OMB WATCH (Mar. 4, 2008) <http://www.ombwatch.org/node/3624>. Adding to their inability to carry out proper inspections, the FSIS inspection force maintains a vacancy rate of approximately ten percent. *Id.*

47. As of 2007, the FSIS employed less than eighty-eight people per billion pounds of meat and poultry inspected, down fifty-four percent from the one hundred ninety workers per billion pounds in 1981. *Id.*

48. FSIS DIRECTIVE 5000.1, *supra* note 42, at 31.

49. *Id.*

specific steps during the slaughter process in proportion to the facility's volume of production.⁵⁰ In addition to conducting these tests, facilities must also comply with any FSIS request to test a random sample for *E. coli* O157:H7 under the HACCP program.⁵¹ Facilities generally receive sampling requests between one to four times per thirty-day period.⁵²

Ground meat products provide additional complications in ensuring that the ultimate product remains unadulterated. Slaughtering facilities inspect individual animals and carcasses according to their HACCP plan for disease or other signs that the meat will be unsafe for consumption.⁵³ Grinding facilities, however, often receive the meat they process from numerous slaughterhouses.⁵⁴ Although the grinders are required to test their own final products,⁵⁵ they typically do not conduct bacterial testing on the individual shipments of the meat trimmings and other ingredients as these shipments are received.⁵⁶ Therefore, when contaminated ground beef

50. 9 C.F.R. § 310.25 (2009). In cattle processing facilities, one in every three hundred carcasses must be tested, with a minimum of one sample per week of operation. *Id.* No sample may exceed 100 CFU/cm², and where more than three samples within the last thirteen samples test positive, FSIS may intervene. *Id.* CFU/cm² indicates the number of viable bacteria ("colony-forming units" or CFU) within the area in which the sample was taken.

51. FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS DIRECTIVE 10,010.1, REVISION 3 (2010), available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10010.1Rev3.pdf> [hereinafter FSIS DIRECTIVE 10,010.1].

52. *Id.* at 17–18.

53. If an inspector condemns a carcass due to adulteration, he or she may detain it and ensure the facility destroys the carcass properly, or under certain circumstances may permit the facility to remove the adulterated portions of the carcass. *See* 9 C.F.R. § 311 (2009) (disposal of diseased or otherwise adulterated carcasses and parts); 9 C.F.R. § 314 (2009) (handling and disposal of condemned or other inedible products at official establishments). Slaughtering facilities that merely portion beef product, but do not grind it or form patties, are not required to submit to random testing for *E. coli* O157:H7. FSIS DIRECTIVE 10,010.1, *supra* note 51, at 17.

54. *See* Gregory L. Armstrong et al., *Emerging Foodborne Pathogens: Escherichia coli O157:H7 as a Model of Entry of a New Pathogen into the Food Supply of the Developed World*, 18 EPIDEMIOLOGIC REVIEWS 29, 44 (1996) ("Methods currently used to produce ground beef make it possible for meat from dozens or even hundreds of cattle to go into any given hamburger patty."). Grocery stores that package and sell their own ground beef often receive coarse ground beef from grinding facilities and then regrind it with trimmings and leftover meat cuts, further obscuring the source of contaminated meat products. *See id.* at 44–45.

55. *See* 9 C.F.R. § 302.1 (requiring "establishments . . . in which any products . . . derived from carcasses of livestock are . . . prepared for transportation or sale as articles of commerce, which are intended for use as human food" to participate in federal inspection programs).

56. *See* Michael Moss, *E. Coli Path Shows Flaws in Beef Inspection*, N.Y. TIMES, Oct. 3, 2009, at A1 (explaining that many large slaughterhouses will not sell their products to

products cause an outbreak of foodborne illnesses, it can be very difficult to trace the tainted product back to one particular facility.⁵⁷ It also makes it more difficult for victims of foodborne illness outbreaks to recover damages from the source of the tainted beef product.⁵⁸

With the task of ensuring product safety placed predominately in the hands of the meat industry, the FSIS limits its compliance enforcement to follow-up sampling at facilities where product has tested positive for *E. coli* O157:H7.⁵⁹ If a slaughter facility fails microbial testing numerous times,⁶⁰ then the FSIS can suspend

processors if those customers test individual shipments of meat for *E. coli* prior to grinding due to a fear that of positive tests will lead to government repercussions). While the USDA encourages processors to inspect shipments of ingredients prior to grinding, each facility designs its own safety plan. *Id.* However, if any sample from a processing facility tests positive for *E. coli* O157:H7, that facility must provide the names and contact information for any supplying establishments to the FSIS, along with supplier lot number, production date, and any other information that may be useful to identify the source of the contaminated material. FSIS DIRECTIVE 10,010.1, *supra* note 51, at 36. If any supplier uses source materials from a foreign company, then that supplier must provide additional identifying information, including the country of origin and importing establishment. FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS NOTICE 58-10 (2010), available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/58-10.pdf> [hereinafter FSIS NOTICE 58-10].

57. For an example of the difficulties in tracing the original source of contamination in a ground beef product, consider the case of Stephanie Smith, who contracted hemolytic uremic syndrome and was ultimately paralyzed as a result of eating hamburgers contaminated with *E. coli* O157:H7. See Moss, *supra* note 56. While the hamburger patty Smith consumed was ground and formed in a plant in Wisconsin, it included various cuts of beef and trimmings from slaughterhouses and other processing facilities in Nebraska, South Dakota, Texas, and Uruguay. *Id.* Although the outbreak led to extensive inspections by the USDA around the country, inspectors were unable to trace the contamination to a particular supplier. See *id.*

58. See Machado, *supra* note 1, at 823. One proposed solution to this problem is to impose collective liability on the beef industry defendants, as permitted in recent handgun litigation. *Id.*

59. See FSIS DIRECTIVE 10.010.1, *supra* note 51, at 31. FSIS compliance enforcement focuses on conducting follow-up sampling at facilities that have supplied trimmings or other product that tested positive, concentrating in particular on establishments that have had multiple positive test results within the previous 120 days. *Id.* When conducting follow-up testing, FSIS will collect up to sixteen samples from the establishment, ordering additional samples as necessary until all follow-up samples test negative. See FSIS DIRECTIVE 10,010.1, *supra* note 51, at 42–44. The FSIS used to follow a “three strike” rule whereby it could suspend inspection services at slaughter facilities that failed microbial testing three times. Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 ADMIN. L. REV. 289, 318 (2005).

60. *Salmonella* testing was the first method used by FSIS inspectors as a general way to determine compliance with HACCP pathogen reduction standards; tests for *E. coli* were not conducted to determine compliance with sanitation SOPs. See McGarity, *supra* note 59, at 317–18 (outlining the HACCP program and its performance criteria). However, the beef industry successfully challenged the regulation of *Salmonella* as a proxy for all microbial contaminants,

inspection services, thereby preventing the facility from producing meat.⁶¹ In order to suspend inspection privileges, however, the FSIS must seek judicial intervention.⁶² Because there are still a number of administrative hurdles to suspending inspection privileges, the FSIS rarely reaches this level of sanction.⁶³

D. RECALLS

Should contaminated meat make its way into the marketplace, the FSIS lacks the authority to mandate a recall.⁶⁴ In response to an outbreak of foodborne illness, the FSIS may initiate an investigation to determine the necessity of a recall.⁶⁵ If a recall is necessary, then the FSIS may convene its Recall Committee to evaluate the situation and determine the scope of a potential recall.⁶⁶ It will then

arguing that the FSIS could not regulate a characteristic of the raw materials used in creating ground meat products. *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir. 2001) (finding that the USDA could not use *Salmonella* tests conducted on a grinding facility's final product to determine whether the facility was infected with § 601(m)(1) adulterant pathogens).

61. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,849; Lassiter, *supra* note 17, at 453; *see also* 9 C.F.R. § 500.6 (2009) (listing the circumstances under which the FSIS may withdraw inspection).

62. *See* 9 C.F.R. § 329.7. Before inspection privileges are suspended the facility is given an opportunity to resolve their sanitation problems. *See* Lassiter, *supra* note 17, at 450. Should those steps prove unsuccessful, or should the facility not cooperate with federal inspectors, an evidentiary administrative hearing is held before an Administrative Law Judge. *See id.* at 451; *see also* 9 C.F.R. §§ 500.2–500.6 (2009).

63. The FSIS Administrator can file a complaint to withdraw its grant of inspection for a variety of violations, including producing and shipping an adulterated product or failing to provide and maintain a HACCP program. 9 C.F.R. § 500.6 (2009). There is then a formal adjudication process through which these complaints must go. *See generally* 7 C.F.R. §§ 1.131–1.151 (2009). Summaries of the recent administrative actions taken by the FSIS can be found in its Quarterly Enforcement Reports, with actions to refuse or withdraw inspection found in Table 12. *See* Food Safety & Inspection Serv., U.S. Dep't of Agric., *FSIS Adjudications*, http://www.fsis.usda.gov/FOIA/FSIS_Adjudications/index.asp (last visited Oct. 8, 2011).

64. *See* McGarity, *supra* note 59, at 378. While the USDA will assist in the administration of any voluntary recall, meat processing companies retain the right to decline a request to recall their products should they not wish to expel the effort and costs of conducting one. *See id.* at 379; *see also* Roberts, *supra* note 1, at 566–71 (describing the voluntary food recall system). *See generally* FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS DIRECTIVE 8080.1, REVISION 6 (2010), *available at* <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf> [hereinafter FSIS DIRECTIVE 8080.1] (describing the procedures involving the voluntary recall of FSIS-inspected meat and poultry products).

65. *See* Roberts, *supra* note 1, at 568.

66. *Id.* at 568–69. Factors considered in determining the scope of a recall include the “plant’s processing and sanitation procedures, the definition of a lot, or specific grouping, and

recommend a recall and negotiate with the meat company in question to initiate a voluntary recall.⁶⁷

If the company chooses to conduct a recall, then the FSIS will issue either a press release, a recall notification report (RNR), or both.⁶⁸ These notifications provide the public with a description of the product, any identifying marks or codes, the reason for the recall, general information about the product's destination, and contact information for the recalling company for use by consumers and the media.⁶⁹

The FSIS classifies all recalls based on the potential threat of severe illness or injury to the public.⁷⁰ Class I recalls involve situations in which "there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death."⁷¹ Class II recalls involve situations in which there is a

whether there is any finished product reincorporated into fresh product (rework)." FSIS DIRECTIVE 8080.1, *supra* note 64, at 3.

67. See FSIS DIRECTIVE 8080.1, *supra* note 64, at 10–11 (describing the recall process). Most companies will cooperate with the FSIS in initiating a product recall in an effort to avoid the negative impact that an outbreak of foodborne illness traced to their products will have on public relations and the economic bottom line. See McGarity, *supra* note 58, at 378–79.

68. FSIS DIRECTIVE 8080.1, *supra* note 64, at 11–13. The FSIS will issue press releases to media outlets in the areas in which the potentially contaminated product was distributed. *Id.* at 12. These press releases are also available through an email listserv to which the public can subscribe. See *FSIS Food Recalls*, FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.fsis.usda.gov/fact_sheets/fsis_food_recalls/Index.asp (last modified Mar. 17, 2006). Both the press release and the RNR are posted on the FSIS website. *Id.* Once a recall has been completed, the notice is moved from current recalls to an online archive dating back to 1994. See *Recall Case Archive*, FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.fsis.usda.gov/FSIS_Recalls/Recall_Case_Archive/index.asp (last modified Aug. 12, 2011) (providing a pull-down menu to review all recalls, organized by year). The archive records provide the establishment and product type, other information including the nature of the defect leading to the recall, and the number of pounds of product recovered during the recall. *Id.*

69. FSIS DIRECTIVE 8080.1, *supra* note 66, at 12–13. Press releases provide information regarding any health risks caused from consumption of the product and how explain how one should handle and dispose of the product should they have already purchased it. See *id.* at 12.

70. See *id.* at 2–3.

71. *Id.* at 2. The presence of *E. coli* O157:H7 in the product at issue would result in a Class I recall. For example, in 2010, due to possible *E. coli* O157:H7 contamination, there were ten Class I recalls of beef products, totaling nearly 2.25 million pounds. See *FSIS Current Recalls & Alerts*, FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp (last modified Oct. 7, 2011); *FSIS Recall Case Archive*, *supra* note 68 (choose 2010 from pulldown bar). An additional 4.9 million pounds of beef and veal products were recalled due to the processing facility's failure to follow

“remote probability” that use of the product could cause adverse health consequences.⁷² Class III recalls involve products that will not cause adverse health consequences.⁷³ The classification level of a recall determines the level of notification that the FSIS will undertake; press releases are issued for most Class I and Class II recalls, and only for Class III if there are overriding public welfare reasons.⁷⁴

Recalls will be “closed” at the recommendation of the Recall Management Staff, who provides a summary of the recall efforts by the company in question and any reports findings from effectiveness and product disposition checks.⁷⁵ A recall cannot be closed if there are any current illnesses associated with the recalled product.⁷⁶ Once the FSIS is satisfied that the recall is complete, it will relocate the case file from the “open” to “archived” section of the FSIS website.⁷⁷ The FSIS conducts no post-recall follow-up with the recalling company, but recommends that the company follow up with its affected customers and assess the performance of its recall plan.⁷⁸

its HACCP plan; the products were recalled over fears of contamination. *See* News Release, Food Safety & Inspection Serv., U.S. Dep’t of Agric., California Firm Expands Recall of Beef Products Due to Possible Adulteration (Feb. 12, 2010), http://www.fsis.usda.gov/News_&_Events/Recall_004_2010_Expanded/index.asp. The seven 2010 recalls completed as of October 10, 2011, resulted in approximately 150,000 pounds of recovered product. *See FSIS Recall Case Archive*, *supra* note 68.

72. FSIS DIRECTIVE 8080.1, *supra* note 66, at 2–3. Class II recalls include the presence of a very small amounts of undeclared allergens or foreign materials that are small and without sharp edges. *Id.*

73. *Id.* at 3. The presence of a non-allergen that is generally recognized as safe will result in a Class III recall. *Id.*

74. *See id.* at 12–13. Public notice of Class III recalls is usually limited to an RNR on the FSIS website. *Id.* Press releases may not be issued for Class I and Class II recalls if the potentially contaminated product has not been shipped beyond the wholesale level and is not likely to have been sold to consumers. *Id.*

75. *Id.* at 20. The FSIS conducts effectiveness checks to ensure that the recalling company has been diligent in notifying its purchasers of the need to recover and dispose of the potentially contaminated product. *Id.* at 15–16. If distribution of the product was limited to the wholesale level and the recalling company has regained control over the product, the FSIS will verify that the recalling company has properly disposed of the recalled product. *Id.* at 16.

76. *Id.* at 20.

77. *Id.* at 20–21.

78. *Id.* at 19–20.

E. CONSUMER RELIANCE

While the FSIS assists producers with a recall when contaminated meat products are distributed, there is still an underlying reliance on the public as the last line of defense in protecting against foodborne illnesses.⁷⁹ Pathogens present in ground beef are destroyed so long as consumers cook the product to a sufficient internal temperature.⁸⁰ Proper preparation and cooking are especially important with *E. coli* O157:H7 contaminated beef because the bacteria can survive at higher temperatures than other pathogens that cause foodborne

79. The beef industry relied in part on this argument in contesting liability for the death of a young girl who ate food contaminated by contact with beef tainted by *E. coli* O157:H7, contending that:

The uniform national standards governing the production of raw meat expressly provide that whole-intact meat containing *E. coli* may be distributed for consumption in interstate commerce. This is because, although pathogenic bacteria (such as *E. coli*) occurs naturally in the production of meat (and is virtually impossible to avoid), safe food-handling readily destroy[s] the bacteria. Instead of requiring meat producers to do the impossible (by completely eliminating the pathogenic bacteria), the federal government relies on the end-user to follow safe food-handling practices to avoid the dangers associated with raw meat.

Stearns, *supra* note 23, at 405 (quoting Excel Corporation's Notice of Motion, Motion for Summary Judgment, and Memorandum of Law in Support of Summary Judgment at i-ii, In re Consolidated *E. coli* O157:H7 Cases, No. 00-CV-006503 (Milwaukee Cir. Ct. May 15, 2002)). The court disagreed with this argument, noting that the FSIS has stressed the need for processors to consider what would happen if a tainted product from their facility made its way to the public: "the health effects of enteric pathogens are relatively well documented. If the pathogens enter the food supply, they do, under certain conditions, cause foodborne illness. If their presence can be prevented, no amount of temperature abuse, mishandling or undercooking can lead to foodborne illness." Estate of Kriefall *ex rel.* Kriefall v. Sizzler USA Franchise, Inc., 665 N.W.2d 417, 432 (Wis. Ct. App. 2003) (quoting Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,962).

80. Both the USDA and the beef industry provide information about proper cooking on their websites, including recommendations to cook ground beef products to an internal temperature of 160 degrees Fahrenheit. See *Food Safety Education: Is It Done Yet?*, FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.fsis.usda.gov/is_it_done_yet/Thermometer_Placement_and_Temps/index.asp (last modified May 26, 2011) (USDA recommendation); Cattlemen's Beef Board & Nat'l Cattlemen's Beef Ass'n, *Commitment to Safety from the Industry and for Those Who Cook Beef*, EXPLORE BEEF, <http://www.Explorebeef.org/safety.aspx> (last visited Aug. 26, 2011) (beef industry recommendation). Rare burgers have an internal temperature closer to 130 degrees Fahrenheit. See RALSTON ET AL., CONSUMER FOOD SAFETY BEHAVIOR: A CASE STUDY IN HAMBURGER COOKING AND ORDERING 19-20 (2002), available at <http://www.ers.usda.gov/publications/aer804/aer804f.pdf> (using internal temperatures of 130, 145, and 155 degrees Fahrenheit to correspond to rare, medium-rare, and well-done, respectively, in an analysis of consumer hamburger preparation behavior).

illnesses.⁸¹ The internal temperature recommended by the USDA to avoid foodborne illness will produce a burger considered “well done” by most standards.⁸² While many restaurants adhere to the USDA temperature recommendations when cooking their food,⁸³ the at-home consumer is more likely to cook to their personal preference without considering potential health consequences.⁸⁴

The USDA requires that all ground beef products shipped in interstate commerce contain labels indicating that they have been “inspected and passed.”⁸⁵ Various criteria for the font and formatting of these labels are set by the Secretary of the USDA to avoid false or misleading labeling.⁸⁶ In the past, the USDA attempted to add additional labels to ground beef products in order to warn consumers about the potential presence of harmful bacteria.⁸⁷ The beef industry

81. *Compare Foodborne Illness: What Consumers Need to Know*, United States Dep’t of Agric., Food Safety & Inspection Serv., http://www.fsis.usda.gov/Fact_Sheets/Foodborne_Illness_What_Consumers_Need_to_Know/index.asp (last modified May 24, 2011) (instructing consumers to cook ground beef to a minimum internal temperature of one hundred sixty degrees Fahrenheit in order to kill E. coli) with Robert Angelotti et al., *Time-Temperature Effects on Salmonellae and Staphylococci in Foods*, 9 APPLIED MICROBIOLOGY 308 (1961) (finding that one hundred percent of *Salmonella* organisms were killed in three different types of food if cooked at 140 degrees Fahrenheit for a sufficient period of time).

82. See RALSTON ET AL., *supra* note 80, at 19–20.

83. Restaurants are typically subject to state or local regulations that dictate minimum cooking times and temperatures, which often mirror or are close to USDA suggestions. See, e.g., FLA. ADMIN. CODE ANN. r. 64E-11.004 (2011) (requiring that comminuted meat products, including hamburger, be cooked to a minimum internal temperature of 155 degrees Fahrenheit for at least 15 seconds); 7 PA. CODE § 46.361 (2011) (dictating minimum cooking times and temperatures for cooking raw animal-derived foods in retail food establishments).

84. See RALSTON ET AL., *supra* note 80, for an analysis of consumers’ preference for palatability over safety and the resulting likelihood of cooking a burger medium-rare or rare.

85. 21 U.S.C. § 607 (2006). This label is affixed to all products determined to be unadulterated. 21 U.S.C. § 606 (2006).

86. See 21 U.S.C. § 607 (2006); 9 C.F.R. §§ 312, 316–317 (2009). In part, these regulations were in response to objections from consumer groups that the labeling practices permitted by the USDA could be misleading and deceptive. See *Fed’n of Homemakers v. Hardin*, 328 F. Supp. 181 (D.C. Cir. 1971) (finding the use of the label “all meat” on products containing up to fifteen percent nonmeat ingredients to be misleading and in violation of the Wholesome Meat Act); see also *Taco Bell Meat: Chain Sued Over 35% Beef Content in ‘Taco Meat Filling’* [UPDATED], HUFFINGTON POST (Jan. 24, 2011), http://www.huffingtonpost.com/2011/01/25/taco-bell-beef-lawsuit_n_813185.html (reporting on lawsuit alleging that fast-food chain’s meat mixture did “not meet the minimum requirements set by the [USDA] to be labeled as ‘beef’”).

87. See Stearns, *supra* note 23, at 419 (explaining the USDA’s effort to include the recommended cooking temperature for ground beef on warning labels after the Jack-in-the-Box outbreak).

has vehemently challenged additional warnings.⁸⁸ For example, following the Jack in the Box outbreak, the USDA sought to place safe-handling labels on all packages of raw meat and poultry, which were to include information regarding the cooking temperatures necessary to kill pathogens.⁸⁹ The beef industry, however, obtained an injunction against use of these safe-handling labels, and the USDA ultimately implemented labels that did not refer to cooking temperatures.⁹⁰

II. ANALYSIS

The current regulatory regime for ground beef products provides little incentive for processing facilities to ensure that the products they send into the marketplace are safe. When cows are raised in one state, slaughtered in another, processed in a third state along with products from numerous other states and/or countries, and ultimately cooked and consumed by the public in perhaps yet a fourth state, it is easy for meat grinders to shift the blame to their suppliers for contaminated products.⁹¹ Furthermore, the reliance on the consumer to properly cook meat products so as to kill any pathogens present at the time of purchase as the last line of defense undermines the necessity for legislation designed to ensure that the meat is safe as is when purchased.⁹² Despite focusing on the importance of consumer responsibility, the beef industry has interfered with USDA attempts

88. *See id.*

89. *See* Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 58 Fed. Reg. 43,478 (Aug. 16, 1993). The parameters of safe handling included “how to safely store raw product and thaw frozen product; how to avoid cross-contamination during preparation; how to cook for optimal safety and palatability; and, how to store leftovers after preparation.” *Id.* at 43,483.

90. *Texas Food Indus. Ass’n v. USDA*, 842 F. Supp. 254 (W.D. Tex. 1993). The USDA sought to implement the use of these new labels on an expedited basis, circumventing the normal notice and comment requirements under the Administrative Procedure Act. *Id.* at 258. The court objected, noting that “[i]f ‘immediate action’ was necessary, the USDA should have implemented, or attempted to implement, the interim rule ‘immediately.’” *Id.*

91. *See* McGarity, *supra* note 59, at 341–42.

92. While the Jack-in-the-Box outbreak was ongoing, the meat industry focused on improper cooking as the source of the problem. *See* SCHLOSSER, *supra* note 9, at 207 (“This recent outbreak sheds light on a nationwide problem: inconsistent information about proper cooking temperatures for hamburger.” (quoting J. Patrick Boyle, President, American Meat Institute)).

to require labels detailing proper cooking temperatures on all ground beef products.⁹³

Although *E. coli* O157:H7 has been identified as an adulterant by the USDA, the USDA does not require that a grinding facility specifically test for that pathogen as part of the HACCP plan.⁹⁴ While microscopic testing is a part of any HACCP system, a facility can test for other bacteria as a way of determining whether fecal matter or other contaminants are present.⁹⁵ The regulation of pathogens under HACCP systems does not extend, however, to “characteristics of the raw materials that exist before the meat product is ‘prepared, packed or held.’”⁹⁶ Grinding facilities, therefore, do not have to test ingredients as they receive them from slaughterhouses and other processing facilities. Furthermore, FSIS sampling takes a secondary role to a facility’s ability to fulfill its orders for customers; should a randomly scheduled sampling interfere with the facility’s ability to produce sufficient product to complete an order, the FSIS cannot take its sample.⁹⁷

With their role limited primarily to reviewing paperwork, FSIS inspectors are largely ineffective. Processing facilities are not required to provide FSIS inspectors with complete access to the facility’s records; but only with the documentation relating to the facility’s HACCP program.⁹⁸ Though there have been reports of

93. See Texas Food Indus. Ass’n, 842 F. Supp. 254. (signaling the beef industry’s successful fight against the USDA’s attempt to place warning labels providing minimum cooking temperatures for food safety on ground beef products); see also Am. Pub. Health Ass’n v. Butz, 511 F.2d 331 (D.C. Cir. 1974) (holding that the USDA need not mandate warning labels with proper handling techniques and cooking temperatures on meat and poultry).

94. See 9 C.F.R. § 310.25 (2009). Slaughtering facilities, and not those that only process meat, are required to test for generic *E. coli* at specific locations on the carcass. See *id.*

95. See SCHLOSSER, *supra* note 9, at 215.

96. Supreme Beef Processors Inc. v. USDA, 275 F.3d 432, 440 (5th Cir. 2000) (internal quotation marks omitted).

97. See FSIS DIRECTIVE 10,010.1, *supra* note 51, at 18. The FSIS randomly selects the days and times from which facilities must sample their products and report their results. See *id.* at 13–16. While it is possible that two samples could be requested from one facility on the same day, the FSIS cannot take both samples if doing so would prevent that establishment from completing customer orders, or if the facility’s inspection personnel’s workload does not permit such sampling frequency. *Id.* at 18.

98. Facilities are not required to provide “copies of HACCP plans, verification documents, or day-to-day operating records to FSIS.” Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,821. At the largest

extensive falsification of this HACCP compliance documentation,⁹⁹ FSIS inspectors have little time to witness the effectiveness of HACCP systems in person.¹⁰⁰ Furthermore, most HACCP documentation of plant conditions is not available under the Freedom of Information Act (FOIA),¹⁰¹ so the public must take the processing facilities at their word that they are complying with their own HACCP procedures.¹⁰² When it suspects a facility's HACCP system is not functioning properly, the FSIS has the ability to "copy appropriate portions of establishment records . . . for further evaluation and possible enforcement action," but those records may be further redacted before the public can access them.¹⁰³

The inability to mandate recalls of potentially contaminated products ties the hands of the USDA when faced with life-threatening outbreaks of foodborne illnesses.¹⁰⁴ A meat processing company must voluntarily conduct a recall, and many will drag their feet in order to limit its scope.¹⁰⁵ The longer a product is in the marketplace, the more

establishments, those producing more than 250,000 pounds of ground beef per day, the FSIS will request sampling reports only up to four times each calendar month. See FSIS DIRECTIVE 10,010.1, *supra* note 51, at 18.

99. See SCHLOSSER, *supra* note 9, at 216.

100. The USDA is currently understaffed with about 7,800 meat inspectors in the field; in the 1970s, prior to the first known *E. coli* outbreak, the USDA had over 12,000 inspectors. *Slaughter Inspection 101*, UNITED STATES DEP'T OF AGRIC. FOOD & SAFETY INSPECTION SERV., http://www.fsis.usda.gov/Fact_Sheets/Slaughter_Inspection_101/index.asp (last modified Apr. 6, 2010); see also SCHLOSSER, *supra* note 9, at 215. When inspectors do make facility inspections, some slaughterhouse workers do whatever is necessary to distract the inspector, including putting the "pretty talkative woman" next to him. Victoria Kim, *Cattle Inspections Thwarted*, L.A. TIMES, Feb. 20, 2008, <http://articles.latimes.com/2008/feb/20/local/me-beef20>. Some inspectors have reported that they receive tremendous pressure to not slow down the line speeds at production facilities. SCHLOSSER, *supra* note 9, at 215.

101. See Machado, *supra* note 1, at 821; SCHLOSSER, *supra* note 9, at 215.

102. HACCP records are arguably trade secrets which are exempted from the FSIS's compliance with FOIA. See FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS DIRECTIVE 1450.1, REVISION 3, 11 (2007), available at <http://www.fsis.usda.gov/PDF/1450-1rev3.pdf>; Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,821. However, the FSIS must have access to all testing results that could disclose the existence of problems with a facility's HACCP program. FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., FSIS DIRECTIVE 5000.2, REVISION 2, 5 (2008), available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5000.2Rev2.pdf>.

103. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,821. The FSIS views portions of HACCP plans as falling under the FOIA disclosure exemption for trade secrets and confidential, commercially valuable information. *Id.*

104. See *supra* notes 71–78 and accompanying text.

105. See McGarity, *supra* note 60, at 379.

likely it will have been consumed by the time the recall is effectuated.¹⁰⁶ The fewer products ultimately available for recall, the lower the costs to the company responsible for the recall.¹⁰⁷

Numerous bills seeking to provide the USDA with the power to mandate recalls have been voted down or have failed to make it out of committee.¹⁰⁸ Opponents of these bills argue that mandatory recall authority harms the cooperative nature of the relationship between the recalling company and the government during the voluntary recall process.¹⁰⁹

Furthermore, when a company does choose to initiate a recall, the USDA has no legal obligation to inform the public or health officials in the region from which the product was distributed that a recall is being conducted.¹¹⁰ From 1996 to 1999, the USDA notified the public of only half of the Class I recalls undertaken.¹¹¹ And when the USDA does announce a recall, it is often limited to publishing a notice on its

106. See, e.g., Roberts, *supra* note 1, at 572–73. In what was at the time the largest meat recall ever conducted, Hudson Foods sought to recall twenty-five million pounds of beef products in 1997. *Id.* at 573. The recall began much smaller, at twenty thousand pounds, and was only increased once Hudson disclosed that it “reworked” leftover meat into hamburger on a rolling daily basis. *Id.* at 572–73. Following this delay in identifying potentially contaminated product, only eight to ten million pounds were ultimately recovered. CTR. FOR PUB. INTEGRITY, *supra* note 6, at 51.

107. Most of the expenses surrounding a recall are borne by the slaughterhouse or processing facility that handled the contaminated product. McGarity, *supra* note 60, at 379. The FSIS only bears the costs of issuing press releases and informing the public, as well as follow-up inspections of the facilities that were subject to the recall. *Id.*

108. See, e.g., Food Safety and Tracking Improvement Act, S. 425, 111th Cong. (2009); Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2009, H.R. 815, 111th Cong. (2009); Unsafe Meat and Poultry Recall Act, S. 1527, 111th Cong. (2009); Food Safety Enhancement Act of 1997, S. 1264, 105th Cong. (1997); Family Food Protection Act of 1995, H.R. 1423, 104th Cong. (1995); The Pathogen Reduction Act of 1994, S. 2453, 103d Cong. (1994). The Food Safety Modernization Act of 2009, H.R. 875, 111th Cong., which recently failed to be signed into law, would have granted mandatory recall authority to the FDA, but it did not address the recall authority of the USDA.

109. See Roberts, *supra* note 1, at 570–71. These opponents believe that a mandatory recall system would result in an adversarial system rife with litigation and blame shifting. *Id.*

110. See Machado, *supra* note 1, at 823–24.

111. *Id.* at 823. The FSIS categorizes recalls into three categories based on relative health risk: Class I, in which there is a reasonable probability that eating the product will cause health problems or death; Class II, in which there is a remote probability that eating the product will result in adverse health consequences; and Class III, in which eating the product will not cause adverse health consequences. See *FSIS Food Recalls*, *supra* note 68.

website.¹¹² It may provide the identification number of the establishment that produced the product in question and regions through which it was distributed,¹¹³ but only in limited circumstances will the USDA identify specific locations at which the product was sold.¹¹⁴

III. PROPOSAL

The USDA needs greater enforcement ability in order to ensure that the ground beef supply remains safe for the public. The inability to order a recall allows meat processing companies to minimize cost at the expense of public safety.¹¹⁵ The lack of financial penalties if contaminated meat products harm the public further reduces companies' incentives to maintain stringent sanitation SOPs and inspection procedures.

Congress should grant the USDA express authority to mandate a recall to stop the distribution of adulterated products. Such power should be a backup, however, after first giving the company in question the opportunity to voluntarily recall its products. If the company is slow to initiate the recall, or refuses to do so, then the USDA should then have the power to step in and order the recall. In making mandatory recall authority a secondary option to a voluntary recall, the USDA can both protect the cooperative nature of the relationship with the beef industry that encourages prompt action in the face of contaminated product distribution and give the USDA the

112. See *supra* notes 68–69 and accompanying text. The FSIS issues press releases for all Class I and Class II recalls, and RNRs for Class III recalls. See *supra* note 74 and accompanying text.

113. In providing recall guidelines for firms, the FSIS requires that the press release “provide general information about the product’s destination.” FSIS DIRECTIVE 8080.1, *supra* note 64, at 12. This can be limited to the identification of the states in which the product was distributed. See *id.*

114. The beef industry argues that the identities of its customers constitute “trade secrets” and should thus remain confidential in the face of a recall. SCHLOSSER, *supra* note 9, at 213. The FSIS will only provide retail sales locations in Class I recalls. See *FSIS Current Recalls & Alerts*, *supra* note 71. In the case of chain grocers, however, it may only identify the states in which the product may have been distributed to that particular chain. *Id.*

115. See *supra* notes 104–06 and accompanying text.

teeth to enforce compliance should a company be reluctant to initiate a recall.¹¹⁶

Further, the USDA should have the ability to impose strict fines for violations of food safety regulations. The current procedure of ongoing follow-up sampling at facilities that have tested positive for *E. coli* O157:H7 allows company practices that may be public health hazards to continue for far too long. The assessment of penalties on a daily basis for as long as a violation continues would serve as a strong incentive for companies to correct problems immediately. Industry arguments against many of the proposed regulations tend to focus on the financial impact of these regulations on small establishments.¹¹⁷ However, a progressive system in which fines are levied in relation to the total production levels of a particular facility, would reduce the burden that a fine would impose on smaller meat processors.

Another cost-efficient USDA regulation would be spot testing. Requiring grinding facilities to inspect each shipment of ingredients they receive prior to incorporating them into a final product would be prohibitively expensive for most facilities to implement¹¹⁸ and would receive intense opposition from the beef industry. However, spot testing of a percentage of all ingredients, in proportion to that facility's overall output, would allow for faster identification of contaminated products, and would prevent them from making it into a final ground product that then enters the marketplace.

116. *See id.*

117. For example, when the USDA proposed the shift to the HACCP system of inspections, it faced intense opposition from meat and poultry trade associations. Dion Casey, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J.L. & PUB. POL'Y 142, 150 (1998). They argued that the costs of implementing the program would force eighty-five percent of small establishments out of business within one year. *Id.*

118. When first implementing the HACCP systems, FSIS estimated that it would cost small establishments eight thousand dollars per year to test one sample a day for microbial pathogens. Casey, *supra* note 117, at 150. If a small facility received its ingredients from numerous suppliers and were thus required to incur testing costs for each shipment, the cost to produce each pound of meat could reach unaffordable levels to keep these facilities in business.

IV. CONCLUSION

The regulation of inspections of ground beef products continues to be a balancing act with the interests of the politically and financially powerful American beef industry against preserving the health and safety of consumers. However, it is ineffective to rely solely on the beef industry to take the necessary steps to render its products as safe as possible when its primary concern is profit margins. The USDA lacks the ability to adequately examine the sanitation and monitoring procedures of all facilities¹¹⁹ and when a contaminated product makes its way into the marketplace, the USDA must count on the producer to undertake a recall. Granting greater compliance enforcement authority to the USDA to mandate recalls and to fine violating facilities will better ensure that the beef industry holds itself to higher standards.

119. When the FSIS is able to conduct inspections, contamination can be discovered before it becomes a major health issue. Huntington Meat Packing, Inc. recently undertook a Class I recall of nearly 5.7 million pounds of beef products that may be contaminated with *E. coli* O157:H7 after a Food Safety Assessment (FSA) by FSIS personnel uncovered potential contamination. News Release, Food Safety & Inspection Serv., U.S. Dep't of Agric., California Firm Recalls Beef Products Due to Possible *E. coli* O157:H7 Contamination (Jan. 18, 2010), available at http://www.fsis.usda.gov/News_&_Events/Recall_004_2010_Release/index.asp. No illnesses have been reported. News Release, Food Safety & Inspection Serv., U.S. Dep't of Agric., California Firm Expands Recall of Beef Products Due to Possible Adulteration (Feb. 12, 2010), available at http://www.fsis.usda.gov/News_&_Events/Recall_004_2010_Expanded/index.asp.