

ARTICLES

FEDERAL REGULATION OF MAD COW DISEASE RISKS

THOMAS O. MCGARITY*

TABLE OF CONTENTS

Introduction	292
I. Mad Cow Disease as a Public Health Issue	298
A. Mad Cow Disease and Other TSEs	298
1. The Cause of TSEs	299
2. The Incidence of Mad Cow Disease	299
3. Detection of BSE in Cattle, Cattle Feed, and Food	300
4. TSEs in Humans	301
5. How TSEs are Communicated.....	302
6. Risk to the U.S. Beef Industry	304
B. Agribusiness Practices Resulting in the Spread of Mad Cow Disease	305
1. Importation of Contaminated Animals, Meat, and Animal Feed.....	305
2. Communication from Animal to Animal	305
3. Communication from Animals to Humans	308
4. Prevention Techniques.....	310
II. Regulation of Mad Cow Risks Prior to January 2004	310
A. USDA Regulation.....	312
1. The HACCP Regulations.....	314
a. HACCP Plans.....	315
b. Sanitation Standard Operating Procedures	316

* W. James Kronzer Chair in Trial and Appellate Advocacy, University of Texas School of Law. Professor McGarity is President of the Center for Progressive Regulation. This Article has benefited greatly from student papers prepared by Caroline Badinelli, Elizabeth Duffy, and Wayne Sanders for the Food Safety Seminar taught at the University of Texas School of Law by Professor Thomas O. McGarity in 2002 and 2004. He would also like to thank Michelle Avallone, Columbia Law School Class of 2006, for her valuable research assistance, and the Center for Progressive Regulation for supporting that research.

c.	Performance Criteria and Standards	317
d.	Public Access to Critical Information	318
e.	Whistleblower Protections	319
f.	The <i>Supreme Beef</i> Challenge	319
2.	USDA Mad Cow Efforts Prior to December 2003	321
a.	The Ban on Imports of Cattle from Countries with BSE-Infected Cattle	322
b.	USDA Surveillance Efforts Prior to December 2003	323
c.	Regulation of AMR and Mechanical Separation Technologies	324
d.	Cattle Identification and Tracking Program	325
B.	FDA Regulation	327
1.	The 1997 Ruminant Feed Regulations	328
2.	Enforcement of the 1997 Feed Restrictions	329
III.	Regulation of Mad Cow Risks After January 2004	330
A.	The January 8, 2004 USDA Regulations	331
1.	The Specified Risk Material Interim Final Rule	332
a.	Definition of SRM	333
b.	Procedures for Removal, Segregation, and Disposition	334
2.	The Advanced Meat Recovery Rule	334
3.	The Ban on Mechanically Separated Meat Technologies	335
4.	Limited "Condemnation" of Downer Cattle	335
5.	The Air Injection Stunning Rule	336
6.	Expanded Governmental Testing, but Zero Nongovernmental Testing	337
B.	The January 26, 2004 FDA Announcement	340
C.	The July 9, 2004 FDA Rule and Considerations for Further Action	341
IV.	Flimsy Firewalls	341
A.	The Import Restriction Firewall	343
B.	The Feed Restriction Firewall	344
1.	Incomplete Feed Restrictions	345
2.	Poor Enforcement of Feed Restrictions	346
C.	The Surveillance Firewall	347
1.	Problems with the USDA's Expanded Testing Program	348
2.	The USDA's Inexplicable Prohibition on Privately Conducted Testing	354
D.	The Downer Cattle Firewall	356
E.	The SRM Restrictions Firewall	357
1.	Insufficiently Broad Definition of "Specified Risk Material"	358
2.	Zero Tolerance with Maximum Flexibility	360
3.	Industry Reliance on Prerequisite Programs	361
4.	The Questionable Legal Rationale for Relying on Prerequisite Programs	367
5.	HACCP's High Tolerance for Contamination	369

2005]	<i>FEDERAL REGULATION OF MAD COW DISEASE RISKS</i>	291
	6. A Verification Vacuum.....	370
	7. Technological Torpidity	373
	8. Sticky Enforcement Triggers	374
	9. Shirking Responsibility	375
	10. The USDA's Limited Legal Authority	376
V.	Faulty Responses to Firewall Failure.....	378
A.	A Perverse Recall Policy	379
B.	Lack of a Universal Animal Identification Program	380
VI.	Why the Firewalls Are Failing—Underlying Causes of Inadequate Regulation	382
A.	Lack of Transparency	382
1.	Lack of Transparency in the Import Restriction Program.....	383
2.	Lack of Transparency in the Administration of HACCP and Prerequisite Programs.....	383
3.	Lack of Transparency in the Animal Identification Program.....	384
4.	Lack of Transparency in the Recall Process	384
B.	Practical Enforcement Difficulties	385
1.	The Limited Capacity of USDA Inspectors.....	386
2.	Pressures on USDA Inspectors.....	388
3.	Lack of Enforcement Options.....	388
C.	Institutional Conflict of Interest	389
D.	The Revolving Door	390
VII.	Suggestions for Change	392
A.	USDA Reforms	392
1.	Ensure that Imported Beef Complies with U.S. Requirements	392
2.	Increase Surveillance	392
3.	Permit Voluntary Testing	393
4.	Deal with the Disposal of Downer Cattle	393
5.	Establish an Effective Animal Identification and Tracking Program	395
6.	Eliminate the Specified Risk Material Loopholes	396
7.	Remove the Option of Relying upon Prerequisite Programs	397
8.	Require Quantitative Testing for SRMs in Implementing any Performance-Based Requirements.....	398
9.	Write Protective Standards for SRM Removal.....	399
10.	Less Tolerance for Repeated Violations.....	400
11.	Prevent Shifting of Responsibility to Downstream Establishments	400
12.	Increase Transparency	401
13.	More Effective Enforcement	401
B.	FDA Reforms	402
1.	Expand the Feed Ban	402
2.	Better Enforcement of the Feed Ban.....	404
C.	Statutory Reforms.....	404
1.	Require Testing of All Downer Cattle.....	404

2. Clarify USDA Authority to Enforce HACCP Programs for SRMs	405
3. Recall Legislation	406
4. Country of Origin Legislation.....	407
5. Civil Penalty Power	408
6. User Fees	408
7. Greater Transparency.....	409
D. Whistleblower Protections.....	409
Conclusion.....	410

[W]hat counts is doing whatever needs doing in the fastest, cheapest, most intensely productive way, expending the least effort or energy with the minimum of raw materials. We call that efficiency—and it has become the value that trumps every other.¹

INTRODUCTION

On December 23, 2003, Secretary of Agriculture Ann Veneman interrupted afternoon television programming to report that the United States Department of Agriculture (USDA or Department) received word that a Holstein cow slaughtered on December 9th in Washington State suffered from Bovine Spongiform Encephalopathy (BSE), or mad cow disease.² The Department had taken tissue from the cow for BSE testing because the USDA inspector at the slaughterhouse concluded that it was a nonambulatory or “downer” cow, a class of cattle that is generally at higher risk for mad cow disease.³ The Department immediately quarantined the Mabton, Washington farm that raised the mad cow and began investigating the Vern’s Moses Lake Meats facility where it had been slaughtered.⁴ It also requested that facilities receiving beef from Vern’s slaughterhouse during the relevant time period voluntarily recall that meat and properly dispose of it.⁵ The USDA Undersecretary for Food Safety, Elsa Murano,

1. Nicols Fox, *The Case Against Efficiency*, WASH. POST, Feb. 15, 2004, at B1.

2. Shankar Vedantam, *Mad Cow Case Found in U.S. for First Time*, WASH. POST, Dec. 24, 2003, at A1 (detailing the first incidence of mad cow disease in America); *see also* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (Jan. 12, 2004) [hereinafter USDA SRM Interim Final Rule] (prohibiting the use of specified materials for human food requirements for the disposition of disabled cattle).

3. *See* Vedantam, *supra* note 2 (presenting opinions supporting and opposing the use of downer cows in the U.S. food supply); *see also* Aaron Zitner, *Bovine Disease Surfaces in U.S.*, L.A. TIMES, Dec. 24, 2003, at A1 (defining “downer” as unable to walk).

4. *See* Vedantam, *supra* note 2 (noting that USDA officials planned to investigate other facilities that handled meat from the infected cow).

5. The recall was initially limited to potentially contaminated beef from the suspect cow and 19 others that were processed at the same time. Matthew L. Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, N.Y. TIMES, Dec. 25, 2003, at A22. Within days, it expanded to five major grocery chains in California, Nevada, Oregon, Washington, Alaska, Hawaii, Idaho, and Montana. The stores had been selling beef purchased from an Oregon meat distributor that processed meat that may have come from the infected cow.

told the media that the USDA would attempt to identify the original birth herd of the Washington State mad cow and locate those animals and their offspring.⁶ Citing a recently completed study by the Harvard Center for Risk Analysis (HCRA), USDA officials predicted that mad cow disease would not spread to other animals in the United States because of feed restrictions that the U.S. Food and Drug Administration (FDA) had put in place in 1997.⁷

At the December 23rd briefing, Secretary Veneman offered the American public strong assurances that any public health risk was “extremely low.”⁸ In fact, she still planned to have beef with her Christmas dinner.⁹ In highly publicized hearings before the Senate Agriculture Committee, Secretary Veneman testified that mad cow disease posed “virtually no risk to public health.”¹⁰ The FDA’s Deputy Commissioner told the same committee that “the risk of exposure to BSE through products the FDA regulates remains extremely low in the U.S.”¹¹ The HCRA confidently concurred in this assessment, offering that the discovery of a mad cow in the United States was “not something to raise a major alarm about.”¹² The American Meat Institute announced that “[f]irst and foremost, the U.S. beef supply is safe.”¹³

These confident assurances apparently had their desired effect on

David Willman & Jube Shiver, *Diseased Cow Traced to Canada, U.S. Says*, L.A. TIMES, Dec. 28, 2003, at A19. Unfortunately, some of the potentially contaminated meat had already been sold to customers, and at least one company urged customers to return the meat for a refund. Shankar Vedantam & Blaine Harden, *Probe of Infected Cow Spreads, So Does Worry*, WASH. POST, Dec. 27, 2003, at A4.

6. See Zitner, *supra* note 3 (explaining that BSE can spread when bone meal made from infected animals is fed to other animals, and that it can spontaneously appear in cattle).

7. See *id.* (articulating that Britain’s lack of a ban on cattle feed containing mostly proteins from mammals was a primary reason for the spread of BSE through Britain in the 1980s and 1990s).

8. See *id.* (allaying public fears of Creutzfeldt-Jakob disease, a fatal disease linked with eating beef contaminated with mad cow disease).

9. See Vedantam, *supra* note 2 (reporting that USDA officials claimed infected portions of the cow were removed and segregated); see also Julian Borger, *First Case of Mad Cow Disease in U.S.*, GUARDIAN, Dec. 24, 2003, at 1 (juxtaposing Veneman’s gesture to the daughter of the former British agriculture secretary eating a hamburger during the mad cow epidemic in Britain).

10. See *To Examine the Current Situation Regarding the Discovery of a Case of Bovine Spongiform Encephalopathy in a Dairy Cow in Washington State as it Relates to Food Safety, Livestock Marketing and Int’l Trade, Hearing Before the Senate Comm. on Agric.*, 108th Cong. 18-22 (2004) (statement of Ann M. Veneman, Sec’y, Dep’t. of Agric.).

11. *To Examine the Current Situation Regarding the Discovery of a Case of Bovine Spongiform Encephalopathy in a Dairy Cow in Washington State as it Relates to Food Safety, Livestock Marketing and Int’l Trade: Hearing Before the Senate Comm. on Agric.* 108th Cong. 23 (2004) [hereinafter Crawford Testimony] (statement of Lester M. Crawford, Deputy Comm’r, FDA).

12. See Zitner, *supra* note 3 (quoting George M. Gray, HCRA director).

13. Steve Mitchell, *USDA Refused To Release Mad Cow Records*, UNITED PRESS INT’L, Dec. 24, 2004, available at <http://www.upi.com/view.cfm?StoryID=20031223-103657-3424r> (last visited Feb. 15, 2005).

American consumers. Belying early fears that U.S. beef consumption would plummet,¹⁴ polls conducted in mid-January showed that consumers continued to eat beef at about the same levels.¹⁵ Although wholesale beef prices steeply declined by fifteen percent because of lost export markets, domestic demand for beef kept retail prices high.¹⁶ Secretary Veneman reported to a congressional committee on January 22nd that “retailers and food service outlets are reporting virtually no adverse effects on consumer demand.”¹⁷

The impact of the mad cow discovery on U.S. beef exports, however, was not nearly so modest. The largest importer of U.S. beef, Japan, announced an immediate halt to all beef imports from the United States,¹⁸ and within a day countries representing two-thirds of the U.S. export market had similarly banned imports of U.S. beef.¹⁹ More than two dozen countries initially banned imports of U.S. beef,²⁰ although a few had lifted or modified their bans in the intervening months.²¹ This was not insignificant to an industry that exported \$3.5 billion in beef and beef products during 2002.²² The immediate impact of the import restrictions was to strand “1,800 to 2,000 containers of American beef and beef products valued at more than \$200 million in foreign ports or at sea.”²³

The discovery of the Mabton mad cow should have been a much needed, if belated, wake up call to a sleeping federal regulatory establishment.

14. See Margaret Webb Pressler, *Beef Businesses May Be Hit Hard*, WASH. POST, Dec. 24, 2003, at A03 (citing predictions that beef producers, beef retailers and restaurants would lose business because of the discovery of the Washington State mad cow).

15. See *Mad Cow Could Keep Cattle Prices Lower for Months*, L.A. TIMES, Jan. 12, 2004, at C3 (elaborating on mad cow disease’s effect on the market).

16. See Jake Thompson, *Mad Cow Scare Didn’t Turn U.S. Against Beef*, OMAHA WORLD-HERALD, May 20, 2004, at A1-A2 (detailing the prices for various types of beef); see also Steve Raabe, *No Mad-Cow Bargains*, DENV. POST, Jan. 13, 2004, at C1 (asserting that the U.S. mad cow scare did not bring beef prices down nor did it reduce consumer beef buying). But see *Mad Cow Could Keep Cattle Prices Lower for Months*, *supra* note 15, at C3 (noting that cattle prices dropped 15% since the first discovery of mad cow in the U.S. despite the fact that American consumers continued to enjoy beef).

17. See Marc Kaufman, *Cattle IDs to Combat Mad Cow*, ATLANTA JOURNAL-CONSTITUTION, Jan. 22, 2004, at A10 (quoting USDA Secretary Ann Veneman). In fact, demand rose 10.4% in the first quarter of 2004 compared to the previous year, as consumers continued to adhere to popular low carbohydrate diets. See Thompson, *supra* note 16.

18. See Pressler, *supra* note 14, at A3 (expressing concern that in addition to Japan and South Korea, other countries will cut off beef imports from the U.S.); see also Zitner, *supra* note 3 (claiming that Japan is the largest overseas purchaser of U.S. beef).

19. See Wald, *supra* note 5 (listing Japan, South Korea, Hong Kong, Taiwan, Singapore, Malaysia, Russia, and South Africa as countries that banned American beef immediately following the discovery of the infected Washington cow).

20. Willman & Shiver, *supra* note 5.

21. See *Mexico Further Relaxes Its Ban on U.S. Beef*, L.A. TIMES, Apr. 14, 2004, at C3 (reporting Mexico’s easing of U.S. beef import restrictions).

22. Margaret Webb Pressler, *Meat Industry Feels Fallout*, WASH. POST, Dec. 25, 2003, at A12.

23. Johanna Neuman & Evelyn Iritani, *USDA Defends Its ‘Mad Cow’ Disease Efforts*, L.A. TIMES, Jan. 1, 2004, at A18.

Instead, the relevant federal agencies treated it as a trivial annoyance that demanded a symbolic but unintrusive regulatory response and an aggressive public relations initiative. After the USDA determined that the Mabton Holstein had been imported into the United States from Canada, the USDA subtly suggested that the incident was a quirk of the international trading regime, and at most a transitional problem stemming from the fact that animal feeding restrictions were not in effect in Canada when the aging cow was growing up.²⁴

Within a week after announcing the discovery of the Mabton mad cow, the USDA attempted to assuage the fears of worried consumers and skittish importers by promulgating a set of “interim final” rules and guidelines purporting to expand the federal government’s regulatory presence.²⁵ Secretary Veneman characterized the new rules as “additional safeguards to protect the public health and maintain the confidence of consumers, industry, and our trading partners in our already strong food safety and protection systems.”²⁶ Soon thereafter, the FDA announced that it would be promulgating a set of regulations aimed at enhancing the effectiveness of its pre-existing ban on feeding risky materials to cattle.²⁷

Unfortunately, these actions and the regulatory activities that preceded them in reality have done surprisingly little to address the very real risk that mad cow disease poses to the health of U.S. citizens. The agencies have previously pointed to three regulatory “firewalls” that the federal government erected years ago to protect public health from the risk of mad

24. See Press Release, USDA, Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Release No. 0451.03 (Dec. 30, 2003) (remarks of Ron DeHaven) (assuaging market and public health fears of BSE), available at <http://www.usda.gov/documents/NewsReleases/2003/12/0451.doc>.

25. See, e.g., Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, 69 Fed. Reg. 1885, 1885 (Jan. 12, 2004) [hereinafter USDA Stunning Device Interim Final Rule] (prohibiting the use of bolt stunning devices that put air into the cattle’s brain); Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, 69 Fed. Reg. 1874, 1881 (Jan. 12, 2004) [hereinafter USDA AMR Interim Final Rule] (amending meat inspection regulations by modifying the definition of meat); USDA SRM Interim Final Rule, *supra* note 2 (defining certain parts of a cow as “specified risk materials,” which cannot be used in human food, and requiring that all non-ambulatory cattle presented for slaughter be condemned); Notice, Bovine Spongiform Encephalopathy Surveillance Program, 69 Fed. Reg. 1892, 1892 (Jan. 12, 2004) (announcing that the Food Service and Inspection Service will not pass and apply its mark of inspection to the carcasses and parts of animals selected for USDA BSE testing until the cattle test negative).

26. Press Release, USDA, Transcript of Agriculture Secretary Ann M. Veneman Announcing Additional Protection Measures to Guard Against BSE, Release No. 0450.03 (Dec. 30, 2003), available at <http://www.usda.gov/documents/newsreleases/2003/12/0450.doc>.

27. See Press Release, USDA, Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), available at <http://www.cfsan.fda.gov/~lrd/hhsbse3.html> (declaring that the FDA plans to limit animal feed measures and ban bovine derived material from human food, dietary supplements, and cosmetics).

cow disease. First, the USDA established import controls prohibiting U.S. companies from purchasing cattle and feed from countries experiencing BSE outbreaks. Second, the USDA initiated a surveillance program in which suspect cattle were identified at the slaughterhouse and some were tested for BSE. Third, the FDA enacted restrictions on the kinds of protein that could be included in feed to cattle and other ruminants (i.e., mammals, like cattle, that chew cud and have multi-chambered stomachs).²⁸ After the discovery of the Mabton mad cow, the agencies announced that they were enhancing two of these firewalls and adding two additional firewalls—a ban on the use of “downer” cattle in human food and a regulatory program to ensure that especially risky materials in animal carcasses did not enter the food supply—to provide additional public health protections.

This Article argues that these much ballyhooed “firewalls” have been so poorly conceived and implemented that they are providing very little protection at all to the American consumer. Although there are many reasons why these firewalls are providing so little protection, the primary underlying flaw with the current system, even as recently enhanced, is its foundational assumption that mad cow disease in the United States is primarily an animal health problem and not a human health concern. Relying upon this assumption, the government has designed the firewalls more to protect the meat industry from economic loss than to protect the health of the American public.

In addition to a demonstrably ineffectual ban on technologies that have not been used for years, the new USDA regulations created a tough sounding, but wholly unenforceable “performance-based” regulatory regime for keeping risky materials, such as brains, tonsils, spinal cords, and small intestines, out of human food. A new animal identification program that Secretary Veneman promised would be “immediately implemented” is still years away,²⁹ stymied by cattle industry fears of the increased liability risks. The program that the USDA announced for testing additional “downer” cattle, even though it was expanded in March 2004, is still far from the random sampling program that is necessary to detect the true incidence of mad cow disease in this country. And the USDA has inexplicably refused to allow companies to test their animals for mad cow disease even at the companies’ own expense. Although the FDA

28. *See id.* (describing five “firewalls,” including import controls, surveillance of the U.S. cattle population, animal feed ban, prevention of high risk tissue from entering the food supply, and effective response planning).

29. Press Release, USDA, Veneman Announces Additional Protection Measures To Guard Against BSE, Release No. 0449.03 (Dec. 30, 2003) (claiming that the USDA will “begin immediate implementation of a verifiable system of national animal identification”), available at http://www.usda.gov/wps/portal/!ut/p/s.7_0_A/7_0_1OB/cmd/ad/ar/sa.retrievecontent/c/6_2_1UH/ce/7_2_5JM/p/5_2_4TQ/_ih/J_2_9s.7_0_A/7_0_1OB?PC_7_2_5J_M_contentid=2003%2F12%2F0449.html (last visited Apr. 2, 2005).

announced in January that it would soon be enhancing its feed restrictions, the agency did nothing for the next five months after the poultry and rendering industries warned against “precipitous” action. When it finally did act, in July 2004, the FDA merely mimicked the USDA’s restrictions for FDA-regulated products, and it reneged entirely on its promise to shore up the cattle feed firewall.

In the final analysis, it is becoming increasingly clear that the so-called “firewalls” are not providing the protection implicit in the metaphor. As the recent disclosure of the secret importation of up to 33 million tons of banned Canadian beef into the United States has made painfully apparent, the firewalls are not keeping infected animals and contaminated meat out of the country. As currently designed, the firewalls will not ensure that the federal government identifies the BSE-positive cattle that almost certainly exist in the United States at the moment. The federal government is not doing enough to prevent the spread of mad cow disease to additional cattle through contaminated cattle feed. Most importantly, the new firewall designed to ensure that processors do not allow edible meat to become contaminated by especially risky materials, such as brain, spinal cord and small intestines, will not ensure the safety of American consumers, because the government is allowing individual companies to decide for themselves how to remove those materials from carcasses and how to go about determining whether the products have become contaminated before they hit the grocery shelves.

Part I of this Article briefly describes mad cow disease, the risks that it poses to human health, and the vehicles through which those risks are communicated. Part II examines the existing regulatory programs, most of which rely upon authorities granted by Congress at the turn of the twentieth century, and some of which are of questionable legality. In Part III, the Article critiques the effectiveness of existing governmental efforts to erect “firewalls” to protect consumers and of the programs in place to respond to “firewall failure.” Part IV suggests some reasons for why the firewalls are generally failing. Finally, Part V suggests several changes that the USDA and the FDA could make in their programs to enhance the effectiveness of the firewalls, and it recommends potential congressional amendments to aging statutes that could provide both clear authority for and be a much needed stimulus to future regulatory action aimed at providing adequate public health protections.

I. MAD COW DISEASE AS A PUBLIC HEALTH ISSUE

A. *Mad Cow Disease and Other TSEs*

BSE, or mad cow disease, is a member of a larger family of chronic, degenerative diseases called transmissible spongiform encephalopathies (TSEs).³⁰ After a prolonged incubation period of months or even years, TSEs cause a progressive debilitating neurological illness that is always fatal.³¹ BSE has so far proven difficult to diagnose in live cattle because the infective agent does not elicit a detectable specific immune response in the animal.³² Hence, an accurate diagnosis of BSE in a cow is only possible by examining the brain tissue of the slaughtered animal, and the most accurate diagnoses examine that tissue microscopically for the telltale “spongiform” changes that uniquely characterize TSEs.³³

BSE was first discovered in cows in Great Britain in 1986.³⁴ Early epidemiological investigations revealed that food contamination was the most likely source of the disease and that feed supplements containing protein obtained from facilities that “rendered” unusable tissue from cattle into usable protein were the probable culprit.³⁵ Milk cows, the predominant victims, had received such supplements since the end of the Second World War as an inexpensive way to boost milk production.³⁶

30. See Joshua T. Cohen et al., EVALUATION OF THE POTENTIAL FOR BOVINE SPONGIFORM ENCEPHALOPATHY IN THE UNITED STATES 4-5 (2003) [hereinafter HCRA BSE REPORT], available at <http://www.hcra.harvard.edu/pdf/madcow.pdf> (last visited Feb. 15, 2005) (providing historical and scientific background information on TSEs); see also USDA, *Bovine Spongiform Encephalopathy (BSE) Overview*, available at <http://www.aphis.usda.gov/lpa/issues/bse/bse-overview.html> (last visited Apr. 3, 2005) [hereinafter *USDA BSE Overview*] (explaining that BSE is in the family of diseases known as TSEs, the causes of which are not fully known). Other TSEs include scrapie in sheep and goats, transmissible mink encephalopathy, feline spongiform encephalopathy, and chronic wasting disease (CWD) in deer and elk. USCA, *Bovine Spongiform Encephalopathy*, *supra* note 30.

31. See HCRA BSE REPORT, *supra* note 30, at 4 (elaborating on the nature of TSEs and their likely cause, prions); see also *USDA BSE Overview*, *supra* note 30 (describing the characteristics of TSEs).

32. See *USDA BSE Overview*, *supra* note 30 (listing the characteristics of TSEs).

33. See *id.* (explaining the effects of TSEs and noting that much remains unknown about TSEs).

34. See HCRA BSE REPORT, *supra* note 30, at 1 (conveying BSE’s history and the risk of its spread in the U.S.); see also *USDA BSE Overview*, *supra* note 30 (commenting that since the 1986 diagnosis of BSE in Britain, over 180,000 cases have been reported worldwide).

35. See RICHARD RHODES, DEADLY FEASTS: THE PRION CONTROVERSY AND THE PUBLIC’S HEALTH 174 (1998) (indicating that epidemiologists determined that one cause of BSE was food contamination, after ruling out other causes and analyzing the differences in the feed of beef and dairy cattle).

36. *Id.*

1. *The Cause of TSEs*

Although there is still some disagreement within the scientific community,³⁷ most scientists believe that TSEs are caused by an abnormally configured protein called a “prion.”³⁸ While much remains to be learned about prions (or whatever other microorganisms cause TSEs), we do know that they are highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria.³⁹ As a result, TSE-inducing prions can survive severe environmental conditions and resist destruction by standard cooking practices, sterilization procedures, and the processes typically used to render cattle tissue into protein for feed supplements.⁴⁰

2. *The Incidence of Mad Cow Disease*

After hitting a peak of about 3,500 cases per month in 1993,⁴¹ the incidence of mad cow disease in England has declined steadily because of the British government’s strict ban on feeding any processed animal protein to farm animals bred for human food.⁴² As of late 2003, about 178,000 total cases of mad cow disease had been confirmed in England on 35,275 farms.⁴³ The disease has been detected in 24 countries, including the recent

37. See SHELDON RAMPTON & JOHN STAUBER, *MAD COW U.S.A.* 115-22 (1997) (providing a historical account of the prion and the scientific community’s harsh reaction to the scientist who claimed that the prion caused BSE); see also Jennifer McKee, *Science Studies Clues To Mad Cow*, BILLINGS GAZETTE, Jan. 25, 2004, available at <http://www.billingsgazette.com/index.php?id=1&display=rednews/2004/01/25/build/state/35-bse-rml.inc> (relating uncertainties cited by scientists at Rocky Mountain National Laboratories); Tom Paulson, *Lab Challenges Usual Theory on Mad Cow*, SEATTLE POST-INTELLIGENCER, Jan. 23, 2004, at A6 (quoting Dr. Bruce Chesebro: “Most scientists think this question (of causation) has been answered, the problem solved,” but “[w]e don’t think so.”).

38. See, e.g., USDA SRM Interim Final Rule, *supra* note 2, at 1863 (recognizing there is some debate over prions being the sole agent causing BSE); HCRA BSE REPORT, *supra* note 30, at 5 (discussing the chemical makeup and scientific data about the prion); *USDA BSE Overview*, *supra* note 30, at 1. For a fascinating description of the discovery of prions and the scientific debate surrounding these strange infective agents, see RHODES, *supra* note 35, at ch. 10.

39. See USDA SRM Interim Final Rule, *supra* note 2, at 1863 (explaining how prions are connected to BSE and Variant Creutzfeldt-Jakob Disease); see also *USDA BSE Overview*, *supra* note 30 (providing a general overview of the nature of BSE, its transmission, and public concerns over BSE).

40. See HCRA BSE REPORT, *supra* note 30, at 1, 38 (recognizing that there is no way to eliminate BSE from food).

41. *Id.* at 14.

42. Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001 (Nov. 7, 2003), available at http://europa.eu.int/eurlex/pri/en/oj/dat/2003/l_173/l_1732003_0711en00060013.pdf.

43. HCRA BSE REPORT, *supra* note 30, at 14.

discovery in the United States.⁴⁴ As of April 2004, more than 180,000 cases of BSE have been reported worldwide.⁴⁵

3. *Detection of BSE in Cattle, Cattle Feed, and Food*

Animals infected with TSEs frequently display clinical manifestations of the disease, including nervousness and aggression, abnormal posture, poor coordination, and difficulty in rising from a down position (hence the frequent reference to “downer” cattle).⁴⁶ Because BSE has an incubation period of two to eight years from exposure to the clinical manifestation, an infected cow may show none of these signs.⁴⁷ Of course, it is also possible that an animal manifesting one or more clinical symptoms is not in fact suffering from the disease.⁴⁸ Because accurate tests do not yet exist for determining the presence of TSEs in live animals,⁴⁹ the only way to be sure that a suspect animal is suffering from mad cow disease is to slaughter it and analyze its brain tissue in a laboratory.⁵⁰ Although tests for BSE have historically taken weeks to complete, scientists have recently developed highly sensitive post-mortem chemical tests that yield results within 24 hours.⁵¹ The accuracy of such tests, however, is still disputed, and it is not clear that they are effective until near the end of the incubation period.⁵² Although they are regularly used in the European Union and Japan, the USDA did not approve any “rapid” tests until spring 2004.⁵³ No tests for BSE in feed or food currently exist, but tests are available for detecting high risk tissues from cattle (frequently referred to as “Specified Risk Materials”) in carcasses and food products.⁵⁴

44. USDA SRM Interim Final Rule, *supra* note 2, at 1863; *see also* *USDA BSE Overview*, *supra* note 30 (listing instances of confirmed BSE diagnoses and explaining the clinical signs of BSE in cattle).

45. *USDA BSE Overview*, *supra* note 30.

46. *Id.*

47. *See id.* (describing the incubation process)

48. *Cf. id.* (noting that clinical signs of BSE in cattle include “changes in temperament; . . . abnormal posture; incoordination and difficulty in rising; decreased milk production; [and] loss of body condition despite continued appetite”).

49. USDA SRM Interim Final Rule, *supra* note 2, at 1871; *see also* *USDA BSE Overview*, *supra* note 30 (explaining that the lack of a detectable specific immune response in the host animal has prevented development of diagnostic tests).

50. *See* HCRA BSE REPORT, *supra* note 30, at 36 (noting a lack of preclinical or clinical BSE identification tests); *see also* Sandra Blakeslee, *Expert Warned That Mad Cow Was Imminent*, N.Y. TIMES, Dec. 25, 2003, at A1 (quoting Dr. Stanley Pruisner, a University of California at San Francisco neurologist, who demanded that the Secretary of Agriculture begin testing every cow in the nation upon slaughter).

51. *See* HCRA BSE REPORT, *supra* note 30, at 37 (examining varying techniques for diagnosing BSE).

52. *Id.*

53. *See infra* Part IV.A.6.

54. *See* HCRA BSE REPORT, *supra* note 30, at 37 (listing tests for screening high risk materials in food and food products); *see also infra* Part III.A.

4. TSEs in Humans

The most common TSE in humans, Creutzfeldt-Jacob Disease (CJD), is a slowly degenerative disease of the central nervous system with an apparently spontaneous incidence of about one-in-one million.⁵⁵ Prior to the mid-1980s, the disease was diagnosed almost exclusively in persons older than fifty years old.⁵⁶ Unlike viral and bacterial diseases, TSEs are not transmitted through the air or through incidental physical contact. In addition to overt cannibalism, TSEs can be communicated among human beings via “iatrogenic transmission” (transmission during medical procedures such as surgery), blood transfusions,⁵⁷ and human consumption of certain human hormones.⁵⁸

The world learned that BSE could be transmitted to humans several years after the outbreak of mad cow disease in England. A government-appointed expert committee, chaired by Oxford zoologist Richard Southwood, initially reported that it was “most unlikely that BSE will have any implications for human health” because “the risk of transmission of BSE to humans appears remote.” By early 1996, however, a clearly identifiable cluster of eight cases of a variant form of CJD (called vCJD) in young people inspired the Secretary of State for Health to announce in the House of Commons that BSE was capable of causing TSEs in humans after all.⁵⁹ With this disturbing revelation, the British government began to purchase and slaughter all cattle of more than thirty months old. It soon halted the program, however, after concluding that previously imposed feeding restrictions would cause BSE to “die out in 2000 or 2001.”⁶⁰ Unfortunately, that assessment proved disastrously wrong as the incidence of mad cow disease continued to increase.⁶¹ As of mid-2004, 150 cases of

55. See HCRA BSE REPORT, *supra* note 30, at 21 (finding that incidence of CJD in humans with no known risk factors or exposure is “relatively constant around the world”); see also USDA BSE Overview, *supra* note 30 (describing CJD’s sporadic occurrence worldwide at a rate of roughly one case per one million per year).

56. HCRA BSE REPORT, *supra* note 30, at 21.

57. Sandi Doughton, *Panel Studies Mad-Cow Risk From Blood Transfusions*, SEATTLE TIMES, Feb. 13, 2004, at B1; see also Audrey Woods, *Transfusion, Mad Cow May Be Linked*, ATLANTA JOURNAL-CONSTITUTION, Feb. 5, 2004.

58. HCRA BSE REPORT, *supra* note 30, at 7.

59. See RHODES, *supra* note 35, at 190, 209-12 (relating the story of the vCJD cases); see also RAMPTON & STAUBER, *supra* note 37, at 183 (stating that although there was no scientific proof, it was likely that there was some connection between the cases of CJD and exposure to BSE before the bovine offal ban in 1989); USDA BSE Overview, *supra* note 30. Although similar to classic CJD, the variant form, vCJD, appeared to differ in several regards. USDA BSE Overview, *supra* note 30. First, it affected much younger individuals. *Id.* Second, it took more than twice as long from the onset of the disease until death. *Id.* Third, the electroencephalographic (EEG) activity in the brain differed from that of classic CJD. *Id.* Fourth, the brain pathology was also somewhat different. *Id.*

60. RHODES, *supra* note 35, at 218.

61. See *id.* at 220 (describing new cases in France and Britain after the British halted their program).

vCJD have been reported worldwide.⁶²

Although there have been no reported cases of vCJD originating in the United States, it is not clear how hard the experts have looked for vCJD among the three-hundred or so people who die each year from naturally occurring, or “sporadic” CJD.⁶³ Autopsies, which are necessary to distinguish vCJD from sporadic CJD, are performed on only about one-half of those who die from the disease. In addition, CJD is frequently misdiagnosed as Alzheimer’s disease.⁶⁴ One especially troubling statistic is that five people under thirty died of a disease diagnosed as sporadic CJD between 1997 and 2001, whereas only one death from the disease in a person under thirty was reported prior to 1996.⁶⁵ The director of the National Prion Disease Pathology Surveillance Center at Case Western Reserve University believes that we need to “make a better effort to really gauge the incidence in the United States and not to miss variant or any other form.”⁶⁶

5. How TSEs Are Communicated

The mad cow prion can be communicated through consumption of the brain, spinal cord, and eyes of cattle.⁶⁷ In experimental studies, frequently involving direct injection of contaminated material into the brain, infectivity has been confirmed in the brain, trigeminal ganglia,⁶⁸ tonsils,

62. USDA SRM Interim Final Rule, *supra* note 2, at 1863. In addition to the U.K., there have been “6 cases of vCJD in France, 1 in Ireland, and 1 probable case in the United States and Italy.” *USDA BSE Overview*, *supra* note 30. The case in the United States was probably caused by meat consumed in England because the victim was a U.K. citizen currently living in Florida. *Id.*

63. See Linda A. Johnson, *Have Scientists Missed Mad Cow in Humans?*, ASSOCIATED PRESS, Jan. 7, 2004 (suggesting the possibility that some cases of CJD from eating tainted beef have been missed).

64. Andrew Nikiforuk, *Diagnosing BSE: An Issue Comes to a Head—North Americans Haven’t Tested Rigorously Enough For Mad-Cow Disease*, GLOBE & MAIL, Jan. 8, 2004, at A21; see also Michael Greger, *Could Mad Cow Disease Already be Killing Thousands of Americans Every Year?*, Jan. 7, 2004, at <http://www.commondreams.org/cgi-bin/print.cgi?file=/views04/0107-07.htm> (citing M. Folstein, *The Cognitive Pattern of Familial Alzheimer’s Disease*, in BIOLOGICAL ASPECTS OF ALZHEIMER’S DISEASE (R. Katzman ed., Cold Spring Harbor Lab. 1983)).

65. See Greger, *supra* note 64 (citing PHILIP YAM, *THE PATHOLOGICAL PROTEIN: MAD COW, CHRONIC WASTING, AND OTHER DEADLY PRION DISEASES* (2003)). The single reported case of vCJD in the U.S. was a Florida woman who grew up in the United Kingdom. Nicholas K. Geranios, *Canadians Irked by U.S. Blame for Mad Cow*, SEATTLE POST-INTELLIGENCER, Jan. 11, 2004.

66. Johnson, *supra* note 63. One amateur epidemiologist’s identification of an alleged “cluster” of CJD cases among persons who had over the years consumed beef products at a New Jersey racetrack has attracted the attention of the media, but the effort has thus far been discounted by the experts. See Faye Flam, *Officials Discount Woman’s Study of 7 Deaths*, PHILA. INQUIRER, Jan. 16, 2004, at B5 (describing the efforts of an accountant from Cinnaminson who brought attention to the New Jersey cases).

67. See USDA SRM Interim Final Rule, *supra* note 2, at 1862 (designating certain parts of cattle as “specified risk materials”).

68. See *id.* at 1864 (explaining that trigeminal ganglia are “clusters of nerve cells

spinal cord, dorsal root ganglia (DRG),⁶⁹ and the distal ileum of the small intestine of cattle.⁷⁰ The USDA has concluded that “BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with the disease at any stage of the disease.”⁷¹ Not all scientists, however, are as confident that consumption of muscle tissue, which does contain some tissue from the nervous system, cannot communicate TSEs.⁷² The USDA’s conclusion is based primarily upon a single long-term British study, and other experiments, not involving beef, that have shown some transmissibility of TSEs via muscle tissue.⁷³ Since no TSEs have been identified in pigs and poultry, scientists regard transmission to humans or cattle through consumption of those species as unlikely.⁷⁴

Studies of clinical manifestation of BSE-infected cattle in England led the USDA to conclude that clinical BSE “has rarely been reported in cattle younger than 30 months of age.”⁷⁵ However, in cattle that have been experimentally infected with BSE, “infectivity has been confirmed in the distal ileum at various stages of the disease process and as early as 6 months after oral exposure to the BSE agent.”⁷⁶ Moreover, “tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent.”⁷⁷ The other tissues that are capable of transmitting mad cow disease have experimentally demonstrated infectivity only at the end stages of the disease, 32 months or more after exposure.⁷⁸

The degree of infectivity appears to vary with the age of the animal being consumed. In animals with clinical BSE disease, the brain and spinal cord generally contain the greatest concentration of the BSE agent, and the quantity of the infective agent increases over the two-to-eight-year incubation period from initial exposure to the onset of the clinical disease.⁷⁹ Thus, the USDA has concluded that “the total infective load in cattle in the

connected to the brain that lie close to the exterior of the skull”).

69. See *id.* (stating that DRG are “clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column”).

70. *Id.* at 1862.

71. *Id.* at 1865.

72. See David Brown, *Scientists Weigh Risks of Beef*, WASH. POST, Jan. 4, 2004, at A8 (quoting Dr. Paul Brown, a physician and neuroscientist at the National Institutes of Health: “I’d like to say for sure that muscle is safe. I’m reasonably sure that muscle is safe. But like everything else in science, the answer is incomplete.”).

73. See *id.* (describing two studies detecting prions in muscle tissue).

74. See HCRA BSE REPORT, *supra* note 30, at 28-32 (asserting that there is no substantial risk that pigs or chickens could be a source of TSEs in cattle).

75. USDA SRM Interim Final Rule, *supra* note 2, at 1862.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.* at 1863.

early stages of the incubation period is believed to be much lower than in cattle approaching the end of the incubation period or in those cattle with overt clinical BSE.”⁸⁰ This is significant for the cattle industry, because approximately eighty percent of the cattle slaughtered at federally inspected facilities are less than thirty months of age.⁸¹

6. Risk to the U.S. Beef Industry

The beef industry is a major player in the United States and world economies. More than one million U.S. farms and ranches benefit from the sales of cattle.⁸² In 2003, beef production in the United States amounted to approximately 26.3 billion pounds from the slaughter of an estimated 36 million cattle.⁸³ Beef production yielded gross farm income of \$44.1 billion in 2003.⁸⁴ Exports of 2.6 billion pounds of beef, veal, and variety meats in 2003 produced \$3.8 billion in income.⁸⁵ The beef sector is the “largest single agricultural enterprise” in the United States,⁸⁶ and it is the world’s largest producer of beef for export markets.⁸⁷ Another important characteristic of the beef industry is the extent to which it has become concentrated. Although thousands of farmers and ranchers supply animals to meat production facilities, more than eighty percent of the output of those facilities is controlled by only five large companies.⁸⁸

Although the discovery of a mad cow in Washington State has had little noticeable adverse effect on the industry beyond the loss of export markets,⁸⁹ further discoveries may have a more dramatic impact. The

80. *Id.*

81. See USDA, FOOD SAFETY AND INSPECTION SERVICE, PRELIMINARY ANALYSIS OF THE INTERIM FINAL RULES AND AN INTERPRETIVE RULE TO PREVENT THE BSE AGENT FROM ENTERING THE U.S. FOOD SUPPLY 5 (2004) [hereinafter FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS], available at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/frpubs/03-025n/bse_analysis.pdf (articulating the high percentage of young cattle slaughtered for food and processed in federally-inspected establishments in the United States).

82. Dan Otto & John D. Lawrence, *Economic Impact of the United States Beef Industry*, available at http://www.beef.org/dsp/dsp_locationContent.cfm?locationId=42 (last visited Feb. 12, 2005) (reporting data to exhibit the United States’ beef industry’s impact on the American economy).

83. See FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 5 (providing general economic information on the U.S. cattle industry).

84. *Id.*

85. *Id.*

86. Otto & Lawrence, *supra* note 82.

87. FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 4-5.

88. The five companies are Tyson, Excel, Swift, National Beef Packing and Smithfield. See Michael Moss, Richard A. Oppel Jr. & Simon Romero, *Mad Cow Forces Beef Industry to Change Course*, N.Y. TIMES, Jan. 5, 2004, at A1; see also Interview by PBS “Frontline” with Patrick Boyle, American Meat Institute [hereinafter Boyle Interview], at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/boyle.html> (last visited Feb. 19, 2005) (observing that four companies account for more than 80% of the beef capacity in the United States).

89. See *infra* Part I.

introduction of contaminated meat into the general marketplace could give rise to lawsuits against producers, manufacturers, and retailers of beef and beef products. In fact, a lawsuit was filed in March 2004 against the grocery chain that may have marketed meat derived from the Washington State mad cow in the Seattle area.⁹⁰ The discovery of a case of vCJD caused by consumption of a domestic mad cow could have a devastating impact on the beef industry.

B. Agribusiness Practices Resulting in the Spread of Mad Cow Disease

Because the U.S. beef market is extremely competitive, modern agribusiness for the last several decades has devoted much of its attention to efficiency in the production, slaughter, processing, and distribution of meat and meat products. In its obsession with efficiency, the industry is inclined to assign safety considerations to a secondary role. Consequently, several modern agribusiness practices have the potential to open the door to mad cow disease in this country.

1. Importation of Contaminated Animals, Meat, and Animal Feed

As illustrated by the Canadian origin of the Mabton mad cow, imported animals and meat have the potential to introduce BSE into the United States. Since 1989, the USDA has banned the importation of ruminants and certain ruminant products from countries where BSE is known to exist.⁹¹ Although the USDA attempted to account for all of the 334 cattle that were imported from the U.K. between 1981 and 1989, it is certainly possible that the remains of some of these animals wound up in cattle feed or human food.⁹² The discovery of a mad cow in Canada in May 2003 brought cattle and meat from that country under the import restrictions.⁹³

2. Communication from Animal to Animal

The original source of BSE may have been consumption by cattle of rendered protein from sheep suffering from a TSE called scrapie, or it may have been a cow suffering from a spontaneous BSE.⁹⁴ Although BSE does not appear to be transmissible though inhalation or incidental contact, it can

90. See Lewis Kamb, *QFC Sued Over Mad Cow Case*, SEATTLE POST-INTELLIGENCER, Mar. 5, 2004, at A1 (discussing the plaintiffs' claimed basis for a class-action lawsuit against QFC).

91. See HCRA BSE REPORT, *supra* note 30, at 22; see also USDA BSE Overview, *supra* note 30 (summarizing the USDA BSE policy and providing that it has set in place import restrictions since 1989, with active surveillance efforts beginning in 1990).

92. HCRA BSE REPORT, *supra* note 30, at 22 (stating that only 161 of the UK-exported cattle were "disposed of in a manner that eliminates the possibility that they could have contaminated either human food or animal feed").

93. See *infra* Part I.

94. See generally USDA BSE Overview, *supra* note 30 (providing an overview of the causes, clinical signs, and modes of transmission of BSE among animals).

be transmitted when an uninfected cow consumes protein from an infected cow. Since cattle are not naturally carnivorous, this route of transmission would occur if cattle were left to their own devices only in the very rare case in which a cow consumed grass in the vicinity of the dead carcass of a BSE-infected animal. Ever on the lookout for ways to improve efficiency, however, modern agribusiness has found highly unnatural uses for animal protein.

As the cattle business became more concentrated and efficient, animal scientists discovered that grain rations supplemented by protein derived from “rendering” tissues from animals of every conceivable size and species could increase milk production and fatten animals more quickly for slaughter.⁹⁵ At the same time, feeding rendered protein to cattle and other food animals solved a serious disposal problem by converting useless material from slaughterhouses into animal feed.⁹⁶

Currently, about 265 rendering plants in the United States convert about 50 billion pounds of tissue from dead animals into protein for animal feed.⁹⁷ During the rendering process, sources of animal protein are placed in large tanks and cooked at temperatures (approximately 300 degrees Fahrenheit) high enough to kill most microorganisms but low enough to prevent the disintegration of the valuable fats and proteins.⁹⁸ The process yields commercially valuable products like tallow and concentrated animal

95. See HCRA BSE REPORT, *supra* note 30, at 32; see also Lewis Kamb, *Cattle Feed Is Often a Sum of Animal Parts*, SEATTLE POST-INTELLIGENCER, Jan. 28, 2004, at A1 (comparing the modern industry trend of consistently preparing cattle for market with permitting cattle to graze in the pastures on their own).

96. See RAMPTON & STAUBER, *supra* note 37, at 63-64; see also Kamb, *supra* note 95, at A1 (quoting a rendering industry lobbying group executive as stating that “[the rendering process] takes material that’s generally useless and adds value back into that material”).

97. See Kamb, *supra* note 95, at A1 (discussing the magnitude of the modern rendering industry and the process through which bacteria and viruses are killed in animal parts as part of that industry). The following graphic description of the inputs for a Baltimore rendering plant illustrates that animal tissue can come from almost anywhere:

Bozeman, the Baltimore City Police Department quarter horse who died last summer in the line of duty. The grill grease and used frying oil from Camden [Y]ards, the city’s summer ethnic festivals, and nearly all Baltimore-area . . . restaurants and hotels. A baby circus elephant who died while in Baltimore this summer. Millions of tons of waste meat and inedible animal parts from the region’s supermarkets and slaughterhouses. Carcasses from the Baltimore zoo. The thousands of dead dogs, cats, raccoons, possums, deer, foxes, snakes and the rest that local animal shelters and road-kill patrols must dispose of each month.

Van Smith, *What’s Cookin?*, BALT. CITY PAPER, Sept. 27, 1995, available at <http://citypaper.com/about/vansmith.asp> (last visited Apr. 2, 2005), quoted in RAMPTON & STAUBER, *supra* note 37, at 61-62. Rendering is obviously not a business for people with weak stomachs.

98. See RAMPTON & STAUBER, *supra* note 37, at 68-70 (detailing rendering industry technology that permits a “continuous” cooking process and allows for the survival of animal proteins); see also Kamb, *supra* note 95, at A1 (stating that the cooking of animal parts at temperatures of 270 to 300 degrees for up to an hour “kills just about all bacteria or viruses”).

protein. This “tanking” step, however, does not disable the prions that cause mad cow disease.⁹⁹

The primary use for rendered protein is to enhance the protein content of animal feeds for cattle, swine, and poultry.¹⁰⁰ Once in animal feed, it is impossible to remove or destroy mad cow prions without destroying the feed.¹⁰¹ Therefore, the best way to prevent transmission of mad cow disease is to ensure that mad cow prions are not present in cattle feed, and the best way to do that is to keep protein from ruminants out of feed for other ruminants. Not long after the discovery of the first mad cow in 1986, the British government imposed a ban on feeding ruminant-derived protein to ruminants.¹⁰² The World Health Organization recommended such a ban in 1996 and the United States followed suit in 1997.¹⁰³

Although the FDA has mentioned the possibility of imposing further limits on the use of animal protein in cattle feed in the future,¹⁰⁴ the following products, all of which could contain mad cow prions, may still lawfully be recycled into cattle feed: plate waste from restaurants, hotels, and amusement parks; gelatin; milk products; blood and blood products; tallow, grease, fat, and oil; various amino acids; dicalcium phosphate; and protein from pigs and horses.¹⁰⁵ Cattle protein may lawfully be included in pet food and feed for swine and chickens, and cattle blood may be fed directly to prematurely weaned calves to replace the mother’s milk consumed by humans, even though blood has been shown to transmit TSEs in sheep.¹⁰⁶

Several of these allowable uses of cattle protein in animal feed provide indirect routes for transmitting mad cow disease. Plate waste may contain unconsumed beef that may contain mad cow prions which, when rendered into protein for cattle feed, could result in the transmission of mad cow

99. See Kamb, *supra* note 95, at A1.

100. RAMPTON & STAUBER, *supra* note 37, at 68 (stating that rendered protein is especially valuable in feed for ruminants like cattle, in which it is referred to as “bypass” protein, because it is not degraded in the first stomach chamber and can therefore proceed into the small intestine where it can enhance tissue growth and lactation with maximum efficiency).

101. See HCRA BSE REPORT, *supra* note 30, at 36 (characterizing attempts to minimize the spread of BSE as “complicated” because of the disease’s tendency not to show clinical signs for an extended period after initial infection and the difficulty in deactivating the disease once such clinical signs do begin to appear).

102. See RHODES, *supra* note 35, at 178 (discussing the British government’s response to its detected BSE problem and the basis for the action it undertook).

103. See HCRA BSE REPORT, *supra* note 30, at 41-42 (providing an overview of the actions taken in Europe and the United States to control the transmission of BSE).

104. See *infra* Part IV.B.

105. See HCRA BSE REPORT, *supra* note 30, at 33 (identifying mammalian-derived products, which the FDA still permits to be included in ruminant feed, despite the fact they have the potential of harboring infectivity).

106. See *id.* at 35 (finding no detectable infectivity in blood or blood components of infected cattle, but detecting such infectivity in sheep).

disease. BSE can be communicated from cow to cow through pigs, if pigs consume feed containing protein from a mad cow and if material from the stomachs and intestines of those pigs are processed into cattle feed.¹⁰⁷ Cattle-derived protein feed supplements fed to chickens can pass through the chickens and wind up in cattle feed that is supplemented with chicken litter, a common practice in the industry.¹⁰⁸

3. *Communication from Animals to Humans*

Human beings consume most of the materials that have demonstrated BSE infectivity in cattle.¹⁰⁹ Cattle brains have been sold chilled, frozen, or canned, and they are still highly valued among some consumers for their use in tasty dishes like brains and scrambled eggs.¹¹⁰ Many meat products, like sausages, bologna, and meat spreads, can also contain risky tissues, like spinal cord and the lining of small intestines.¹¹¹

Risky materials can wind up in human food accidentally. Many large slaughterhouses employ huge assembly lines where animals are stunned, bled, beheaded, eviscerated, skinned, cleaned, and split in half down the spine in one rapidly moving continuous operation.¹¹² Large meatpacking plants slaughter more than 4,000 cattle per day, and line speeds operate at rates exceeding 300 cattle per hour.¹¹³ The key to efficiency, and therefore profit, is keeping the line speeds up, and the worst calamity that can occur from an efficiency perspective is for the line to come to a halt. In this high

107. *See id.* at 31 (observing that uninfected pigs may still contain BSE-contaminated material in their digestive tract when they die even if that infection never matures within the pig itself); *see also id.* (concluding that “the potential is limited for BSE to be recycled through the guts of pigs,” and it did not include that possibility in its risk assessment).

108. *See id.* at 32 (recommending that although chicken themselves do not generally pose a substantial TSE risk to cattle, the inclusion of chicken litter as a feed supplement should be investigated).

109. *See* USDA SRM Interim Final Rule, *supra* note 2, at 1865 (identifying such materials as a cattle’s brain, eyes, trigeminal ganglia, spinal cord, DRG, and the distal ileum of the small intestine as being permissibly included in human food under the Food Safety Inspection Service’s regulations). Although permitted under the Food Safety Inspection Service’s regulations, human consumption of cattle eyes has been uncommon in the United States. *Id.*

110. *See id.* (highlighting the fact that under government regulation, 9 C.F.R. 317.2(f)(1) (2004), any use of cattle brains as a byproduct ingredient must be listed in a product’s ingredients statement).

111. *See* RHODES, *supra* note 35, at 175 (noting that cattle brains were incorporated into hamburger and meat pies).

112. *See* Interview by PBS “Frontline” with Michael Pollan [hereinafter Pollan Interview], at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/pollan.html> (last visited February 17, 2005) (detailing the steps taken at beef plants when a cow is taken to slaughter and the rationale for each step in the process).

113. *See Frontline: Modern Meat* (PBS television broadcast, Apr. 18, 2002), available at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/etc/script.html> (observing the doubling of the “line speed” over the past 30 years also carries with it the increased possibility for human worker mistake and entry of dangerous pathogens from the cow into the produced meat).

pressure context, where employees are removing heads with sharp knives, removing intestines with large hooks, and literally sawing carcasses in half with power saws, efficiency and safety concerns are pulling in opposite directions.

Certain humane slaughter techniques like “air-injection captive bolt stunning,” a process through which a metal bolt and compressed air are driven into the cranium of cattle,¹¹⁴ pose a high risk of contaminating tissue destined for human consumption with brain and other material from the central nervous system (CNS). In addition, various meat separation techniques, like mechanical separation and Advanced Meat Recovery (AMR) techniques, can result in risky materials being included in meat products. Mechanical separation systems force bone and the skeletal muscle remaining attached to the bone at high pressure through very fine sieves that remove bone particles.¹¹⁵ AMR systems employ hydraulic pressure to emulate the physical action of high-speed knives to remove skeletal muscle tissue from bone.¹¹⁶ Although the product resulting from AMR techniques should not contain any risky material, USDA sampling programs have routinely detected spinal cord material and DRG in around ten percent of the AMR system products in the field.¹¹⁷ Even hand deboning techniques, when conducted at high speed and driven by efficiency concerns, can result in the unintentional addition of spinal cord and other CNS material into meat destined for human consumption.¹¹⁸

Once contaminated meat leaves the slaughterhouse, it can be transported rapidly throughout the United States and even the world. Much beef these days is processed into ground beef, not by local butchers as in the past, but by large “grinders” that specialize in mixing fat with muscle tissue at just the right levels to make the resulting ground beef a perfect source for tasty hamburgers. Because grinders combine meat from thousands of animals into the final product, a single hamburger can contain tissue from hundreds of different animals.¹¹⁹

114. See 9 C. F. R. § 310.13(a)(2)(iv)(C) (2004) (providing that the process identified as air-injection captive bolt stunning is among those processes that are federally-approved).

115. USDA SRM Interim Final Rule, *supra* note 2, at 1866.

116. See USDA AMR Interim Final Rule, *supra* note 25, at 1876 (providing a brief overview of the AMR system’s meat-removal process).

117. See *id.* (citing routine regulatory sampling conducted from March to December 2003, in which spinal cord was detected in 6.8% of samples, and DRG in 10.9% of samples).

118. See USDA SRM Interim Final Rule, *supra* note 2, at 1868 (“Because of its proximity to the vertebral column, some hand-deboned meat may contain DRG depending on the technique used to recover the meat from the bone.”).

119. See *Frontline: Modern Meat*, *supra* note 113 (quoting Dr. Robert Tauxe as stating, “I suspect that there are hundreds or even thousands of animals that have contributed to a single hamburger.”).

4. Prevention Techniques

The easiest way to prevent the spread of mad cow prions through direct human consumption of high-risk material is to ban the sale of such material for human consumption.¹²⁰ It may be possible to prevent communication from animals to humans by requiring that animals be tested for BSE before the meat may be used for human food. Since a false negative is always possible, however, this solution still leaves consumers of high infectivity tissues at risk. Another broad-brush technique for preventing human consumption of high-risk material is to specify a category of particular tissues from all cattle older than an easily determined age as especially risky and ban the sale of such “specified risk material” (SRM) or meat contaminated with such SRM for human consumption.¹²¹ Although it may be impossible in the modestly controlled environment of the modern slaughterhouse to ensure that edible tissue is entirely free of accidental contamination, it is possible to cut contaminated tissue off of edible muscle tissue when it is spotted by alert employees on the line.¹²² It is also possible to use scientific testing procedures to test samples of the end product for the presence of risky materials from the nervous system.¹²³

II. REGULATION OF MAD COW RISKS PRIOR TO JANUARY 2004

When Congress created the USDA in 1862, its primary aim was to ensure an adequate supply of food for American tables.¹²⁴ The USDA did, however, have a relatively minor safety-related function: to conduct ante- and post-mortem inspection of livestock.¹²⁵ Reacting to the public uproar resulting from the publication of Upton Sinclair’s *The Jungle*, Congress enacted the Federal Meat Inspection Act (FMIA) in 1906. That statute

120. See Food Standards Agency, BSE & BEEF, at <http://www.food.gov.uk/bse/beef> (last visited Apr. 2, 2005) (removing high-risk material from cattle substantially reduces the risk of BSE to consumers); see also HCRA BSE REPORT, *supra* note 30, at 40 (delineating measures instituted by the European Union and other international organizations to curb the spread of BSE, including the elimination of high-risk material from the feed chain and from human food).

121. See *infra* Part IV.A.1.

122. See *id.* This is in fact what USDA regulations require.

123. See NATIONAL MEAT ASSOCIATION, GOOD MANUFACTURING GUIDELINES FOR THE REMOVAL OF SPINAL CORD DURING SLAUGHTER OPERATIONS AND SAMPLING AND TESTING OF ADVANCED MEAT RECOVERY PRODUCT FOR GLIAL FIBRILLARY ACIDIC PROTEIN ANALYSIS 3 (Feb. 14, 2002) [hereinafter USDA TESTING GMPs] (enumerating the procedure by which meat samples from cattle are tested for the presence of SRMs).

124. MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY AND BIOTERRORISM 63 (Univ. of Cal. Press 2003) (noting that the principal purpose for creating the USDA was to secure enough food to sustain the population).

125. See Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, Proposed Rule, 60 Fed. Reg. 6774 (1995) (proposed Feb. 3, 1995) [hereinafter USDA HACCP Proposed Rule] (observing that Congress conferred the USDA with the responsibility for conducting ante- and postmortem inspection of livestock slaughtered for the distribution of meat in the United States).

provided for the establishment of sanitary standards for beef slaughter and processing establishments and mandated ante mortem inspection of food animals and postmortem inspection of every carcass. In addition, the statute required government inspectors to be present at all facilities that manufactured meat for commerce.¹²⁶ The slaughterhouse meat inspection program that grew out of these requirements relied upon “organoleptic inspections,” based on sight, touch, and smell, by USDA-employed veterinarians.¹²⁷ The primary concern was to reduce or eliminate “filth” in meat used for food.¹²⁸

The Pure Food and Drugs Act,¹²⁹ enacted in 1906, prohibited marketing misbranded or adulterated food other than meat subject to the FMIA.¹³⁰ Although the statute focused on chemical contamination as well as filth, it resembled the FMIA in its failure to address specific pathogens.¹³¹ Unlike the FMIA, however, the statute did not require physical inspection of every source of human food. Rather, the implementing agency had to rely upon random and programmed inspections and statistically determined sampling of food products.¹³² A major rewrite of the statute in 1936 left the basic structure intact with a continued focus primarily upon filth as the measure of adulteration.¹³³

126. *See id.* at 6775. In relevant part, the statute states:

The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as “inspected and passed.”

Federal Meat Inspection Act, 21 U.S.C. § 608 (2000).

127. *See* USDA HACCP Proposed Rule, *supra* note 125, at 6,775 (observing that, to keep contaminated meat out of the food supply, the meat inspection program of the early twentieth century mandated federal inspectors, under the supervision of veterinarians, to visually inspect every live animal and every carcass for signs of disease).

128. *See* INSTITUTE OF MEDICINE, NATIONAL RESEARCH COUNCIL, SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD 14 (2003) [hereinafter SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT] (asserting that, in spite of enlightened knowledge in microbiology, public health officials still subscribed to the notion “disease breeds in filth”).

129. Pure Food and Drugs Act, Pub. L. No. 59-384, ch. 3915, 2, 34 Stat. 768 (1906) (superceded by the FD&C Act in 1938).

130. *See* SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 14-15 (commenting that the FFDA was the direct result of USDA investigation into and widespread publicity about the adulteration of common foodstuffs).

131. *See id.* at 15 (maintaining the FFDA erroneously focused on the elimination of chemical contaminants and filth, rather than the exclusion of dangerous pathogens).

132. *See* Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 95-96 (2000) (debating the efficacy of the FDA’s regulatory approach).

133. *See* SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 15

A. USDA Regulation

The FMIA¹³⁴ prohibits anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or meat food product.¹³⁵ The USDA has authority to seize any meat that is “adulterated,” a term that is defined to mean “unsound, unhealthful, unwholesome, or otherwise unfit for human food.”¹³⁶ The burden of proof, however, is on the USDA to establish that any particular meat or poultry is in fact “unhealthful” or otherwise adulterated.¹³⁷ Meat products that contain any poisonous or deleterious added substance which may render them injurious to health, and meat products that contain inherent substances in sufficient quantity to ordinarily render them injurious to health are also “adulterated.”¹³⁸ The term “adulterated” is further defined to include products that have been “prepared, packed, or held under insanitary conditions whereby [they] may have become contaminated with filth, or whereby [they] may have been rendered injurious to health.”¹³⁹

The USDA’s Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat products for human consumption are safe, wholesome, and correctly marked, labeled, and packaged.¹⁴⁰ As of the mid-1990s, FSIS employed 7,400 inspectors to inspect about 6,200 meat and poultry slaughtering and processing plants by “continuous carcass-by-carcass inspection during slaughter” and by daily inspection during processing.¹⁴¹ The inspectors must ensure that meat is not “adulterated” or “misbranded” within the meaning of the FMIA.¹⁴² Meat may not be sold unless it is marked “Inspected and Passed” by an FSIS inspector.¹⁴³

(lamenting the continued focus on filth within the definition of food adulteration).

134. 21 U.S.C. § 601 (2000).

135. *Id.* § 610.

136. *Id.* § 601(m)(3).

137. *See* United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914) (affirming that the FMIA places upon the government the burden of establishing adulteration so that such adulteration renders the food injurious to health); *see also* United States v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds, and 541 Boxes of Offal Weighing Approximately 17,732 Pounds, 516 F. Supp. 321, 326 (D.C. Kan. 1981) (“[T]he concept of due process, in the Court’s view, imposes the burden of persuasion on the proponent, here the government, and this burden does not shift.”).

138. 21 U.S.C. § 601(m)(1) (2000).

139. *Id.* § 601(m)(4).

140. *See* INSTITUTE OF MEDICINE, NATIONAL RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 27 (1998) [hereinafter SAFE FOOD REPORT] (elucidating the regulatory jurisdiction of the FSIS); *see also* Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806, 38,807 (Jul. 25, 1996) (to be codified at 9 C.F.R. pt. 304, et al.) [hereinafter USDA HACCP Final Rule] (“The mission of the FSIS is to ensure that meat, poultry, and egg products are safe, wholesome, and properly marketed, labeled, and packaged.”).

141. SAFE FOOD REPORT, *supra* note 140, at 27.

142. 21 U.S.C. § 603(a) (2000).

143. *See id.* §§ 604, 606, 607 (mandating that inspectors mark, label, stamp, or tag

When an FSIS inspector determines that a carcass is adulterated, he or she may require the carcass to be destroyed or order the carcass detained for a period not to exceed twenty days.¹⁴⁴ If the producer fails to detain or destroy an adulterated carcass, FSIS may suspend inspections. Since the producer may not conduct meat processing activities without an FSIS inspector, the producer is effectively out of business during any such suspension of inspection activities.¹⁴⁵ The agency may only order a suspension, however, after a hearing before an independent Administrative Law Judge.¹⁴⁶

The USDA has historically taken the position that its function is not to ensure that meat is free of deadly pathogens, a function that is the obligation of the entity that prepares the meat for human consumption.¹⁴⁷ In *American Public Health Ass'n v. Butz*,¹⁴⁸ the D.C. Circuit Court of Appeals in 1974 deferred to the USDA's conclusion that meat is not per se adulterated merely because it contains pathogenic organisms. To justify a conclusion that any particular piece of meat is adulterated, FSIS must prove that it is so contaminated with pathogenic micro-organisms that it is unhealthful even on the assumption that it will be adequately prepared by the consumer.¹⁴⁹ The court was confident that "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."¹⁵⁰ The applicability of this reasoning process to meat contaminated with mad cow prions, which are not destroyed by ordinary cooking techniques, remains a critical question for FSIS as it struggles to protect the public from vCJD.

unalderated carcasses, parts, meat and meat food products as "inspected and passed," and label, mark, stamp, or tag as "inspected and condemned" all adulterated carcasses, parts, meat and meat food products); *see also* USDA HACCP Proposed Rule, *supra* note 125, at 6780 (discussing the requirement that inspected meat products found not to be adulterated bear the words "inspected and passed").

144. 21 U.S.C. §§ 604, 672 (2000).

145. *See id.* §§ 604, 606, 607, 608, 671 (empowering the Secretary of Agriculture to remove inspectors from any establishment which fails to destroy condemned carcasses, parts, meat and meat food products, maintain sanitary conditions, or properly package meat or meat food products for distribution); *see also* 9 C.F.R. §§ 329, 329.9, 335.11 (2004) (authorizing the detention of uninspected carcasses, parts, meat and meat food products, and providing criminal offenses for interference with an inspector's duties).

146. 9 C.F.R. §§ 305.3-305.6 (2004).

147. *See* NICOLS FOX, *SPOILED: THE DANGEROUS TRUTH ABOUT A FOOD CHAIN GONE HAYWIRE* 252 (BasicBooks 1997) (relaying former FSIS Administrator Dr. Russell Cross' remarks regarding the FSIS's position on E. Coli).

148. 511 F.2d 331 (D.C. Cir. 1974).

149. *See id.* at 332-35 (determining that the presence of Salmonella in meat does not constitute adulteration as the term is defined in the FMIA; rather, the definition is directed at "poisonous or deleterious additives and filthy, putrid, or decomposed substances . . .").

150. *Id.* at 334; *see also* Supreme Beef Processors, Inc. v. USDA, 275 F.3d 432, 439 (5th Cir. 2001) (reaffirming the *Butz* holding that Salmonella is not a per se adulterant).

1. *The HACCP Regulations*

As the meatpacking industry became more concentrated, it became increasingly apparent that individual FSIS inspectors were losing the battle with increased line speeds driven by constant pressure for increased efficiency.¹⁵¹ Perhaps more importantly, scientists studying outbreaks of foodborne illness caused by contaminated beef were concluding that old fashioned “poke and sniff” inspections were not capable of identifying meat that carried too high a risk of spreading disease.¹⁵² By the mid-1990s, FSIS had concluded that organoleptic inspections were no longer adequate to ensure that meat was not leaving slaughterhouses in an adulterated state.¹⁵³

On July 25, 1996, the USDA promulgated regulations requiring slaughterhouses and certain other meat processing establishments to adopt a “Hazard Analysis at Critical Control Points” (HACCP) approach to meat safety.¹⁵⁴ A radical departure from traditional organoleptic inspections, the HACCP rule is a “performance-based” standard that gives slaughterhouses greater autonomy while placing greater responsibility on them for establishing “process control” measures capable of meeting FSIS performance standards.¹⁵⁵ HACCP is also “science-based” because it relies upon quantitative measurements, rather than qualitative judgments of individual inspectors, when quantitative techniques are available.¹⁵⁶ An understanding of the HACCP process for meat is critical to an

151. See NESTLE, *supra* note 124, at 67 (discussing the origins of the Hazard Analysis at Critical Control Points method for keeping pathogens out of the meat supply).

152. See USDA HACCP Proposed Rule, *supra* note 125, at 6780 (acknowledging that visual inspection of meat products is inadequate in light of the safety concerns posed by microscopic foodborne bacteria); see also SAFE FOOD REPORT, *supra* note 140, at 27 (contending that sensory evaluation inspection methods are outdated and deficient).

153. USDA HACCP Proposed Rule, *supra* note 125, at 6783 (ascertaining the futility of the organoleptic inspection system in detecting and potentially eliminating harmful pathogenic microorganisms in raw meat).

154. USDA HACCP Final Rule, *supra* note 140, at 38,806. The HACCP approach originated in a 1958 cooperative effort of the National Aeronautics and Space Administration and the Pillsbury Company to come up with procedures for ensuring that astronauts did not contract food poisoning during their extended flights. See NESTLE, *supra* note 124, at 67.

155. USDA HACCP Final Rule, *supra* note 140, at 38,808 (“With the shift to HACCP and greater reliance on performance standards, establishments will be afforded greater autonomy in decision-making affecting their own operations and, in return, be expected to take responsibility for setting up site- and product appropriate process control measures to achieve FSIS-established performance standards.”). For a general discussion of the HACCP approach, see JEAN M. RAWSON, CONGRESSIONAL RESEARCH SERVICE REPORTS, CRS ISSUE BRIEF FOR CONGRESS, MEAT AND POULTRY INSPECTION ISSUES 1 (2003) [hereinafter CRS ISSUE BRIEF AUG. 1, 2003] (evaluating HAACP reforms). See also Margaret O’K. Glavin, *HACCP: We’ve Only Just Begun*, 56 FOOD & DRUG L. J. 137, 138 (2001) (contemplating the progression of the HAACP inspection system).

156. See USDA HACCP Final Rule, *supra* note 140, at 38,811 (touting HAACP in conjunction with food safety performance standards as the most effective means by which to control and reduce harmful bacteria in raw meat).

understanding of the January 2004 mad cow regulations, because the most important of those regulations merely incorporates BSE-related risks into pre-existing HACCP programs.

a. HACCP Plans

Under the HACCP approach, meatpackers must come up with a food safety implementation plan. FSIS must approve the plan and all significant substantive revisions.¹⁵⁷ The first step in a HACCP plan is a “hazard analysis” that identifies the food safety risks at each stage of the food production process.¹⁵⁸ The operator must then identify “critical control points” (CCPs) at which risks can be quantitatively monitored (or qualitatively monitored if quantitative monitoring technologies are unavailable) and can be “prevent[ed], eliminat[ed], or reduc[ed] to an acceptable level.”¹⁵⁹ The third step is for the operator to define and establish “critical limits” for each of the CCPs.¹⁶⁰ Critical limits are typically based on “process parameters,” like temperature, pH, or moisture level, or “product parameters” such as the presence of target pathogens in the end-product.¹⁶¹

The next step is the most important from the standpoint of enforceability. The operator must establish monitoring requirements capable of measuring whether the parameters established in the critical limits are exceeded at any of the CCPs.¹⁶² Although FSIS prefers that monitoring be done continuously, it must in any event be undertaken with sufficient frequency to ensure that every CCP is in fact under control.¹⁶³ As discussed below, the failure to establish enforceable monitoring parameters is a debilitating weakness of the industry’s implementation of the January 2004 mad cow rules.¹⁶⁴

HACCP plans must specify “corrective action” that the operator must undertake when monitoring identifies deviations from a critical limit at a

157. *See id.* at 38,818 (explaining that teams of USDA inspectors review and approve the HACCP plans upon initial promulgation and significant substantive amendments “to verify their scientific validity and ongoing adequacy for preventing food safety hazards”).

158. *See id.* at 38,815 (instructing that a hazard analysis must be carried out). A “hazard” is “any biological, chemical, or physical property that may cause a food to be adulterated or otherwise unsafe for human consumption.” *Id.*

159. USDA HACCP Final Rule, *supra* note 140, at 38,815.

160. *See id.* at 38,816 (stating that a critical limit is “the maximum or minimum value to which a process parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the identified . . . food safety hazard”).

161. *Id.* at 38,816.

162. *See id.* at 38,816 (“Monitoring . . . consists of observations or measurements taken to assess whether a CCP is within the established critical limit.”).

163. *Id.* (“[W]hen [continuous monitoring] is not feasible, monitoring frequencies must be sufficient to ensure that the CCP is under control.”).

164. *See infra* Part V.E.6.

CCP.¹⁶⁵ This requirement reflects the USDA's understanding that "the existence of a HACCP plan does not guarantee that problems will not arise."¹⁶⁶ Operators must put record-keeping procedures into place to document monitoring and corrective action and make those records available to FSIS inspectors.¹⁶⁷ Finally, establishments must systematically verify the effectiveness of their HACCP systems initially and over time.¹⁶⁸

b. Sanitation Standard Operating Procedures

The HACCP rule requires operators to establish sanitation standard operating procedures (Sanitation SOPs), as a complement to its HACCP requirements, to ensure that "poor food handling practices, improper personal hygiene, and similar insanitary practices" do not "create an environment conducive to contamination of products."¹⁶⁹ For example, Sanitation SOPs must address "pre-operational sanitation procedures for cleaning facilities, equipment, and utensils."¹⁷⁰ An operator-drafted "sanitation plan"¹⁷¹ must prescribe sanitation procedures for preventing direct contamination and adulteration of meat products.¹⁷² The plans specify the frequency with which the procedures must be conducted, identify the employees responsible for their implementation and maintenance, and keep accurate daily records documenting compliance.¹⁷³ The "responsible employee," however, may be the very employee who is responsible for carrying out the procedure.¹⁷⁴ The plans also provide for taking corrective action when either an employee or FSIS determines that the sanitation SOPs or their implementation "may have failed to prevent direct product contamination or adulteration."¹⁷⁵ So long as an establishment takes steps to correct the insanitary conditions resulting from the violation of one of the SOPs "in a timely manner," however, it is still "considered to be in compliance with the Sanitation SOP's regulations."¹⁷⁶

An extreme departure from the previous "prescriptive" sanitation regulations,¹⁷⁷ the 1996 requirements for sanitation plans are flexible to a

165. USDA HACCP Final Rule, *supra* note 140, at 38,816.

166. *Id.*

167. *Id.* at 38,817.

168. *Id.*

169. *Id.* at 38,829.

170. *Id.* at 38,834.

171. USDA HACCP Final Rule, *supra* note 140, at 38,831.

172. *Id.* at 38,830.

173. *Id.* at 38,831.

174. *Id.* at 38,830.

175. *Id.* at App. A, B.

176. *Id.* at 38,834.

177. Prior to promulgating the 1996 HACCP regulations, the FSIS had ensured proper sanitation "primarily through a combination of prescriptive sanitation regulations, detailed guidance materials, and direct, hands-on involvement by inspectors in day-to-day pre-operational and operational sanitation procedures in inspected establishments." USDA

fault. Each establishment must “analyze its own operations” to identify possible sources of direct contamination and “determine for itself” what procedures are “necessary to prevent insanitary conditions.”¹⁷⁸ The regulations themselves are sorely lacking in detail as to what constitutes an adequate sanitation SOP, and FSIS even suggested that, for some establishments, the process of drafting sanitation SOPs would consist of little more than writing down their current practices.¹⁷⁹ Unlike HACCP plans, FSIS approval of a company’s sanitation plan is not required.¹⁸⁰ Only “persistent and serious failures” will result in suspension or withdrawal of inspection with a consequent cessation of operations.

c. Performance Criteria and Standards

Although FSIS regulations do not specify particular techniques and procedures, every HACCP and sanitation plan must meet FSIS-prescribed “microbiological performance standards.”¹⁸¹ HACCP programs must reduce the prevalence of Salmonella contamination in the end product to a level “below the current national baseline prevalence.”¹⁸² In the agency’s view, this performance standard is achievable using available technology.¹⁸³ Establishments must “meet the standard consistently over time as a condition of maintaining inspection.”¹⁸⁴ Salmonella levels are not to be used, however, to “judge whether specific lots of product are adulterated under the law.”¹⁸⁵ Sanitation plans must attain performance “criteria” for *E. coli* contamination based on the prevalence of

HACCP Final Rule, *supra* note 140, at 38,832. Two years after promulgating of the final HACCP rule, the FSIS amended its pre-existing sanitation rules to “convert[] many of the highly prescriptive sanitation requirements into performance standards.” See USDA, Food Safety and Inspection Service, Sanitation Requirements for Official Meat and Poultry Establishments, Final Rule, 64 Fed. Reg. 56,400, 56,401 (Oct. 20, 1999) [hereinafter USDA Sanitation Requirements Final Rule]. The agency explained that it “could not justify” retaining sanitation regulations that were inconsistent with the “recently finalized” HACCP and Sanitation SOP regulations. *Id.* Henceforth, Sanitation SOPs would be written by the operators of the relevant establishments and merely reviewed by FSIS inspectors under the more “flexible” HACCP regulations.

178. USDA HACCP Final Rule, *supra* note 140, at 38,832-33.

179. See *id.* at 38,830 (explaining that the new requirements will be essentially the same but aim to clarify and grant flexibility in meeting the new standards).

180. See *id.* at 38,832, 38,834 (stating that “FSIS will not approve Sanitation SOP’s,” and that “FSIS inspectors will not be tasked with directing an establishment’s sanitation procedures, nor with ‘approving’ the establishment’s Sanitation SOP’s”).

181. See *id.* at 38,836.

182. USDA HACCP Final Rule, *supra* note 140, at 38,838 (“As proposed, FSIS will require that no establishment can have a prevalence of Salmonella contamination . . . greater than the baseline prevalence.”).

183. See *id.* at 38,836 (emphasizing that the targets for performance criteria and pathogen reduction performance standards are currently set at the national baseline prevalence of contamination).

184. *Id.* at 38,838.

185. *Id.* at 38,836.

contamination of E. coli on carcasses produced nationwide.¹⁸⁶ A failure to meet the performance criteria does not by itself constitute a violation of law, but it is an indication that greater sanitation efforts and/or corrective action are necessary.¹⁸⁷

FSIS inspectors perform Salmonella testing to determine compliance with the HACCP pathogen reduction performance standards, but they need not test for E. coli to determine compliance with the sanitation SOP requirements.¹⁸⁸ A facility that fails the Salmonella test twice must “reassess its HACCP plan” and “modify it as necessary to achieve the Salmonella performance standard.”¹⁸⁹ Under the regulations, a third failure results in a suspension of FSIS inspection services, which as a legal matter means that the facility must stop processing meat.¹⁹⁰ This “three-strike” rule, however, has never been applicable to Sanitation SOPs.

d. Public Access to Critical Information

During the HACCP rulemaking, the industry expressed concern about the extent to which FSIS would make records from HACCP programs available for inspection by the general public.¹⁹¹ Consumer groups argued that all HACCP-related documents should be available for public inspection.¹⁹² The final rule allows FSIS inspectors to copy “appropriate portions of establishment records, as needed, for further evaluation and possible enforcement action,” but only when they “suspect that an establishment’s HACCP system is not operating correctly.”¹⁹³ Since operators are not generally required to submit copies of HACCP-related records to FSIS, copies of such records are not ordinarily located in FSIS files where they would be generally available to the general public under the Freedom of Information Act (FOIA).¹⁹⁴ The preamble to the final rule

186. *See id.* at 38,837-38 (explaining that the performance criteria and required testing will allow each establishment to maintain and achieve a required level of performance over time).

187. *See id.* at 38,838 (“FSIS intends to consider the establishment’s results and corrective actions, together with other information and inspectional observations, in evaluating whether a problem exists that requires regulatory action or other measures to protect consumers.”).

188. *See* USDA HACCP Final Rule, *supra* note 140, at 38,848 (adding that this information will help FSIS to target its compliance testing after the standards go into effect).

189. *Id.* at 38,849.

190. *See id.* (noting that the suspension will be in effect until the facility can meet the specified performance standard).

191. *Id.* at 38,821 (“Most commenters stated that HACCP records should not be available to requestors through the Freedom of Information Act (FOIA).”).

192. *Id.* (“Some commenters requested that HACCP records be generally available to the public.”).

193. *Id.*

194. *See* USDA HACCP Final Rule, *supra* note 140, at 38,821, 38,833 (explaining that some records may be copied and used by agencies for official purposes and that proprietary, personal, and other information exempt from disclosure would be protected).

noted that such HACCP and sanitation SOP records that did wind up in FSIS files would still be subject to the various FOIA exemptions, such as the “trade secrecy” exemption for commercially valuable confidential information.¹⁹⁵ Thus, the agency effectively assuaged industry concerns by assuring it that the public would not be able to find out much about the nature and effectiveness of individual HACCP plans.

e. Whistleblower Protections

Whistleblower protections are legal requirements designed “to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers.”¹⁹⁶ In the HACCP context, whistleblower protections could protect employees of operators who report attempts by management to falsify HACCP reports. Without whistleblowers, the likelihood that FSIS will detect fraud in HACCP documentation is exceedingly small. Since FSIS enforcement is highly dependent upon the reliability of such reports under the new “performance-based” HACCP regulations, it is especially important that whistleblowers know that they will not be subject to adverse employment consequences when they report illegal activity that undermines the integrity of the reporting process.¹⁹⁷ Although FSIS understood the importance of encouraging employees to reveal instances of falsification, it was not confident of its legal authority to provide whistleblower protections to private sector employees and therefore declined to do so.¹⁹⁸

f. The Supreme Beef Challenge

Two years after the USDA promulgated the HACCP regulations, FSIS for the first time proposed to withdraw inspection from a small Texas meat processing and grinding establishment that had violated the “three strike” rule for Salmonella.¹⁹⁹ On the day that FSIS was to cease inspections, the company obtained a temporary restraining order from a federal district court against any agency action.²⁰⁰ The court later ruled on the merits that the HACCP regulations were invalid as applied to grinding

195. *See id.* (noting that the FSIS’s experience and understanding in the area of meat and poultry inspection will be considered confidential).

196. *Id.* at 38,822.

197. *Id.* (“[W]ithout whistleblower protection, it is much less likely that FSIS will know about falsifications.”).

198. *Id.* (“As a legal matter, FSIS is not empowered by the FMIA and PPIA to build explicit whistleblower protection into the regulations.”).

199. *See Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 435-36 (5th Cir. 2001) (recalling that the FSIS gave Supreme Beef six days to demonstrate that its HACCP pathogen controls were adequate or to show that it had achieved regulatory compliance).

200. *See id.* at 436 (arguing that the FSIS had overstepped its authority by creating the Salmonella tests).

establishments,²⁰¹ and the United States Court of Appeals for the Fifth Circuit later affirmed the district court's decision.²⁰²

The Fifth Circuit noted first that FSIS conceded that Salmonella was "not an adulterant per se, meaning its presence does not require the USDA to refuse to stamp such meat 'inspected and passed.'"²⁰³ This was "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.'"²⁰⁴ Indeed, FSIS routinely labeled Salmonella-containing beef "inspected and passed."²⁰⁵ The court next observed that a product is adulterated if it has been "prepared, packed or held under insanitary conditions . . . whereby it may have been rendered injurious to health."²⁰⁶ In the court's view, the statute's use of the word "rendered" indicated that "deleterious change in the product must occur while it is being 'prepared, packed or held' owing to insanitary conditions."²⁰⁷ The problem with the HACCP regulations was that "a characteristic of the raw materials that exists before the product is 'prepared, packed or held' in the grinder's establishment cannot be regulated by the USDA."²⁰⁸

The court rejected the agency's argument that it could regulate Salmonella as a proxy for all microbiological contaminants in its HACCP "performance" standard, reasoning that "the Salmonella performance standard, whether or not it acts as a proxy, regulates more than just the presence of pathogen controls."²⁰⁹ Noting that the company had consistently maintained that the Salmonella detected in its ground meat came in the beef "trimmings" that it purchased from other companies for grinding into ground beef,²¹⁰ the court held that the USDA was powerless to "regulate characteristics of the raw materials that exist before the meat product is 'prepared, packed or held.'"²¹¹ Since neither the performance standard in general nor the Salmonella test in particular necessarily

201. See *Supreme Beef Processors, Inc. v. USDA*, 113 F. Supp. 2d 1048, 1055 (N.D. Tex. 2000) ("The flaw in such tests is that the presence of Salmonella is not solely—or even substantially—dependent upon the sanitation in a grinder's establishment.")

202. See *Supreme Beef Processors*, 275 F.3d at 432 (stating that USDA could not use Salmonella tests to determine whether meat processing plants were insanitary).

203. *Id.* at 439.

204. *Id.*

205. See *id.* (noting that this approval allowed contaminated products to be sold to consumers).

206. 21 U.S.C. § 601(m)(4) (2000).

207. *Supreme Beef Processors*, 275 F.3d at 440.

208. *Id.*

209. *Id.* at 439.

210. See *id.* at 441 (explaining that the Salmonella standard provides evidence of whether the grinder uses incoming raw materials, such as beef "trimmings," that are disproportionately infected with pathogens).

211. *Id.*

evaluated the actual conditions of a particular meat processing establishment, FSIS could not conclude that meat from that establishment was adulterated solely upon the basis of three failures to meet the Salmonella-based performance test.²¹²

In response to the *Supreme Beef* decision, the USDA took the position that the court limited its ability to enforce performance standards based on Salmonella, but had not affected FSIS's power to use the Salmonella standards as a tool for verifying an individual plant's Sanitation SOPs and HACCP program.²¹³ FSIS continued to require establishments subject to the HACCP regulation to prepare HACCP plans and Sanitation SOPs and to ensure that corrective action is taken if critical levels are exceeded at critical control points.²¹⁴ On the other hand, it seems clear that after *Supreme Beef*, FSIS will have to justify very carefully any decisions to withdraw inspection from plants that repeatedly fail to measure up to the expectations of their HACCP plans.

2. USDA Mad Cow Efforts Prior to December 2003

As mad cow disease became a serious animal health problem in Great Britain in the late 1980s, the USDA took several steps to protect the U.S. cattle population by imposing import restrictions, conducting limited surveillance, and educating U.S. cattle producers. In 1997, the FDA promulgated regulatory restrictions on the preparation and use of animal feeds aimed at preventing the spread of mad cow disease should the disease find a niche in the U.S. cattle herd.²¹⁵ At about the same time, the USDA drafted a contingency plan specifying the steps that the various departmental units would take should its surveillance efforts turn up a BSE-positive animal.²¹⁶ Prior to December 2003, the USDA had undertaken a number of additional actions that were not directly related to mad cow disease but were nevertheless useful in preventing its spread.

212. See *id.* at 439 (highlighting the district court's finding that an examination of a processing establishment's end product is distinct from the conditions tested using the Salmonella standard).

213. See JEAN M. RAWSON & JEFFERY S. BECKER, CONGRESSIONAL RESEARCH SERVICE REPORTS, CRS ISSUE BRIEF FOR CONGRESS, MEAT AND POULTRY INSPECTION ISSUES 6 (Aug. 3, 2003) [hereinafter CRS ISSUE BRIEF Aug. 3, 2003] (commenting that USDA appealed the *Supreme Beef* ruling in 2001 and the district court's decision was ultimately upheld).

214. See *id.* (stating that under the HACCP rule, all plants must have an HACCP plan and site-specific standard operating procedures).

215. See *infra* Part III.B.1.

216. See USDA, BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RESPONSE PLAN 3 (1998) [hereinafter BSE RESPONSE PLAN] (explaining that the contents of the plan detail comprehensive instructions for USDA staff to respond in the event that BSE were to be diagnosed in the United States), available at <http://www.aphis.usda.gov/lpa/issues/bse/bseum.pdf> (last visited Apr. 3, 2005).

a. *The Ban on Imports of Cattle from Countries with BSE-Infected Cattle*

Since 1989, the USDA's Animal and Plant Health Inspection Service (APHIS) has imposed a ban on the importation of live ruminants and certain ruminant products from countries where BSE is known to exist.²¹⁷ In the intervening years, the USDA gradually expanded the ban to include imports of virtually all ruminant products and rendered protein products from BSE-restricted countries.²¹⁸ In May 2003, Canada joined the list of restricted import countries when it announced the discovery of a BSE-positive cow in Alberta.²¹⁹ After Canada implemented additional risk mitigation measures, Secretary Veneman, in August 2003, announced that the USDA would accept applications for import permits for certain low-risk products.²²⁰ The USDA amended the low-risk Canadian products list in late 2003 and early 2004, but a U.S. District Court, on April 26, 2004, issued a temporary restraining order prohibiting APHIS from issuing permits for products other than those on the original list.²²¹

217. See HCRA BSE REPORT, *supra* note 30, at 23 (discussing current APHIS regulations with regard to the importation of ruminant meat and listing the countries that have provided the United States with meat in the past); see also *USDA BSE Overview*, *supra* note 30, at 5 (explaining that APHIS monitors cattle imported from regions with known BSE risk factors); FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 9 (stating that in an effort to prevent BSE from entering the United States, APHIS placed importation restrictions on all European countries).

218. See *USDA SRM Interim Final Rule*, *supra* note 2, at 1863 (discussing the various procedures that the United States government has implemented in order to decrease the risk importing BSE contaminated products); see also *USDA BSE Overview*, *supra* note 30, at 5 (explaining that the USDA continually monitors all ongoing events and research findings on spongiform encephalopathies to revise prevention measures as needed); 9 C.F.R. § 94.18 (2002) (restricting the importation of meat and edible products from ruminants due to bovine spongiform encephalopathy).

219. See 9 C.F.R. § 94.18(a)(1) (2002) (listing countries with BSE-infected animals); see also *USDA, Animal and Plant Health Inspection Service, Importation of Processed Canadian Beef Products Regulatory Timeline* (June 10, 2004) (tracking the regulation of imported processed Canadian beef products), available at <http://www.aphis.usda.gov/lpa/issues/bse/bsechronjune10.pdf> (last visited Apr. 3, 2005); Press Release, USDA, Statement by Ann M. Veneman Regarding Canada's Announcement of BSE Investigation (May 20, 2003) (stating that although the case of BSE appeared to be isolated, the USDA placed Canada under BSE restriction guidelines), available at <http://www.usda.gov/documents/NewsReleases/2003/05/0166.doc>.

220. See Press Release, USDA, Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted (August 8, 2003) ("Our experts have thoroughly reviewed the scientific evidence and determined that the risk to public health is extremely low."), available at <http://www.usda.gov/documents/NewsReleases/2003/08/0281.doc>.

221. See *id.* On November 4, 2003, the USDA published in the *Federal Register* a proposal to amend the BSE regulations to establish a new category of regions that recognize countries that pose minimal risk of introducing BSE into the U.S. via the importation of certain low-risk live ruminants and ruminant products, and proposed to add Canada to this list. See *Bovine Spongiform Encephalopathy*, 68 Fed. Reg. 62,386, 62,387 (proposed Nov. 4, 2003) (to be codified at 9 C.F.R. pts. 93, 94, 95); see also Press Release, USDA, *USDA Issues Proposed Rule to Allow Live Animal Imports from Canada* (Oct. 31, 2003) (discussing the USDA's proposal to amend its BSE regulations by establishing a new

b. USDA Surveillance Efforts Prior to December 2003

The accuracy with which the USDA and the general public can ascertain the true incidence of BSE in the U.S. cattle population depends upon the range and intensity of the surveillance efforts that the USDA undertakes to discover BSE. APHIS is the USDA agency responsible for promoting agricultural health and protecting the Nation's agriculture from pests and disease, and it is therefore responsible for implementing the Department's BSE testing program.²²² Because brain tissue is necessary for accurate testing, BSE surveillance efforts prior to January 2004 focused primarily on slaughterhouses where FSIS inspectors or company employees could easily take samples of brain tissue from animals selected for testing.²²³

Since the early 1990s, FSIS inspectors have been on the lookout for non-ambulatory (downer) cattle and cattle exhibiting signs of CNS disorders,²²⁴ and they condemned cattle in the latter category and sent samples to APHIS laboratories for BSE analysis.²²⁵ Not all non-ambulatory cattle were tested, however, and the meat from tested animals could be conveyed to downstream distributors before the results of the tests were made available to the establishments that slaughtered the animals.²²⁶ In 1990, APHIS began an active BSE surveillance program aimed at sampling the brains of several hundred downer cattle per year.²²⁷ APHIS laboratories

category for regions that pose a minimal risk of introducing BSE contaminated products into the country), available at <http://www.usda.gov/Newsroom/0372.03.html>. A proposed minimal risk region would include regions in which an animal has been diagnosed with BSE but in which specific preventive measures have been in place for an appropriate amount of time, thus reducing the risk that its imports will introduce BSE into the U.S. *Id.* The USDA is currently reviewing the public comments it received regarding this proposed rule.

222. See *Welcome to Animal and Planet Health Inspection Service Website!*, at <http://www.aphis.usda.gov/lpa/about/welcome.html> (last visited Mar. 28, 2005) (maintaining that without APHIS, "bovine spongiform encephalopathy (mad cow disease) could devastate our livestock industry and our food supply"); see also *Bovine Spongiform Encephalopathy (BSE) Surveillance* (May 20, 2004), at <http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html> (detailing the APHIS BSE surveillance program).

223. See Denise Grady, *9 Cows Linked to Mad Cow Inquiry Have Been Found*, N.Y. TIMES, Jan. 1, 2004, at A16 (reporting that testing is shifting from slaughterhouses into rendering plants and farms).

224. See *Potential Transmission of Spongiform Encephalopathies to Humans: The Food and Drug Administration's [FDA] Ruminant Feed Ban and the Safety of Other Products: Hearing Before the House Comm. on Government Reform and Oversight*, 105th Cong. 48, 49 (1997) [hereinafter *Detwiler Testimony*] (statement of Dr. Linda A. Detwiler, Chair, TSE Working Group) (stating that as of December 31, 1996, USDA laboratories had tested more than 5,211 cattle brains).

225. See U.S. GEN. ACCOUNTING OFFICE, GAO-02-13, MAD COW DISEASE: IMPROVEMENTS IN THE ANIMAL FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S. PREVENTION EFFORTS 20 (2002) [hereinafter 2002 GAO MAD COW REPORT]; see also *Detwiler Testimony*, *supra* note 224, at 49 (encouraging private veterinarians to refer possible cases of CNS disorders to APHIS for BSE analysis).

226. See FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 11 (stating that inspection personnel will not pass and apply the mark of inspection to the parts of the cattle until test results are received).

227. See *Detwiler Testimony*, *supra* note 224, at 49; see also RHODES, *supra* note 35, at

tested almost 14,000 brains out of hundreds of millions of cattle slaughtered between 1990 and 2001, when the testing was expanded to include more downer cattle.²²⁸ By the end of 2002, APHIS had tested a total of about 30,000 downer cattle from among the 300,000,000 animals slaughtered during the previous nine years.²²⁹ In fiscal year 2003, APHIS expanded the testing program once again, and it later reported testing more than 20,000 cattle for BSE in that year alone.²³⁰ Even 20,000 was less than five percent of the more than 400,000 downer cattle that appear annually in the U.S. cattle population,²³¹ and it was a tiny fraction of the 35 million cattle slaughtered annually in the United States.²³²

c. Regulation of AMR and Mechanical Separation Technologies

FSIS has traditionally regulated meat products produced by Advanced Meat Recovery (AMR) systems under its authority to prevent misbranding of meat and meat products.²³³ Under FSIS misbranding regulations promulgated in 1994, any product resulting from AMR systems identified as “meat” is misbranded if it contains any spinal cord material.²³⁴ Prior to January 2004, FSIS had not taken any regulatory action against AMR products identified as “meat” if they contained DRG and other CNS-type

223 (detailing the USDA and APHIS surveillance programs beginning in 1990). This program targeted only cattle exhibiting signs of neurologic disease in the field, cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories, neurologic cases submitted to laboratories and hospitals, and a very small nonrandom sampling of nonambulatory (downer) cattle. HCRA BSE REPORT, *supra* note 30, at 45.

228. See HCRA BSE REPORT, *supra* note 30, at 45 (demonstrating that the USDA is considering rapid diagnostic tests for surveillance in the future).

229. See Donald G. McNeil Jr., *Mad Cow Case May Bring More Meat Testing*, N.Y. TIMES, Dec. 26, 2003, at A1 (comparing United States beef industry inspections with the inspection systems of other countries).

230. Marian Burros & Donald G. McNeil, Jr., *Inspections for Mad Cow Lag Those Done Abroad*, N.Y. TIMES, Dec. 24, 2003, at A19.

231. See Bette Hileman, *Mad Cow Disease*, 82 CHEM. & ENG'G NEWS 21, 22 (2004) (estimating that approximately 446,000 cattle become too sick or injured to walk every year).

232. See Burros & McNeil, *supra* note 230 (explaining that the low percentage of testing was a byproduct of the fact that there had not been any domestic cases of mad cow disease in the past).

233. A meat or meat food product is misbranded under any number of circumstances, including if its labeling is false or misleading; if it is offered for sale under the name of another food; if it is an imitation of another food, unless its label bears (in type of uniform size and prominence) the word “imitation” and, immediately thereafter, the name of the food imitated; or if it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by regulations, unless it conforms to the regulations and its label bears the name of the food specified in the definition and standard. 21 U.S.C. §§ 601(n)(1)-(3), (7) (2000); see also USDA AMR Interim Final Rule, *supra* note 25, at 1875.

234. 9 C.F.R. § 301.2 (2004); see also Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems, 59 Fed. Reg. 62,551 (Dec. 2, 1994) (to be codified at 9 C.F.R. pts. 301, 318, 320) (outlining the parts of cattle that, if found, make the meat misbranded).

tissues.²³⁵ A 2002 USDA survey of AMR establishments, however, found that meat products from 76% of the establishments tested positive for spinal cord, DRG, or both materials.²³⁶ Subsequently implemented routine testing of AMR material for spinal cord and DRG material continued to identify such material in a substantial proportion of the tested meat product.²³⁷ The USDA concluded that attempts to remove spinal cords before processing vertebral columns in AMR systems did not result in the removal of all spinal cord and DRG material.²³⁸ USDA regulations for mechanically separated meat were even less effective at keeping potentially prion-contaminated tissues out of the resulting meat product.²³⁹

d. Cattle Identification and Tracking Program

The United States is currently without a comprehensive system for expeditiously tracing livestock during disease outbreaks. While other countries have mandatory animal tracking systems,²⁴⁰ the United States has lagged behind, due largely to producer concerns over costs, legal liability, and privacy.²⁴¹ As the recent experience with the Washington State mad cow has highlighted,²⁴² it is exceedingly difficult for the USDA to

235. USDA AMR Interim Final Rule, *supra* note 25, at 1876.

236. *Id.*; see also USDA SRM Interim Final Rule, *supra* note 2, at 1866 (noting that a survey also found about 35% of final AMR products tested were found to contain spinal cord, DRG, or both).

237. USDA AMR Interim Final Rule, *supra* note 25, at 1876; see also USDA SRM Interim Final Rule, *supra* note 2, at 1866 (reporting that follow-up regulatory testing in 2003 detected spinal cord material in 23 of the 340 randomly scheduled samples).

238. USDA AMR Interim Final Rule, *supra* note 25, at 1876; see also USDA SRM Interim Final Rule, *supra* note 2, at 1866.

239. USDA SRM Interim Final Rule, *supra* note 2, at 1866.

240. See Drew, et al., *Despite Mad-Cow Warnings, Industry Resisted Safeguards*, N.Y. TIMES, Dec. 28, 2003, at 25 (describing animal tracking programs in the European Union, Canada and Japan).

241. See Stephanie Simon, *USDA Plans to Beef Up Livestock ID System*, L.A. TIMES, Jan. 11, 2004, at A1, A16 (discussing the Washington State incident).

242. Within less than a week USDA investigators were able to place the infected animal within a group of 81 cows imported into the United States from Alberta, Canada. Press Release, USDA, Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Release No. 0451.03 (Dec. 30, 2003) (remarks of Ron DeHaven), available at http://www.usda.gov/wps/portal/!ut/p/s.7.0.A/7.0.1OB/cmd/ad/ar/sa.retrievecontent/c/6.2.1UH/ce/7.2.5JM/p/5.2.4TQ/d/0/th/J.2.9D/s.7.0.A/7.0.1OB?PC.7.2.5JM_contentid=2003/12/0451.html&PC.7.2.5JM_navtype=RT&PC.7.2.5JM_parentnav=TRANSCRIPTS_SPEECHES&PC.7.2.5JM_navid=NEWS_RELEASE#7.2.5JM (last visited Apr. 3, 2005). The USDA then launched into the much more difficult task of identifying other animals in the herd that presumably ate the same contaminated feed and tracing those animals forward to determine their whereabouts or, more likely, the disposition of the meat resulting from their slaughter. On February 9, 2004, the USDA announced that it had ended its investigation. The Department reported that it had located 29 of the 81 animals in the birth herd of the Washington State mad cow. Of the 25 cows most likely to have eaten the same feed as the mad cow, the USDA had located only 11. The search for the 81 took USDA investigators to 189 farms and ranches where they identified and slaughtered 225 “animals of interest,” none of which were afflicted with the disease. See *U.S. Ends Its Hunt for More Cases of Mad Cow Disease*, L.A. TIMES, Feb. 10, 2004, at A15 (summarizing the

determine the origins of a suspect cow that is identified at a slaughterhouse. As importantly, there is no way to know whether a producer has quietly disposed of an animal demonstrating clear signs of mad cow disease, because it is perfectly lawful at this time for producers to bury animals that die on the premises, haul them to a landfill, or otherwise dispose of them.²⁴³

Since 2002, government and industry groups have been attempting to draft a nationwide Animal Identification Plan (AIP).²⁴⁴ After the discovery of the Mabton mad cow, the USDA put that plan on a fast track for implementation.²⁴⁵ The current version of the plan would assign identification numbers to animal premises, individual animals, and groups of animals.²⁴⁶ Identification devices could employ either visible methods, such as an ear tag, or electronic methods, such as radio frequency identification, whereby an electronic transponder is inserted into an ear tag.²⁴⁷ The plan's goal is to ensure traceability within forty-eight hours through consistent identification of both premises and individual animals.²⁴⁸ Information would be maintained by producers and slaughterhouses and submitted to a national animal identification database that would be available to state and federal agricultural health officials.²⁴⁹

findings of the *Technical Briefing and Webcast with U.S. Government Officials on BSE Case*; see also Shankar Vedantam, *U.S. Ends Investigation of Mad Cow Case*, WASH. POST, Feb. 10, 2004, at A1 (quoting a Department spokesperson who said that despite the disappointing results, it was "time to move on").

243. See 2002 GAO MAD COW REPORT, *supra* note 225, at 21 (noting that the USDA's testing program does not include any samples from cattle that die on farms).

244. See National Identification Development Team, *U.S. Animal Identification Plan, Version 4.1*, 2 (Dec. 2003) [hereinafter *Draft U.S. Animal Identification Plan*] (emphasizing that the effort to develop a national identification plan dates back over three decades), available at <http://usaip.info/USAIP4.1.pdf> (last visited Apr. 3, 2005).

245. See Transcript of Remarks by Agriculture Secretary Ann M. Veneman Before the House Agriculture Committee (January 21, 2004) (stating that the USDA plan was first developed in 1990 and had been continually updated since then to reflect the latest knowledge and experiences of other countries), available at <http://www.usda.gov/Newsroom/0031.04.html> (last visited Feb. 15, 2005). Initially developed under the auspices of the private National Institute for Animal Agriculture, the plan is now being drafted by a National Identification Development Team consisting of government and industry representatives. See *Draft U.S. Animal Identification Plan Information Site*, at <http://www.usaip.info/index.htm> (last visited Mar. 28, 2005).

246. See *Draft U.S. Animal Identification Plan*, *supra* note 244, at 5 (reiterating that identification numbers are necessary to achieve the plan's "48-hour" traceback objective).

247. See, e.g., *id.* at 28 (explaining that, although the AIP does not commit to one method over the other overall, radio frequency is cited as the preferred method for cattle); *NDSU Researchers Say Radio Tags Could Track Livestock*, BISMARCK TRIB., Feb. 22, 2004, available at <http://www.bismarcktribune.com/articles/2004/02/22/news/state/sta04.txt>; *NDSU Researchers Say Radio Tags Could Track Livestock*, U.S.A. TODAY, Feb. 23, 2004, available at http://www.usatoday.com/tech/news/techinnovations/2004-02-23-bessie-goes-rfid_x.htm; *Mobile Lab to Help N.D. Fight Bioterrorism*, BISMARCK TRIB., Dec. 15, 2004, at 8C (explaining that an electronic system would facilitate data transmittal and tracking); *Draft U.S. Animal Identification Plan*, *supra* note 244, at 13.

248. See *Draft U.S. Animal Identification Plan*, *supra* note 244, at 5-14 (detailing the systems and methods required to achieve this objective).

249. See *id.* at 17-22 (describing the information system that will allow for the

The program would be phased in and oversight would be provided by a board made up of state and federal government officials and members of the industry.²⁵⁰

B. FDA Regulation

The FDA is part of the Department of Health and Human Services and administers the food safety provisions of the Pure Food and Drugs Act of 1906.²⁵¹ In addition, the FDA has responsibility for implementing the “food additive” provisions of the 1958 Amendments to the Food, Drug and Cosmetic Act of 1938 (FDCA).²⁵² The FDCA defines a “food additive” as

[A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.²⁵³

To meet the “generally recognized as safe” (GRAS) exception, the proponent of a substance that would otherwise be a food additive must conclude on the basis of expert opinion that “there is a reasonable certainty that the material is not harmful under the intended conditions of use.”²⁵⁴ Any food containing a food additive that has not been approved by the FDA is adulterated and subject to seizure.²⁵⁵ In 1997, the FDA exercised those authorities and its general authority to promulgate implementing regulations²⁵⁶ to produce its Ruminant Feed Regulations.²⁵⁷

identification of each premises and the recording of the U.S. Animal Identification Numbers and the U.S. Group/Lot Identification Numbers).

250. *See id.* at 25, 35 (listing the responsibilities of the Oversight Board, including evaluating and making recommendations relating to the performance and maintenance of the plan and monitoring program elements at both the federal and state levels).

251. Pure Food and Drugs Act, Pub. L. No. 59-384, ch. 3915, 2, 34 Stat. 768 (1906) (superseded by the FD&C Act in 1938).

252. *See SAFE FOOD REPORT, supra* note 140, at 22 (summarizing the development of the Food and Drug Administration, from its origins as the USDA Bureau of Chemistry in 1906, through its current state as an entity in the Department of Health and Human Services).

253. 21 U.S.C. § 321(s) (2000).

254. *See* Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Final Rule, 62 Fed. Reg. 30,936, 30,937 (Jun. 5, 1997) (to be codified at 21 C.F.R. pt. 589) [hereinafter 1997 Feed Rule] (noting that the expert opinion would need to address topics such as whether it is reasonably certain that BSE does not, or will not, occur in the United States; whether it is reasonably certain that the BSE agent will not be transmitted through animal feed; and whether it is reasonably certain that the agent will not be transmitted to humans through consumption of ruminant products).

255. 21 U.S.C. §§ 334, 342 (2000).

256. 21 U.S.C. § 701(a) (2000).

257. Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (1997); *see*

1. *The 1997 Ruminant Feed Regulations*

On June 5, 1997, the FDA promulgated regulations banning the use of protein derived from all mammalian tissues, with certain exceptions, in ruminant feed.²⁵⁸ The all-important exceptions, however, include blood and blood products, gelatin, plate waste, milk products, and any product whose only mammalian protein consisted entirely of pig or horse protein.²⁵⁹ In addition, the rule does not apply to materials that are not proteins, such as tallow, fats, oils, grease, amino acids, and dicalcium phosphate.²⁶⁰ Moreover, ruminant protein can still be used in feed for chickens, pigs, and pets, and protein from those sources can still be rendered into cattle feed.²⁶¹

To discourage “cross-feeding,” the rule requires renderers, protein blenders, and feed manufacturers to place the following cautionary statement on feeds for nonruminant species that contained animal proteins: “Do not feed to cattle or other ruminants.”²⁶² In addition, those companies must maintain records sufficient to track the materials.²⁶³ Finally, the regulations require establishments and individuals, including individual cattle producers and feedlots, that are responsible for feeding ruminant animals to maintain copies of purchase invoices and labeling for all feeds containing animal protein products that they receive.²⁶⁴ It appears from the FDA’s inspection spreadsheet that small entities have received at least some attention from the FDA and state inspectors.²⁶⁵

also Crawford Testimony, *supra* note 11 (prohibiting ruminant feed from containing certain protein derived from mammalian tissues).

258. See generally 1997 Feed Rule, *supra* note 254. The regulations technically determined that protein derived from all mammalian tissues, with certain exceptions, was not generally recognized as safe (GRAS) for use in ruminant feed, but rather a food additive subject to the full food additive requirements under the act. *Id.* Since the agency was highly unlikely to grant a food additive petition for such protein, this meant that as a practical matter any ruminant feed containing any animal protein would be adulterated and subjected to seizure. *Id.*

259. See 21 C.F.R. § 589.2000(a)(1)(2004); see also HCRA BSE REPORT, *supra* note 30, at 43; RHODES, *supra* note 35, at 233 (citing examples of protein derived from mammalian tissues).

260. See 1997 Feed Rule, *supra* note 254, at 30,938 (listing the suggested exclusions from the agency’s alternatives to a ruminant-to-ruminant prohibition, including proteinaceous tissues, nonproteinaceous materials, and materials that are not considered to be tissues).

261. See RHODES, *supra* note 35, at 233 (noting that this use of ruminant protein will be permitted despite the known susceptibility of pigs and cats to spongiform encephalopathy and the possible passage of the disease agent through chickens into their manure).

262. 21 C.F.R. § 589.2000(c)(1)(i) (2004); see also 1997 Feed Rule, *supra* note 254, at 30,937 (simplifying the cautionary statement for animal feeds containing mammalian-derived proteins).

263. 21 C.F.R. § 589.2000(c)(1)(ii) (2004); see also 1997 Feed Rule, *supra* note 254, at 30,937 (explaining that this information must be made available for inspection).

264. See 21 C.F.R. § 589.2000(f) (2004) (explaining what information must be available for inspection by the FDA).

265. See FDA BSE/Ruminant Feed Inspections Firms Inventory, available at <http://www.accessdata3.fda.gov/BSEInspect> (last visited Apr. 3, 2005) (listing the firms that are subject to FDA BSE/Ruminant feed inspections).

2. Enforcement of the 1997 Feed Restrictions

The FDA Feed Rule applies to almost 5,000 large and small feed manufacturers and distributors and to large feedlots, a substantial enough number of establishments to stretch even an ample enforcement budget.²⁶⁶ However, it also applies to hundreds of thousands of individual farmers and ranchers, many of whom purchase and store feed for both ruminants and nonruminants and some of whom engage in their own feed-mixing operations.²⁶⁷ Unlike FSIS, which has an inspector at every slaughterhouse and meat production facility, the FDA uses a sampling strategy whereby inspectors pay “periodic visits to settings where food is produced, processed, or stored to verify compliance with its requirements.”²⁶⁸

The 1997 Feed Rule got off to a spotty start. In a July 2001 update on its BSE enforcement activities, the FDA reported that of the 2,653 firms handling prohibited materials at their most recent inspection, 431 had improperly labeled their products, 222 lacked proper procedures for preventing co-mingling of prohibited feed with feed destined for ruminant consumption, and 112 firms were out of compliance with one or more record-keeping requirements.²⁶⁹ Moreover, when re-inspected to determine if violations had been corrected, eight percent of the violators remained out of compliance.²⁷⁰

A report prepared in January 2002 by the United States General Accounting Office (GAO) noted that the FDA was not confident four years after the feed restrictions went into effect that it had identified all of the unlicensed feed mills that were subject to it.²⁷¹ Although the FDA and state inspectors had undertaken more than 10,000 inspections and reported hundreds of firms out of compliance since the ban went into effect, its only real enforcement actions consisted of two warning letters.²⁷² The GAO

266. 2002 GAO MAD COW REPORT, *supra* note 225, at 47.

267. The FDA promulgated a “Small Entities Compliance Guide” for feeders of ruminant animals with and without on-farm mixing operations. See FDA, *Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Mixing Operations* (February 1998) [hereinafter FDA Small Entities On-Farm Compliance Guide].

268. See SAFE FOOD REPORT, *supra* note 140, at 22 (noting that the FDA’s authority expanded further in 1958 with the passage of the Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938). The FDA has also entered into cooperative arrangements with state agencies under which state inspectors conduct about 80% of all animal feed inspections. 2002 GAO MAD COW REPORT, *supra* note 225, at 22.

269. FDA, CVM Update: Ruminant Feed (BSE) Enforcement Activities (July 6, 2001) [hereinafter FDA Feed Rule Activity Report], available at <http://www.fda.gov/cvm/CVM-Updates/bse72001.htm> (last visited Apr. 3, 2005).

270. See *id.* at 4 (suggesting that problems can be corrected through further training of employees about the rule, developing systems to prevent co-mingling, re-labeling products properly, and adhering to record keeping regulations).

271. See 2002 GAO MAD COW REPORT, *supra* note 225, at 47 (noting that an estimate was developed in 1997 by trade, industry, and state officials, but that the feed industry has consolidated since that time).

272. See *id.* at 23 (noting the few enforcement actions levied on hundreds of firms that

found “several instances in which firms were out of compliance in repeated inspections, yet the FDA had not even issued a warning letter.”²⁷³ The GAO concluded that the FDA’s feed restrictions were not being adequately implemented and enforced.²⁷⁴

The FDA has historically suffered from a chronic lack of resources for enforcement of its feed additive requirements,²⁷⁵ a situation that changed rather dramatically after the September 11th terrorist attacks. In fiscal years 2002 and 2003, the FDA used an additional appropriation to hire an additional 655 new food personnel, 433 of whom were assigned to duties relating to imports enforcement.²⁷⁶ Although it is not clear how many of the remaining 222 new slots have been devoted to animal feed inspections, the FDA announced in January 2004 that it would be increasing its inspections of feed mills and renderers in 2004.²⁷⁷

III. REGULATION OF MAD COW RISKS AFTER JANUARY 2004

The discovery of the Mabton mad cow automatically triggered the USDA’s previously promulgated BSE Response Plan,²⁷⁸ and the Department pursued the steps set out in the plan throughout the Christmas holidays.²⁷⁹ First, the USDA received a definitive confirmation from a British laboratory that the Washington Holstein was BSE-positive, and it immediately informed the public of that fact.²⁸⁰ Second, the USDA

are out of compliance); *see also* FDA Feed Rule Activity Report, *supra* note 269, at 3 (reporting that 431 of the 2,653 firms handling prohibited materials had products that were not labeled as required, 222 did not have adequate systems to prevent co-mingling, and 112 did not adequately follow record keeping regulations).

273. 2002 GAO MAD COW REPORT, *supra* note 225, at 23.

274. *See id.* at 10-11 (outlining the FDA’s weaknesses in BSE prevention and detection efforts). In particular, GAO found that as of January 2002, FDA had “no enforcement strategy for feed ban compliance that includes a hierarchy of enforcement actions, criteria for actions to be taken, time frames for firms to correct violations, and time frames for follow-up inspections to confirm that violations have been corrected.” *Id.* at 24.

275. *See* SAFE FOOD REPORT, *supra* note 140, at 87 (noting that “FDA’s shrunken inspection force is seriously over-extended, and FDA appears to have insufficient resources to meet its statutory obligations”).

276. *See* FDA, Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation’s Food Supply (July 23, 2003) (allocating new field personnel to support the conduct of consumer safety investigations at U.S. ports of entry, laboratory analyses on imported products, criminal investigations of import activities, and domestic efforts), available at <http://www.cfscan.fda.gov/~dms/ fsrep.html> (last visited Apr. 3, 2005).

277. *See* Crawford Testimony, *supra* note 11 (explaining that the FDA, working with state agencies and partners, will inspect 100% of all known renderers and feed mills that process products containing prohibited materials).

278. *See* BSE RESPONSE PLAN, *supra* note 216; *see also* FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 9 (recalling that the plan was activated on December 23, 2003, after the cow’s test results came back as presumptively positive).

279. *See* Mark Sherman, *British Lab Confirms That Mad Cow Disease is in US*, BOSTON GLOBE, Dec. 26, 2003, at A3 (noting that the implementation of the plan would prevent a potential outbreak of the deadly disease and calm public fears about the food supply).

280. *See id.* (explaining that federal investigators traced the path the infected animal took

immediately began to investigate the origin of the mad cow and its herd mates.²⁸¹ Third, the Department attempted to persuade the slaughterhouse, renderers, and marketers of beef that might have come from the cow to undertake a voluntary recall of what was expected to be about 10,000 pounds of potentially contaminated beef from the suspect cow and 19 others that were processed at the same time.²⁸² In sum, the Department implemented its BSE Emergency Response Plan carefully and effectively.

A. The January 8, 2004 USDA Regulations

By the end of the weekend following the discovery of the Mabton mad cow, the Bush Administration was taking strong criticism from Democratic presidential candidates who were themselves in the heat of the presidential primary season.²⁸³ From the vacationing President's Crawford, Texas ranch, a "senior administration official" promised that President Bush would endorse additional protections for consumers of beef.²⁸⁴ Two days later, on December 30, 2003, USDA Secretary Veneman announced that the USDA would be implementing "additional safeguards to bolster the U.S. protection systems" against BSE and "further protect public health."²⁸⁵ In addition, Secretary Veneman promised that the USDA would "begin immediate implementation of a verifiable system of national animal identification."²⁸⁶

FSIS followed up on January 8, 2004, with a notice requiring slaughterhouses to hold meat from BSE-tested cattle from the market until the agency received testing reports (the "Product Holding Guideline").²⁸⁷ In addition, the agency sent interim final rules for specified risk material, AMR processes, and the air-injection stunning of cattle to the *Federal Register*.²⁸⁸ The rules for "specified risk material" (the SRM Rules) included a requirement that all downer cattle be "condemned"²⁸⁹ and a ban on the use of mechanically separated meat.²⁹⁰ The promised "immediate implementation of a verifiable national animal identification program,"

from birth to slaughter).

281. See Wald, *supra* note 5 (noting that a lack of centralized records on the animal's history has made this process difficult).

282. See *id.* (asserting that the recall worried people in restaurants and supermarkets, who feared infected beef products would be in their freezers in the weeks to come).

283. Mike Allen, *Candidates Criticize Bush on Beef Safety*, WASH. POST, Dec. 29, 2003, at A3 (outlining several of the Democratic candidates' plans for beef safety).

284. *Id.*

285. See USDA Press Release, *supra* note 29.

286. *Id.*

287. USDA, FSIS Notice, Bovine Spongiform Encephalopathy Surveillance Program, 69 Fed. Reg. 1892 (Jan. 12, 2004).

288. See *infra* note 25.

289. 9 C.F.R. § 309.3 (2004).

290. *Id.* § 319.5.

however, was only at the initial planning stages where it had been stalled for a year-and-a-half, and it would not be implemented for at least another year-and-a-half.²⁹¹

1. *The Specified Risk Material Interim Final Rule*

The USDA assured the public that its new regulations governing “specified risk material” would be a “fourth firewall” aimed particularly at preventing human beings from contracting vCJD from BSE-infected cattle.²⁹² The regulations prohibit the use in human food of SRM from cattle. The term SRM is defined to include brain, skull, eyes, trigeminal ganglia, spinal cord of cattle more than thirty months old,²⁹³ and the tonsils and distal ileum (part of the small intestine) of all cattle.²⁹⁴ FSIS estimates that 84% of the 4,033 federal and state inspected establishments, or 3,388 establishments, regularly deal with SRM.²⁹⁵

The SRM regulations require meatpackers to “develop, implement, and maintain written procedures for the removal, segregation, and disposition” of SRMs.²⁹⁶ Covered establishments must incorporate such procedures into their formal HACCP plans or, if appropriate, into less formal Sanitation SOPs or “prerequisite programs.”²⁹⁷ When either the establishment or FSIS determines that the establishment’s procedures or the implementation of those procedures has “failed to ensure” that SRMs are removed from edible materials and disposed of properly, the establishment must take “appropriate corrective action.”²⁹⁸ Finally, the rules require establishments to maintain daily records sufficient to document the implementation and monitoring of the required SRM removal procedures and any corrective action.²⁹⁹

291. See Denise Grady, *Way to Track U.S. Cattle Isn't Ready for Quick Use*, N.Y. TIMES, Jan. 3, 2004, at A9 (noting that the animal identification system would take a year or two to phase in); see also *infra* Part IV.B.

292. Press Release, FDA, Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004) (“The fourth firewall, recently announced by USDA, makes sure that no bovine tissues known to be at high risk for carrying the agent of BSE enter the human food supply regulated by USDA.”).

293. See 9 C.F.R. § 310.22(e) (2004) (providing that the above-listed materials will be “deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter”).

294. *Id.* § 310.22(a). The SRM regulations provide that “[s]pecified risk material are inedible and shall not be used for human food.” *Id.* § 310.22(b).

295. FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 5.

296. 9 C.F.R. § 310.22(d)(1) (2004).

297. *Id.*

298. *Id.* § 310.22(d)(2). Such establishments are also required to “routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition” of SRM, and they must “revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.” *Id.* § 310.22(d)(3).

299. *Id.* § 310.22(d)(4).

a. *Definition of SRM*

The agency decided to implement a complete prohibition on the use of any SRM in human food to “ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.”³⁰⁰ The regulations designate “all materials from cattle that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue.”³⁰¹ Thus, some “bone-in” beef products (e.g., T-bone steaks) from animals greater than thirty months old contain spinal cord, DRG, or both and are therefore banned.³⁰² The preamble to the interim final rule noted that in one test, bone marrow had demonstrated infectivity thirty-eight months after exposure, but FSIS concluded that the findings of that study were “not conclusive.”³⁰³

The thirty month age cut-off for CNS material reflected the agency’s conclusions that “the total infective load in cattle in the early stages of the incubation period is believed to be much lower than in cattle approaching the end of the incubation period or in those cattle with overt clinical BSE” and that “only 0.01%” of the animals in the field demonstrating clinical symptoms of BSE were less than thirty months of age.³⁰⁴ While conceding that younger animals could transmit the disease, the Department ultimately concluded that “cattle younger than 30 months of age are less likely to be in the later stages of BSE incubation than older BSE-infected cattle, and hence, are less likely to contain high levels of BSE infectivity.”³⁰⁵

Of particular concern to the agency were reports from Japan of BSE detected in cattle under twenty-four months of age as part of that country’s program of testing all cattle destined for human consumption.³⁰⁶ To the

300. USDA SRM Interim Final Rule, *supra* note 2, at 1869.

301. *Id.* at 1868.

302. *Id.* at 1865. Because head meat, cheek meat, and tongue are not technically part of the skull, those materials are not designated as SRM, even though they could easily become contaminated with SRM from within the skull during the slaughter and preparation of meat. *Id.* at 1868.

303. *Id.* at 1864.

304. *Id.* at 1863-64. The USDA faced a practical problem in determining the age of cattle at the time of slaughter because the United States does not have a national cattle identification and tracking system. USDA SRM Interim Final Rule, *supra* note 2, at 1870. The Department therefore decided to adopt a combined approach for verifying the age of cattle at the time of slaughter. If the establishment had “accurate and reliable” records documenting the age of slaughtered cattle, those records would suffice. If, however, the USDA inspector found “significant reasons for questioning their validity,” the inspector would verify the age of the cattle through dental examination. The latter approach was reasonably accurate because the permanent incisors of cattle erupt between 24 and 30 months of age. *Id.* at 1869. Processors unable to document the age of a carcass or parts thereof would have to assume that they were from cattle more than 30 months old. *Id.* at 1869-70.

305. USDA SRM Interim Final Rule, *supra* note 2, at 1864.

306. *Id.*

USDA, however, the “immediate implications” of these findings were “not readily apparent at this time.”³⁰⁷ Acknowledging that “confirmed cases of BSE in animals younger than 30 months of age have also been reported in the United Kingdom and in some other European countries,” the agency expected that the younger infected cattle in Europe had received very high doses of the BSE agent early in their lives.³⁰⁸ In support of its narrower definition of SRM, FSIS noted that its definition of SRM was identical to the Canadian definition.³⁰⁹

b. Procedures for Removal, Segregation, and Disposition

Although the strict prohibition of SRM in meat for human consumption applies to all establishments handling such meat, the SRM rule also addresses how establishments should go about implementing the strict ban. The agency elected, however, not to prescribe specific procedures for establishments to follow, preferring instead to give establishments “the flexibility to implement the most appropriate procedures that will best achieve” the zero-tolerance for SRM that the rule mandated.³¹⁰ Rather than addressing BSE as a unique public health problem, the agency decided to allow establishments to adapt existing HACCP and prerequisite programs, which were designed to reduce levels of infectious microorganisms in meat, to SRM. In short, FSIS decided to let covered establishments decide for themselves how to address SRMs, subject to the limited oversight of USDA inspectors.

2. The Advanced Meat Recovery Rule

As discussed above, AMR systems have consistently produced beef product that has tested positive for spinal cord and DRG.³¹¹ FSIS had in fact formally proposed in April 1998 to adopt a “zero tolerance” for the presence of spinal cord in AMR product,³¹² but the proposal languished in the Department for nearly five years until the discovery of the Mabton mad cow. The AMR interim final rule prohibits the use of the word “meat” to describe the output of any AMR process that contains “any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia” without regard to the age of the animal from which the meat was derived.³¹³ It also applies the same restriction to skulls and vertebral column bones from

307. *Id.*

308. *Id.*

309. *Id.* at 1868.

310. USDA SRM Interim Final Rule, *supra* note 2, at 1869.

311. USDA AMR Interim Final Rule, *supra* note 25, at 1876; *see also infra* Part II.A.

312. Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems, 63 Fed. Reg. 17,959 (proposed Apr. 3, 1998).

313. 9 C.F.R. § 318.24 (2005).

cattle thirty months of age or older.³¹⁴

Like the SRM rule, the AMR rule requires the thirty or so establishments operating AMR systems to come up with procedures to ensure that their production processes comply with the zero-tolerance restrictions.³¹⁵ For cattle-processing establishments, the program must be included in an “HACCP plan, Sanitation SOP, or other prerequisite program.”³¹⁶ All plans must describe the establishment’s “on-going verification activities,” including “the testing of the product exiting the AMR system for” prohibited materials.³¹⁷ Any product not meeting the requirements of the rule and labeled “meat,” is unlawful and subject to seizure.³¹⁸

3. *The Ban on Mechanically Separated Meat Technologies*

Because the USDA’s existing rules did not prohibit the incorporation of SRM into mechanically separated meat and because the separation processes involved in producing mechanically separated meat could result in such contamination, FSIS decided to ban mechanically separated meat technologies altogether.³¹⁹ This did not represent a significant regulatory action because few, if any, U.S. companies had employed mechanically separated meat technologies since the mid-1990s.³²⁰

4. *Limited “Condemnation” of Downer Cattle*

In addition to addressing SRMs directly, the SRM regulations require that all “seriously crippled” and non-ambulatory disabled livestock be identified as “suspect.”³²¹ Furthermore, all non-ambulatory disabled cattle must be condemned and properly disposed of in accordance with the USDA’s condemnation regulations.³²² Disabled cattle that are not non-

314. *Id.* § 318.24(a). As with the SRM rule, the restriction does not apply to bone marrow. USDA AMR Interim Final Rule, *supra* note 25, at 1883.

315. *Id.* § 318.24(b); *see also* FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 6 (stating that 30 establishments produce AMR products derived from beef vertebrae).

316. *Id.* § 318.24(b)(2).

317. *Id.*

318. *Id.* § 318.24(c).

319. *See* USDA SRM Interim Final Rule, *supra* note 2, at 1862, 1865 (justifying banning human consumption of all carcasses of non-ambulatory disabled cattle based on the inability of current diagnostic tests to properly identify infected BSE cattle tissue).

320. *See* FSIS BSE INTERIM RULES PRELIMINARY ANALYSIS, *supra* note 81, at 52 n.43 (noting that “very few, if any, establishments were intentionally producing MS(beef) before the SRM rules became effective”).

321. 9 C.F.R. § 309.2(b) (2005). The term “seriously crippled” is not defined in the regulations.

322. *Id.* §§ 309.2(b), 309.3(e). The regulations define “non-ambulatory disabled livestock” as “livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.” *Id.* § 309.2(b).

ambulatory may still be slaughtered for human consumption.³²³ FSIS based these requirements on European studies indicating that “non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle” and that “clinical signs of BSE cannot always be observed in non-ambulatory cattle.”³²⁴ It understood that a complete prohibition on the use of non-ambulatory cattle for human food is likely to be overly broad because it involves no inquiry into the reason for an animal’s non-ambulatory status. The prohibition applies, for example, to a cow that becomes non-ambulatory because of an acute injury on the way to the slaughterhouse.³²⁵ Nevertheless, FSIS believed that complete prohibition on the use of downer cattle for human consumption was justified because it would provide a greater level of protection than relying exclusively upon tests.

The agency’s pre-existing condemnation regulations require condemned animals to be killed and disposed of in accordance with FSIS disposal regulations.³²⁶ The disposal regulations in turn allow for condemned animals to be disposed of by incineration, by “denaturing” through a process specified in the regulations, or by “tanking.”³²⁷ While the first two options should destroy any mad cow prions, the “tanking” option, which is a commonly employed technology in the rendering industry, will not destroy those prions. In the “tanking” process, the condemned carcass is heated to a high enough temperature “for sufficient time to effectively destroy the contents for human food purposes.”³²⁸ Since rendering is a lawful disposal option for condemned downer cattle, the “firewall” against ruminant consumption of protein from downer cattle remains the FDA Rule, which permits the use of protein from ruminants, including downer cattle, in nonruminant cattle feed. Protein rendered from downer cattle may be used in poultry and swine feed and for other uses that come within the broad exemptions contained in that Rule.³²⁹

5. *The Air Injection Stunning Rule*

The Humane Methods of Slaughter Act (HMSA) requires slaughterhouses to use humane methods in slaughtering livestock.³³⁰ Under

323. See USDA SRM Interim Final Rule, *supra* note 2, at 1870 (stating “suspect” cattle may be used for human food if not “adulterated”).

324. *Id.* at 1863, 1870.

325. *Id.* at 1870.

326. 9 C.F.R. § 309.13 (2005).

327. *Id.* §§ 314.1, 314.3 (2005).

328. *Id.* §§ 314.1(a)(1) (2004).

329. See Grady, *supra* note 223 (quoting chief USDA veterinarian Ron DeHaven, explaining that the USDA’s position is that companies may still render downer cattle into feed for poultry and swine and other products such as tallow and oils).

330. 7 U.S.C. §§ 1901-06 (2000).

that statute, the USDA had approved “air-injection captive bolt stunning,”³³¹ a process through which a metal bolt and compressed air are driven into the cranium of cattle to “disrupt the brain structures and induce total and prolonged unconsciousness.”³³² Recent studies, however, showed that this technique could force pieces of brain and other central nervous system tissue into the circulatory system, where it could be transferred to otherwise edible tissues.³³³ Moreover, malfunctioning captive bolt stunners could transfer much higher amounts of such tissue into edible meat.³³⁴ The regulations, therefore, prohibit the use of such stunning devices in cattle.³³⁵ Since the USDA was “not aware” of any U.S. slaughterhouses that used air-injection stunning,³³⁶ this regulation had no impact on the industry.

6. Expanded Governmental Testing, but Zero Nongovernmental Testing

After the discovery of the Mabton mad cow, the beef industry announced that it would not oppose more comprehensive BSE testing,³³⁷ and the USDA yielded to public pressure for greater testing by gently expanding its existing program from 20,000 tests per year to 40,000.³³⁸ APHIS continued to limit the program to downer cattle and adult cattle displaying signs of CNS disorders, and the program continued to be wholly voluntary.³³⁹ After an International Advisory Panel appointed by Secretary Veneman and an FDA advisory committee both recommended that the USDA expand the testing program even further³⁴⁰ and public interest groups continued to

331. 9 C. F. R. § 310.13(a)(2)(iv)(C) (2005).

332. USDA Stunning Device Interim Final Rule, *supra* note 25, at 1887.

333. *Id.*

334. *See id.* at 1888 (describing the Harvard study concluding that stunning devices using air-injection potentially expose humans to BSE more than other stunning devices even when the stunning device has not malfunctioned).

335. 9 C.F.R. § 313.15(b)(2)(ii) (2004).

336. *See* USDA SRM Interim Final Rule, *supra* note 2, at 1867; USDA Stunning Device Interim Final Rule, *supra* note 25, at 1889.

337. *See* McNeil, *supra* note 229.

338. Sandi Doughton, *Groups Urge Expanded Mad-Cow Protections*, SEATTLE TIMES, Jan. 16, 2004, at B1. The USDA based its decision to test 20,000 animals on its assumption that there were 200,000 downer cattle per year in the relevant population and that 20,000 negative tests would provide a 95% degree of confidence that there were no afflicted animals in that population. The decision to expand the testing to 40,000 animals was based on a new assumption that there were 400,000 downer animals per year in the U.S. *See* Donald G. McNeil Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, N. Y. TIMES, Feb. 9, 2004, at A1.

339. *See* RHODES, *supra* note 35, at 223; *see also* USDA BSE Overview, *supra* note 30, at 4.

340. Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy of the Secretary's Foreign Animal and Poultry Disease Advisory Committee, *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, at 6-7 (Feb. 2, 2004) [hereinafter *International Panel Report*], available at www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf (last visited Apr. 3, 2005); *see also* Alicia Ault, *Federal Panel Recommends More Testing for Mad Cow*, N. Y. TIMES, Feb. 14, 2004, at A1.

demand additional testing,³⁴¹ APHIS inaugurated a one-time only enhanced testing program. On March 15, 2004, Secretary Veneman announced that USDA would reprogram \$70 million of USDA funds to pay for testing as many animals as possible in the high-risk population of downer cattle and cattle showing signs of CNS disorders over a one-and-a-half-year period beginning on June 1, 2004.³⁴² The program would for the first time include approximately 20,000 healthy looking animals of more than thirty months in age.³⁴³

To meet this greatly increased testing load, in May 2004 the USDA announced that it had certified twelve geographically diverse state laboratories to conduct recently approved rapid BSE tests to assist in the expanded surveillance program.³⁴⁴ The program, however, remained entirely voluntary.³⁴⁵ It would not be random, but would instead concentrate on the forty slaughterhouses that have historically slaughtered eighty-six percent of all slaughtered cattle at federally inspected plants.³⁴⁶ The additional sampling program for 20,000 “normal” animals would also not be random and would be limited to cattle older than 30 months of age.³⁴⁷

At the same time the USDA was dramatically expanding its own testing program, it refused to allow individual producers and slaughterhouses to test their cattle voluntarily for mad cow disease. In late February 2004,

341. See Matthew Daly, *Consumer Groups Want More Cattle Testing*, ASSOCIATED PRESS, Jan. 16, 2004 (outlining pressure from consumer groups wanting greater testing).

342. Press Release, USDA, Veneman Announces Expanded BSE Surveillance Program, Release No. 0105.04 (Mar. 15, 2004), available at <http://www.usda.gov/Newsroom/0105.04.html> (last visited Mar. 19, 2005); see also Hileman, *Mad Cow Disease*, *supra* note 231, at 22 (acknowledging the substantial decrease of beef exports because the United States does not test all slaughtered animals for BSE).

343. Marc Kaufman, *Testing for Mad Cow Disease To Expand*, WASH. POST, Mar. 16, 2004, at A1; see also Press Release, *supra* note 342. The USDA predicted that this would increase the total number of animals tested to between 200,000 and 268,000 animals over the 1.5 year life of the expanded testing program; Steve Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, UNITED PRESS INT'L, Mar. 16, 2004 (estimating 200,000 animals), available at <http://www.organicconsumers.org/madcow/lacking31604.cfm> (last visited Mar. 19, 2005).

344. See Press Release, USDA, USDA Certifies Five New Laboratories for BSE Sample Analysis (May 11, 2004), available at http://www.aphis.usda.gov/lpa/news/2004/05/bselabs_vs.html (last visited Mar. 18, 2005); see also Press Release, USDA, USDA Certifies Seven Laboratories for BSE Sample Analysis (Mar. 29, 2004), available at http://www.aphis.usda.gov/lpa/news/2004/03/bse_labs.html (last visited Mar. 18, 2005).

345. Shannon Dininny, *Critics Say Voluntary Mad Cow Testing Doesn't Equal Surveillance*, ASSOCIATED PRESS, Mar. 18, 2004.

346. Press Release, USDA, Transcript of Technical Briefing with Bill Hawks, Under Secretary for Marketing and Regulatory Services, Dr. Elsa Murano, Under Secretary for Food Safety, Dr. Ron DeHaven, Administrator of the Animal Plant Health Inspection Service, and Dr. Barbara Masters, Acting Administrator of the Food Safety Inspection Service, Release No. 0204.04 (May 21, 2004), available at www.usda.gov/Newsroom/0204.04.html (last visited Mar. 18, 2005).

347. *Id.*

Creekstone Farms, a small Kentucky-based company specializing in gourmet meats for export, announced that it had received assurances from its Asian customers that their governments would accept its beef products if the company voluntarily tested all of the animals that it slaughtered at its Kansas plant for BSE.³⁴⁸ Creekstone immediately petitioned the USDA to allow it to use one of the rapid BSE testing kits that had recently become available to conduct universal testing on its animals.³⁴⁹ Creekstone even invested \$500,000 in a state-of-the-art mad cow testing laboratory.³⁵⁰ The American Meat Institute's reaction to this effort by a small company to regain its lost export markets was surprisingly negative. Noting that BSE testing had always been conducted by the federal government, it saw no need to take such an "unprecedented" step.³⁵¹

Under the Virus-Serum-Toxin Act,³⁵² establishments that manufacture and import veterinary biological products, like the BSE test kits that Creekstone wanted to use, must be licensed by the USDA.³⁵³ No person may sell "a harmful virus, serum, toxin or analogous product that is intended for use in the treatment of domestic animals" unless the substance was prepared at a licensed facility in accordance with USDA regulations.³⁵⁴ Long ago, the USDA issued regulations banning the shipment within the United States of individual veterinary biological products unless the manufacturer satisfies USDA requirements for purity, safety, potency, and efficacy.³⁵⁵ Relying upon none of those stated rationales, the USDA rejected Creekstone's petition.³⁵⁶ The head of APHIS explained that the USDA was determined to "stick to the science" in testing for mad cow

348. Libby Quaid, *Lawmakers Pushes USDA on Mad Cow Testing*, June 23, 2004; see also Sandra Blakeslee, *A Producer of U.S. Beef Wants to Test All Its Cattle*, N.Y. TIMES, Feb. 27, 2004, at A18; Roxana Hegeman, *Kansas Meatpacker Plans to Test All Cattle for Mad Cow*, ASSOCIATED PRESS, Feb. 27, 2004.

349. Blakeslee, *supra* note 348. In May 2004, another small establishment, Gateway Beef, filed a similar petition. Stephanie Simon, *U.S., Some Ranchers Clash Over Mad Cow Tests*, L.A. TIMES, May 24, 2004, at A1.

350. Marc Kaufman, *Company's Mad Cow Tests Blocked*, WASH. POST, Apr. 16, 2004, at A1.

351. Roxana Hegeman, *Kansas Meatpacker Plans to Test All Cattle for Mad Cow*, ASSOCIATED PRESS, Feb. 27, 2004.

352. 21 U.S.C. §§ 151-58 (2000).

353. *Id.* §§ 152, 154-55. The original statute barred only the interstate shipment of such products, but the Food Security Act of 1985 expanded the USDA's authority to include intrastate shipments. See Pub. L. No. 99-198, § 1768, 99 Stat. 1654 (codified at 21 U.S.C. §§ 151, 154-154a, 157, and 159).

354. 21 U.S.C. § 151 (2000).

355. 9 C.F.R. § 113 (2004).

356. Kaufman, *supra* note 350; see also Donald G. McNeil, Jr., *U.S. Won't Let Company Test All Its Cattle for Mad Cow*, N.Y. TIMES, Apr. 10, 2004, at A1 (challenging testing of all slaughtered cattle as "impl[ing] a consumer safety aspect that is not scientifically warranted"); Libby Quaid, *USDA Rejects Meatpacker's Mad Cow Plan*, SEATTLE POST-INTELLIGENCER, Apr. 9, 2004.

disease.³⁵⁷ As discussed *infra*, Creekstone and many others have been sharply critical of this determination.³⁵⁸

B. The January 26, 2004 FDA Announcement

On January 26, 2004, Health and Human Services Secretary Tommy G. Thompson announced that the FDA would be implementing new “public health measures . . . to strengthen significantly the multiple existing firewalls that protect Americans from exposure to the agent thought to cause” BSE.³⁵⁹ First, the FDA would ban from human food and dietary supplements a wide range of bovine-derived material to match the USDA’s recently promulgated restrictions on downer cattle and SRMs in meat. Second, the FDA would amend the feed ban rule to eliminate the exemptions for mammalian blood, poultry litter, and plate waste and to require any feed manufacturing facilities using prohibited protein to be dedicated exclusively to non-ruminant feed.³⁶⁰ Finally, the FDA promised to increase inspections of feed mills and renderers to ensure compliance with the revised feed rule.³⁶¹ While not conceding that the 1997 Feed Rule had failed to protect the public health, Secretary Thompson avowed that “we must never be satisfied with the status quo where the health and safety of our animals and our population is at stake.”³⁶² The new regulations would, of course, be “science-based.”³⁶³

Not unreasonably, the press read the FDA’s statements to mean that the agency had actually taken the action that it promised. The next day, *USA Today* reported that the FDA “took some of its biggest steps yet to protect the American public against mad cow disease.”³⁶⁴ Other newspapers reported the story as if the promised regulations were either an accomplished fact or would be in place within the next few days.³⁶⁵

357. Kaufman, *supra* note 350.

358. *See infra* Part IV.A.6.

359. Press Release, FDA, Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/hhs_012604.html (last visited Apr. 3, 2005).

360. *Id.*

361. *Id.*

362. *Id.* (praising the new regulations as a response to the evolution of “science and our own experience and knowledge in this area”).

363. *Id.*

364. Elizabeth Weise, *FDA Toughens Its Mad Cow Safeguards*, USA TODAY, Jan. 27, 2004, at 3A.

365. *See* Denise Grady & Donald G. McNeil, Jr., *Rules Issued on Animal Feed and Use of Disabled Cattle*, N.Y. TIMES, Jan. 27, 2004, at A12 (reporting that the “Food and Drug Administration imposed new rules yesterday to prevent the spread of mad cow disease” and that they would “take effect in a few days, as soon as they are published in The Federal Register”); *see also* Shankar Vedantam, *Ban on Meat From “Downers” Grows*, WASH. POST, Jan. 27, 2004, at A3 (reporting that the promised regulation “will go into effect as soon as it is published in the Federal Register, which is expected to happen within days”); Phuong Cat Le, *Cattle Blood Banned From Feed*, SEATTLE POST-INTELLIGENCER, Jan. 27,

Editorials indicated that the FDA's actions were a step in the right direction.³⁶⁶

C. The July 9, 2004 FDA Rule and Considerations for Further Action

Although the FDA published an Advance Notice of Proposed Rulemaking in 2002³⁶⁷ and was presumably prepared to promulgate the promised "interim final" regulations immediately, a curious silence followed Secretary Thompson's dramatic announcement that lasted for more than five months. On July 8, 2004, the FDA announced that it was not sending two interim final rules to the *Federal Register* as promised, but only a single interim final rule limited to the ban on including SRMs and meat from downer cattle in any food, cosmetics, or dietary supplements.³⁶⁸ Instead of the promised elimination of the mammalian blood, chicken litter, and plate waste exemptions from the 1997 Feed Rule, the FDA and the USDA issued a joint Advance Notice of Proposed Rulemaking (ANPR) that merely offered some additional "considerations for further action."³⁶⁹

IV. FLIMSY FIREWALLS

Experience teaches that government regulation is absolutely necessary to protect the consuming public from unsafe food. The marketplace provides some incentive for commercial food manufacturers, distributors, and preparers to keep food reasonably safe. If too many people get sick from eating food from a particular restaurant or supplier, word will get out and consumers will no longer purchase that food. In the modern marketplace, where consumers eat meat that was raised in one state, slaughtered in

2004 (reporting that the FDA strengthened those feed rules on the previous day).

366. See *Litter In The Feed*, ST. PETERSBURG TIMES, Feb. 11, 2004, at 14A.

367. Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 67 Fed. Reg. 67,572 (proposed Nov. 6, 2002) (to be codified at 21 C.F.R. pt. 589).

368. Use of Materials Derived from Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,256 (July 14, 2004) (to be codified at 21 C.F.R. pts. 189, 700) [hereinafter FDA Food and Cosmetics Rule]. The FDA also proposed an additional rule containing recordkeeping requirements to aid the agency in enforcing that ban. Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle, 69 Fed. Reg. 42,275 (proposed July 14, 2004) (to be codified at 21 C.F.R. pts. 189, 700).

369. Federal Measures to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 42,288 (proposed July 14, 2004) (to be codified at 9 C.F.R. pts. 50-85) [hereinafter USDA/HHS BSE ANPR]. The USDA/HHS BSE ANPR requested public comment on whether the USDA's long awaited national cattle identification program should be voluntary or mandatory and on whether the FDA should amend the 1997 Feed Rule to remove SRMs from all animal feed, whether the FDA should require dedicated equipment for handling and storing feed to prevent cross-contamination, whether the FDA should prohibit the use of all mammalian and poultry protein in ruminant feed, and whether the FDA should prohibit the use of materials from dead and downer cattle in all animal feed. *Id.*

another, ground along with meat from many different states in still another state, and sold and cooked in yet another state, the market incentive is not especially powerful.³⁷⁰ The unfettered marketplace is, in the words of a National Academy of Sciences Report, “unlikely to be an effective producer of safety because of the commodity nature of most food transactions, as well as the difficulty of connecting foodborne illness with particular eating occasions or individual foods.”³⁷¹

Similar obstacles to imposing accountability for negligent conduct reduce the incentive provided after-the-fact by the common law of torts.³⁷² Although the probability of any human being contracting vCJD from meat containing brain or spinal material is quite low, the consequences are very high. The unique nature of the disease could make the link between the disease and consumption of contaminated meat fairly easy to prove, but the connection between a victim’s disease and a particular meat producer may be exceedingly difficult to establish, especially in the absence of an animal tracking system. The potential for tort liability may act as a somewhat stronger incentive than pure market forces to keep food free of materials that may contain mad cow prions, but it is still not an especially powerful one.

Rather than reacting after the fact to foodborne disease outbreaks, Congress mandated that the USDA and the FDA take proactive action to protect the public health.³⁷³ As described above, both agencies took some precautionary steps to fulfill that responsibility prior to December 2003. They erected three regulatory “firewalls” to protect the public from mad cow disease: 1) the USDA’s import controls, 2) the FDA’s feed restrictions, and 3) the USDA’s BSE surveillance program. In the wake of the discovery of the Mabton mad cow, the USDA’s leadership offered strong assurances that the protections already in place were adequate to protect the public health, but it promised to do even more. To put the public’s mind at ease, in January 2004 the USDA announced that it had erected two additional firewalls aimed directly at protecting human health, rather than the cattle industry: a ban on the use of downer cattle in human food and SRM restrictions. In addition, the FDA promised to enhance the

370. See Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 WILLAMETTE L. REV. 411, 443 (1997) (discussing how the lawsuits that were filed in the wake of the E.coli outbreak in Seattle in 1993 serve as an example of how little civil action suits do to change corporate behavior).

371. SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 16.

372. See *id.* (noting that “personal injury litigation provides only a weak incentive for food companies to improve their food safety efforts” because of a “low probability that they will be sued for foodborne illness, the damages they would pay are likely to be small, and there is a low probability that such litigation would have negative public relations consequences”).

373. See *infra* Part IV.A.6.

feed restriction firewall by eliminating some of the original exemptions.

The reality of the current regulatory regime, even as supplemented by the USDA's January 2004 actions, belies these bold assurances. Although the Administration's initial reactions to the Mabton mad cow reflected solid advance planning and a sensible approach to ensuring that meat from future cows identified for BSE testing did not enter the food supply before completion of the testing, it undertook very little in the way of genuine substantive reform to a hobbled regulatory regime. Unfortunately, none of the frequently alluded to "firewalls" provide the precautionary protections that are implied in the "firewall" metaphor and demanded by the meat safety laws. If they are firewalls at all, they are flimsy firewalls and much in need of repair or replacement.

A. The Import Restriction Firewall

The first regulatory firewall erected was the USDA restriction on the importation of ruminants and certain ruminant products from countries where BSE is known to exist.³⁷⁴ The importation of the Mabton cow from Alberta did not technically breach this firewall, however, because it occurred prior to the May 2003 discovery of mad cow disease in Canada. The importation firewall was significantly jeopardized on April 19, 2004, when the USDA quietly informed import brokers that it would immediately lift the ban on imports of all edible beef products from Canadian cattle under thirty months of age, including processed meat that contained bones and offal.³⁷⁵ A USDA official told the media that the modification of the import restrictions was intended to "test the U.S. industry's reaction."³⁷⁶ At least one segment of the industry reacted very strongly when the Ranchers Cattlemen Action Legal Fund (R-CALF) persuaded a court to issue a

374. See Press Release, USDA, Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004) (describing the three "firewalls"); see also *USDA BSE Overview*, *supra* note 30, at 7; HCRA BSE REPORT, *supra* note 30, at 22.

375. See Press Release, USDA, Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted (Aug. 8, 2003), available at http://www.usda.gov/wps/portal/!ut/p/s.7_0_A/7_0_1OB/.cmd/ad/.ar/sa.retrievecontent/.c/6_2_1UH/ce/7_2_5JM/p/5_2_4TQ/_th/J_2_9D/_s.7_0_A/7_0_1OB?PC_7_2_5JM_contentid=2003%2F08%2F0281.html (stating that the government had weighed the risk in light of international standards, an exhaustive epidemiological investigation into Canada's preventive measures, and additional risk mitigation measures Canada adopted in response to its recent BSE case); see also Dawn Walton, *U.S. Lifts Ban on Canadian Beef*, MONTREAL GLOBE & MAIL, Apr. 19, 2004, at A7 (stating that as a result of the announcement, the Canadian beef industry will be "poised to regain \$170 million in annual exports"); Becky Bohrer, *USDA Blocked on Canada Beef Imports*, THE WICHITA EAGLE, Apr. 26, 2004, available at <http://www.kansas.com/mld/kansas/business/8526162.htm> (reporting the USDA had previously lifted the ban for imports that, in the Department's opinion, had a very low risk of BSE).

376. Walton, *supra* note 375.

preliminary injunction against the rescission of the import ban.³⁷⁷ The court found it “troubling” that the USDA would quietly rescind important aspects of its previous order when it was at the time engaged in a public rulemaking to determine whether to do just that.³⁷⁸ This reaction was more than enough to cause the USDA to back down and rescind its previously unannounced policy directive.³⁷⁹

In connection with the litigation, however, R-CALF uncovered that APHIS had covertly allowed U.S. meatpackers to breach the firewall altogether by importing 33 million pounds of beef from Canada between September 2003 and May 2004, despite Secretary Veneman’s August 2003 announcement that she was extending the May 2003 ban on such meat.³⁸⁰ Although the border was “officially” closed to beef imports from Canada, APHIS officials had quietly granted individual “exemptions” to the ban for meat processors that agreed to certain “mitigations,” including agreeing to accept only cattle less than thirty months old and agreeing to remove SRM material before processing the meat.³⁸¹ After receiving a severe bipartisan grilling from several congresspersons, the USDA acknowledged that “the process and our failure to announce some of these actions were flawed.”³⁸²

B. The Feed Restriction Firewall

The 1997 FDA Ruminant Feed Rule,³⁸³ the most important of the three original firewalls from the human health perspective, is faulty for two reasons: 1) the restrictions contain too many exceptions that are arguably too risky in a country in which BSE has now been detected, and 2) the restrictions are, in any event, not adequately enforced.

377. Bohrer, *supra* note 375.

378. Marc Kaufman & Cindy Skrzycki, *USDA Rescinds Policy Allowing Sale of Canadian Beef*, WASH. POST, May 6, 2004, at A2 (reporting on the USDA reversal in response to the criticism from U.S. District Judge Richard F. Cebull sitting in Billings, Montana).

379. *See id.* (citing a USDA spokesperson who admitted, “we probably could have been more clear in our administrative steps”).

380. *See* Marc Kaufman, *USDA Allowed Canadian Beef In Despite Ban*, WASH. POST, May 20, 2004, at A1 (reporting on the controversial importation uncovered by the litigation).

381. *Id.*

382. Marc Kaufman, *USDA Says It Erred on Beef*, WASH. POST, May 22, 2004, at A3.

383. *See* Guy Gugliotta & Christopher Lee, *Mad Cow Alerts Began Years Ago*, WASH. POST, Dec. 27, 2003, at A6 (quoting to the HCRA Director for the proposition that the feed ban is “the main thing that prevents the spread”); *see also* USDA, Ron DeHaven, Remarks at the Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Release No. 0451.03 (Dec. 30, 2003), available at http://www.texasattle raisers.org/tscra2003/BSE_Info_Page/USDA_briefing_12.30.03.htm (calling the feed ban “the most important thing we can do in terms of preventing the spread of the disease animal to animal is through an effective feed ban”).

1. Incomplete Feed Restrictions

The 1997 Feed Rule prohibited protein derived from all mammalian tissues in ruminant animal feed, but it provided gaping exceptions for blood and blood products, gelatin, plate waste, milk products, and any product whose only mammalian protein consisted entirely of pig or horse protein.³⁸⁴ Under the rule, cattle protein may be fed to pigs and chickens, which can in turn be rendered into cattle feed.³⁸⁵ Litter from poultry farms may be fed to cattle, despite the fact that it could easily contain significant amounts of uneaten poultry feed made from protein derived from ruminants.³⁸⁶ The International Advisory Panel that Secretary Veneman appointed to provide advice in light of the discovery of the Mabton mad cow bluntly concluded that “the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent.”³⁸⁷

Instead of promulgating an interim final rule eliminating the risky exemptions, the FDA, five months later, issued a second Advance Notice of Proposed Rulemaking, soliciting additional comments.³⁸⁸ By putting off the promised additional regulation,³⁸⁹ the FDA preserved the rendering market for downer cattle, most of which must now be condemned under the USDA’s SRM Rule.³⁹⁰ Once the promised restrictions go into effect, rendering downer cows into protein via the “tanking” condemnation option may no longer be economically viable, because fewer markets will be available for the rendered protein. It appears that the poultry industry also played a role in the FDA’s reluctance to deliver its promised regulations. Adding poultry litter to cattle feed may pose a high risk of transferring uneaten prion-laden chicken feed to cattle, but it solves a messy disposal problem for the poultry industry. The poultry industry strongly opposed the idea of banning chicken litter from cattle feed, and it apparently convinced the FDA that fertilizer markets could not easily adsorb millions of pounds of poultry litter.³⁹¹

384. 21 C.F.R. § 589.2000(a)(1) (1997); *see also* HCRA BSE REPORT, *supra* note 30, at 43; RHODES, *supra* note 35, at 233 (detailing the list of exempted materials and describing the materials as “disturbing compromises”).

385. *See* Drew, *supra* note 240 (demonstrating one of the regulation’s “glaring loopholes”).

386. *See supra* Part III.B.1; *see also* Stephanie Simon, *Mad Cow Case Casts Light on Beef Uses*, L.A. TIMES, Jan. 4, 2004, at A1 (describing a scenario in which the ban on cattle eating cattle could be circumvented); Wald, *supra* note 5 (citing former USDA official Dr. Linda Detwiler’s concern for the proposition that the prospects of evading the feed ban make the rule inadequate).

387. *International Panel Report*, *supra* note 340, at 9.

388. USDA/HHS BSE ANPR, *supra* note 369.

389. *See supra* Part IV.B.

390. *See infra* Part V.D.

391. Chris McGann, *Hot Debate Over Chicken Dung In Cattle Feed*, SEATTLE POST-INTELLIGENCER, Apr. 22, 2004, at B1 (demonstrating the difficulty in disposing of poultry litter in a manner that keeps it away from cattle).

2. Poor Enforcement of Feed Restrictions

The FDA's spotty record of enforcing its feed restrictions is especially disturbing in light of the fact that poor enforcement of animal feed regulations very similar to those currently in place in the United States greatly exacerbated the mad cow disease outbreak in the U.K.³⁹² Although there are indications that the FDA's enforcement record has improved,³⁹³ it is not at all clear that the agency has achieved the degree of compliance necessary to ensure against the spread of mad cow disease in the United States.

Soon after the Mabton mad cow was discovered, the FDA told the press that the feed manufacturing industry had achieved a ninety-nine percent compliance rate.³⁹⁴ On closer examination, however, it turned out that the agency's conclusion was based upon an inspection of company records and not on any independent testing of actual feed at feed manufacturing establishments, dairies, and ranches.³⁹⁵ This was to some extent unavoidable because there are no FDA-approved chemical tests that can distinguish banned ruminant proteins from allowable swine proteins.³⁹⁶ The FDA's claim of ninety-nine percent compliance with its feed restrictions is also inconsistent with a March 2004 survey of the FDA's records of inspections of California feed companies showing that about

392. Sandi Doughton, *Should U.S. Follow U.K. on Mad Cow?*, SEATTLE TIMES, Feb. 5, 2004, at A3 (likening the 1997 U.S. feed ban to similar U.K. regulations from 1988 that failed to stop the U.K. epidemic, according to Roy Smith of the U.K. Department for Environment, Food and Rural Affairs).

393. The April 2004 update on FDA and state enforcement activities under the 1997 Feed Rule reported that at the most recent inspection, only 11 of 2,474 inspected firms handling restricted feed materials were guilty of OAI violations, a classification that includes "significant objectionable conditions or practices" that warrant regulatory sanctions in order to address lack of compliance. Press Release, FDA, Update on Ruminant Feed (BSE) Enforcement Activities, CVM Update (Apr. 22, 2004) [hereinafter FDA Feed Rule Enforcement Update, 4/22/04], available at <http://www.fda.gov/cvm/index/updates/bse42004.htm>. At the same time, 80 firms were classified as VAI, a classification that occurs when "objectionable conditions or practices" were found that "do not meet the threshold of regulatory significance, but do warrant advisory actions" taken on a voluntary basis. *Id.*

394. Vanessa Ho, *FDA Blasted over Past Enforcement of Feed Ban*, SEATTLE POST-INTELLIGENCER, Dec. 27, 2003; see also Guy Gugliotta & Dan Morgan, *Inspection Practices Examined*, WASH. POST, Dec. 25, 2003, at A16 (quoting FDA Deputy Commissioner Lester M. Crawford as stating that implementation of the 1997 feed ban had taken some time, but that compliance now stands at ninety-nine percent).

395. Ben Feller, *Mad Cow Case Renews Feed Testing Debate*, ASSOCIATED PRESS, Dec. 29, 2003, available at <http://www.bradenton.com/mld/bradenton/news/7589471.htm>.

396. See Doughton, *supra* note 392 (underscoring the difficulty the FDA faces since it lacks a test to distinguish banned cattle proteins from legal gelatin or pig proteins). Scientists at the University of California at Davis have recently reported that they have developed a species specific test for animal protein in cattle feed that could solve this problem in the future. Jim Evans, *UCD Has Quicker Feed Test*, SACRAMENTO BEE, Feb. 24, 2004, at D1 (announcing news of the DNA-based test); see also *Test May Provide Safeguard Against Mad Cow* (ABC News, KERO-TV 23 television broadcast, Mar. 10, 2004).

forty percent of all California feed manufacturing companies and over one-half of all feed-handling establishments nationwide had not been inspected at all since the end of 2002.³⁹⁷

State agencies that are under contract with the FDA play a major role in the enforcement of the 1997 Feed Rule, conducting more than seventy percent of all inspections under that rule.³⁹⁸ The FDA cannot effectively evaluate the adequacy of the state inspection programs, however, because it lacks authority to “require that all states track and report to FDA enforcement actions taken.”³⁹⁹ The FDA has recently received a hefty increase in funding for enforcing its Ruminant Feed Rule, and it has promised to undertake 2,800 inspections of renderers, protein blenders and feed mills in 2004 and to work with state agencies to fund an additional 3,100 contract inspections.⁴⁰⁰ Whether these additional resources will improve the FDA’s enforcement record remains to be seen.

C. The Surveillance Firewall

Although FSIS is the agency within the USDA responsible for promulgating and implementing the BSE regulations, an entirely separate agency—APHIS—is responsible for conducting the BSE surveillance program. This split in responsibilities has a great potential for miscommunication and disputation that can only hinder effective overall implementation of the USDA’s mad cow program. APHIS has historically taken the position that its testing program is an animal health surveillance program designed to detect a one-in-a-million incidence of mad cow in the cattle population, and it is not a food safety program designed to protect the public health of the sort that FSIS implements.⁴⁰¹ Consequently, in the nine years prior to 2003, APHIS tested only about 30,000 downer animals for BSE.⁴⁰²

397. See Jon Ortiz, *Feed Checks Falling Short*, SACRAMENTO BEE, Mar. 28, 2004 (reporting that perhaps more troubling was the fact that almost 20% of the facilities designated by the FDA as “high priority” had not been inspected during that same period).

398. See FDA Feed Rule Enforcement Update, 4/22/04, *supra* note 393, at 1 (finding that state agencies perform around 70% of all inspections under the 1997 Feed Rule); see also 2002 GAO MAD COW REPORT, *supra* note 226, at 22 (reporting that state agencies conduct more than 80% of all inspections under the 1997 Feed Rule).

399. See 2002 GAO MAD COW REPORT, *supra* note 225, at 49 (noting also that states have differing levels of inspection and enforcement authority under state laws).

400. Crawford Testimony, *supra* note 11, at 25.

401. See Donald G. McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, N.Y. TIMES, Dec. 26, 2003 at A1 (quoting Dr. Ron DeHaven, the USDA’s chief veterinarian: “It is ‘a surveillance system, not a food safety test.’”).

402. See *supra* Part III.A.2.b.

1. Problems with the USDA's Expanded Testing Program

Public pressure and strong advice from scientists outside the USDA forced APHIS to initiate a one-time testing program of as many downer animals as possible plus 20,000 healthy looking animals of more than thirty months in age.⁴⁰³ Even the greatly expanded program, however, suffers from several critical weaknesses that will greatly limit its potential for determining the true incidence of mad cow disease in the U.S. cattle population.

First, the program put too much emphasis on downer cattle, despite the well-known fact that not all cattle suffering from BSE are nonambulatory or exhibit clinical signs of BSE infection.⁴⁰⁴ The expanded testing program will test an additional 20,000 apparently healthy older cattle, but that remains an exceedingly small sample. A doctor for a prominent public interest group concluded that the expanded program “seems to be designed to give the public and would-be importers of American cattle false assurance.”⁴⁰⁵

Second, the cattle that are selected will be drawn from a population that is not representative of the entire cattle population. FSIS's sensible ban on the use of downer cattle for human consumption complicated the implementation of the surveillance program. Since downer cattle will no longer be presented for slaughter at commercial slaughterhouses, the APHIS surveillance program will have to focus on rendering establishments, local veterinarians, and the producers themselves to locate downer cattle.⁴⁰⁶ Because the program remains entirely voluntary, however, APHIS will not have access to cattle from producers who decline to participate, and it will have only limited access to cattle at rendering establishments.⁴⁰⁷ Although the Department plans to use some of the \$70 million re-allocated to the BSE surveillance program for providing

403. See Press Release, USDA, Veneman Announces Expanded BSE Surveillance Program, Press Release No. 0105.04 (Mar. 15, 2004), available at <http://www.usda.gov/Newsroom/0105.04.html> (announcing details for new BSE surveillance effort); see also Hileman, *supra* note 231, at 22 (“Most of the animals to be tested will be chosen from the estimated 446,000 downer cattle, but 20,000 randomly chosen, healthy looking, older animals will also be sampled.”).

404. See McNeil, *supra* note 338 (noting that “some experts question the assumption that only downers are at risk, since many healthy-looking animals in Europe have tested positive”).

405. Steve Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, UNITED PRESS INTERNATIONAL, Mar. 16, 2004, available at <http://www.organicconsumers.org/madcow/lacking31604.cfm> (quoting Dr. Peter Laurie of the consumer group Public Citizen).

406. Sandi Doughton, *U.S. to Expand Mad-Cow Testing*, SEATTLE TIMES, Mar. 16, 2004, at B1; see also Denise Grady, *9 Cows Linked to Mad Cow Inquiry Have Been Found*, N.Y. TIMES, Jan. 1, 2004, at A16 (quoting chief USDA veterinarian Ron DeHaven).

407. See *Critics Say Voluntary Mad Cow Testing Doesn't Equal Surveillance*, ASSOCIATED PRESS, Mar. 18, 2004, available at <http://www.newstribune.com/articles/2004/03/18/business/0318040051.txt> (discussing problems with a completely voluntary system).

financial incentives to owners of downer animals to present those animals for testing,⁴⁰⁸ there will still be a strong incentive on their part to avoid testing.

Third, the program will not be “scientific” in any rigorous sense because it is incapable of taking a random selection of the incomplete universe of cattle from which it is able to draw. APHIS’s extremely limited BSE surveillance program has historically been conducted in an entirely unsystematic way that was by no means random.⁴⁰⁹ To a large extent, this is attributable to the fact that the program is entirely voluntary. For example, after expanding the program to 20,000 downer animals in 2002,⁴¹⁰ the USDA had such difficulty persuading companies to participate in the voluntary program in the Northwest that it failed to meet its goals for that region.⁴¹¹ Worse, once the discovery of the Mabton mad cow was reported in the media in late December 2003, voluntary participation plummeted across the country so that nationwide testing declined in January 2004 to

408. See Doughton, *supra* note 406 (discussing the cost of testing and the benefits of using the newly allocated resources to help farmers comply with the program).

409. See Shannon Dininny, *Mad Cow Surveillance System Criticized*, BOSTON GLOBE, Mar. 15, 2004 (discussing the limited nature of the program), at http://www.boston.com/business/articles/2004/03/15/mad_cow_surveillance_system_criticized; see also McNeil, *supra* note 338 (announcing that critics believe the current testing program is unscientific because so many plants are not included); Steve Mitchell, *No Mad Cow Tests in Washington*, UNITED PRESS INTERNATIONAL, Jan. 15, 2004 (noting various flaws in the surveillance program), available at <http://www.organicconsumers.org/madcow/mitchell11404.cfm>.

410. In an 18-page affidavit prepared for a House committee investigation, Thomas A. Ellestad, one of the principle operators of Vern’s Moses Lake Meat, Inc., explained how the APHIS BSE Surveillance Sampling Program has worked in the real world. After one of Vern’s largest customers was publicly attacked by animal rights groups, the customer adopted a no-downer policy and demanded that its suppliers do so as well. Consequently, in February 2003, Vern’s implemented a “humane” policy in which it no longer accepted downer cattle for slaughter. Thomas A. Ellestad, Affidavit (Feb. 9, 2004), at 3, available at http://www.house.gov/reform/min/pdfs_108_2/pdfs_inves/pdf_health_usda_mad_cow_feb_12_attach.pdf [hereinafter Ellestad Affidavit]. In June 2003, APHIS offered to pay Vern’s \$10.00 apiece for samples from the brains of up to 1,000 downer cattle. Because Vern’s no longer accepted downer cattle, it declined the proffered contract. USDA officials, however, pressed Ellestad to accept the contract because the USDA was having difficulty in that region obtaining the number of samples required for the surveillance program. After much negotiation, Vern’s signed an amended contract that did not require the samples to be from downer animals. Since the contract did not specify any sampling protocol, Vern’s employees selected the brains to be sampled for the APHIS program from among the ambulatory cattle processed at the plant. *Id.* at 2. Testimony from FSIS inspectors suggests that APHIS commonly allows the slaughterhouses to choose the animals to be tested. See Doughton, *supra* note 338 (quoting USDA inspector Paul Carney as stating: “We just trust the industry to pick out the most suspect cows from their own herds, then we test those and tell the public there is no mad cow.”).

411. See Sandi Doughton, *Number Of Mad-Cow Tests In NW Didn’t Reach Federal Agency’s Goal*, SEATTLE TIMES, Feb. 24, 2004, at A1 (announcing that the “[f]ederal government fell short of its goal for mad-cow tests last year in the Northwest”). FSIS inspectors can also sample the brains of suspect cattle and send those samples to APHIS laboratories for testing, but only if APHIS agrees to accept them. See *infra* Part V.C. However, these samples are not random. To the extent that slaughterhouses have refused to participate, cattle from the herds sent to those slaughterhouses remain untested unless fortuitously selected by an FSIS inspector. *Id.*

1,608 animals from 3,064 in December 2003.⁴¹²

The newly expanded program will test 20,000 apparently healthy cattle greater than thirty months old, but these animals will be selected from the forty slaughterhouses that process most of the older dairy cattle.⁴¹³ The Department would not reveal the names of the companies because it feared that it would make the companies less cooperative.⁴¹⁴ Although the USDA's chief veterinarian assured the press that the animals would be randomly selected, he did not say whether APHIS would test cattle over the objections of a slaughterhouse in order to ensure the statistical validity of the tests.⁴¹⁵ Even a random selection from a limited universe of only 40 out of 700 slaughterhouses will not necessarily represent a random selection of the U.S. cattle population. Even if they were chosen randomly, testing only 20,000 of the 35 million animals slaughtered per year is probably not sufficient to yield statistically significant results.⁴¹⁶

Fourth, there are several disturbing indications that APHIS has adopted a "see-no-evil" approach to administering its surveillance program in the past, and there is little indication that the agency plans to abandon that approach in the future. Within a week after confirming that a mad cow had been slaughtered at the Vern's Moses Lake facility, APHIS ordered the facility to discontinue all sampling of brains for BSE testing.⁴¹⁷ If one or more of the dairy farms and producers that were sending cattle to Vern's for slaughter were harboring BSE-positive herds, the "scientific" response would surely have been to expand testing to include as large a sample of the cattle being slaughtered at that facility as possible to determine the extent of the mad cow outbreak in that geographical area. The media reported soon thereafter that APHIS officials in Washington State were not testing any milk cows from the same region as the Mabton mad cow when they were sold for slaughter.⁴¹⁸

APHIS's apparent "see no evil" policy is more strongly evidenced by its response to a recently reported BSE testing request from a Texas FSIS

412. Dininny, *supra* note 409 (citing critics' arguments that the U.S. system failed before the mad cow announcement in December).

413. See Doughton, *supra* note 406 (discussing elements of the selection process for testing).

414. See Steve Mitchell, *No Mad Cow Tests at Texas Firm in 2004*, UNITED PRESS INT'L, May 14, 2004 (quoting Ron DeHaven, Chief Veterinarian, USDA, who discussed the reasoning behind keeping plant names confidential).

415. See Doughton, *supra* note 406 (noting the USDA's new authority to require facilities to participate in testing).

416. See Jerry Hagstrom, *Senator Challenges USDA Mad Cow Testing Plan*, CONGRESS DAILY, May 11, 2004 (noting Senator Harkin's comment that some scientists and veterinarians believe that 20,000 may be insufficient to yield statistically valid conclusions in a very large sub-population of apparently healthy cattle).

417. Ellestad Affidavit, *supra* note 410, at 3-11.

418. Ray Rivera, *Hunt for Infected Cows Leaves Out "Slaughter Auctions,"* SEATTLE TIMES, Jan. 15, 2004, at A1.

inspector. When a cow at the San Angelo facility staggered and collapsed, the FSIS veterinarian at the plant determined that it should be tested for BSE and contacted the Regional Office of APHIS in Austin.⁴¹⁹ The APHIS regional director, for no stated reason, determined that testing would not be required and ordered the animal not to be held for testing.⁴²⁰ The cow was then rendered into feed for pigs without ever being tested for BSE.⁴²¹ The twelve year old animal had consumed cattle feed manufactured prior to the FDA's 1997 feed restrictions, and it might very well have contracted mad cow disease during its earlier years.⁴²² Since the animal's brain was not preserved for testing, the question of whether the cow was in fact BSE-positive will never be answered.⁴²³

Finally, although the desirability of a universal testing program for all cattle or all cattle above a prescribed age is a very controversial topic, the USDA has adamantly rejected any sort of universal testing approach, even of the subcategory of animals more than thirty months old, despite its adoption in several other countries that have experienced mad cow outbreaks.⁴²⁴ Given its failure to demand even random testing, the

419. Richard Cowan, *USDA: Mad Cow Testing Procedure Violated in Texas*, REUTERS, May 3, 2004, at http://www.nodowners.org/media_reuters4.htm.

420. Donald G. McNeil, Jr., *Calls for Federal Inquiry Over Untested Cow*, N.Y. TIMES, May 6, 2004, at A28; see also Steve Mitchell, *Only 3 Mad Cow Tests Done At Texas Firm*, UNITED PRESS INT'L, May 4, 2004, at <http://washingtontimes.com/upi-breaking/20040504-062108-3791r.htm>.

421. Hileman, *supra* note 231, at 24.

422. See Richard Cowan, *FDA Links Condemned Texas Cow, Pre-Ban Type Feed*, REUTERS, May 6, 2004 (reporting on the possible link between "a condemned cow in Texas and eight-year-old animal feed that was not protected against mad cow disease").

423. See Suzanne Gamboa, *Federal Officials OK Texas Cow Material For Swine Feed*, ASSOCIATED PRESS, May 4, 2004 (stating that the cow was destroyed before it could be tested), at http://foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum=1015301; see also Steve Mitchell, *USDA Vet: Texas Mad Cow Breach Not Unique*, UNITED PRESS INT'L, May 4, 2004, at <http://washingtontimes.com/upi-breaking/20040504-012834-2365r.htm>. The media later discovered that although the San Angelo plant was the 18th largest slaughterhouse in the United States, only 3 cows from that facility (all of which were downers) had been tested for mad cow disease out of about 350,000 cattle slaughtered at the plant during the past two years. Mitchell, *supra* note 420. The USDA explained that BSE tests had not been performed at the plant in recent months because the plant no longer accepted downer cattle. Mitchell, *supra* note 414. The USDA attempted to quell the public relations storm that resulted from these revelations by immediately (and very publicly) issuing a brief memorandum to all APHIS regional directors reiterating that it was official APHIS policy "to sample all cattle condemned by FSIS on ante mortem inspection for exhibiting signs compatible with central nervous system diseases, regardless of age." Memorandum from John R. Clifford and William Smith to VSMT, Regional Directors/AVICs, Veterinary Services, *Policy statement regarding BSE sampling of condemned cattle at slaughter plants—for immediate implementation* (May 5, 2004), available at <http://disc.server.com/discussion.cgi?disc=167318;article=1351;title=CJD%20WATCH>. On the next day, however, USDA's Dallas district office issued a gag order forbidding all Texas employees from discussing the San Angelo cow with the press and instructing them to refer all inquiries to the USDA Congressional Public Affairs office. Steve Mitchell, *USDA Orders Silence On Mad Cow in Texas*, UNITED PRESS INT'L, May 11, 2004, at <http://www.organicconsumers.org/madcow/silence51104.cfm>.

424. Donald G. McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, N.Y. TIMES,

Department's invocation of "sound science" in this context is unconvincing. Science is generally hungry for data because every additional valid data point can enhance understanding. USDA trade advisor David Hegwood probably came closer to the mark when he maintained that it was "scientifically not necessary, not justified and we don't want to go down that road because it diverts resources from where we really need to be putting them in doing surveillance and taking other risk mitigation measures for this disease."⁴²⁵ The question of whether an additional test is "scientifically necessary" is not the same as whether it is *desirable* from a scientific perspective. The diversion of resources is not strictly a scientific question at all. To the extent that the resources that go into BSE testing are not available for other scientific enterprises, universal testing may detract from the pursuit of science in a very limited way, but no one has suggested that the monies expended on additional BSE testing would otherwise be devoted to scientific research. It is much more likely that such dollars would go toward increasing the wealth of beef industry shareholders or perhaps toward keeping U.S. beef prices low. It is, frankly, silly to suggest that the pursuit of science will be significantly hampered by universal BSE testing.

Devoting additional scientific resources to studying the incidence of mad cow disease, which can be debilitating to the beef industry and to human beings who contract vCJD, would not be wholly out of order. Given the huge uncertainties that attend the scientific understanding of how BSEs are transmitted, any additional data point in the otherwise woefully incomplete data set on the incidence of BSE in the United States is undeniably desirable from a scientific perspective.⁴²⁶ Dropping one more object from the Leaning Tower of Pisa to test the theory of gravitation may be scientifically senseless. Dramatically increasing testing for mad cow disease in a huge population of cattle that has not historically been carefully monitored is clearly supported by "sound" scientific considerations.

The trend in other countries that have experienced mad cow outbreaks has been to increase BSE testing dramatically to the point of universal testing of all slaughtered cattle or universal testing of cattle beyond a prescribed age. Japan requires testing of all cattle upon slaughter and prior

Dec. 26, 2003, at A1 (quoting Dr. Ron DeHaven).

425. Charles Abbott, *Test All Cattle To Be Safe From Mad Cow-Nobelists*, REUTERS, Jan. 28, 2004, at http://foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum=1012739.

426. See Nikiforuk, *supra* note 64 (quoting Professor David Westaway, a molecular biologist and prion specialist at the Centre for Research in Neurodegenerative Diseases at the University of Toronto, who stated that "tests are better than no testing").

to release for human consumption.⁴²⁷ In 2000, the European Union (EU) mandated testing of all cattle over thirty months of age for BSE.⁴²⁸ The EU also requires testing of all downer cattle of greater than twenty-four months in age.⁴²⁹ Germany, Italy, and France all test for BSE in all cattle older than twenty-four months prior to slaughter.⁴³⁰ This amounts to about one in every four animals slaughtered.⁴³¹ Thus, France tests more cows in one week than the United States has tested in a decade.⁴³²

Not surprisingly, universal testing has resulted in the detection of more mad cows. For example, of the more than 1.6 million animals that have been tested in Italy, 103 have tested positive for BSE.⁴³³ Although this may be disturbing to the cattle industry, it has yielded important scientific information that could be useful in preventing the further spread of mad cow disease. Because Italy tests all animals over thirty months of age for BSE prior to slaughter, Italian scientists detected two cases of mad cow disease in healthy looking cows and further discovered that the strain of BSE that infected the cows was very similar to the TSE that causes sporadic CJD in humans.⁴³⁴ This represents a real, if highly disturbing, contribution to the scientific understanding of TSEs.

The fundamental problem with the USDA's approach to BSE surveillance is the fact that it views its primary mission as one of protecting animal health and not human health. In defending the APHIS BSE surveillance program, an APHIS spokesperson was explicit about this: "APHIS is not a human-health agency. APHIS is an animal-and-plant agency."⁴³⁵ The APHIS testing program may be reasonably effective as a surveillance program to determine the incidence of mad cow disease in the

427. See Sandra Blakeslee, *Mad Cow Disease in the United States: Expert Warned that Mad Cow was Imminent*, N.Y. TIMES, Dec. 25, 2003, at A1 (explaining that Japan's testing has led them to find the disease in young asymptomatic animals).

428. See generally *Community Legislation on BSE*, at http://europa.eu.int/comm/food/fs/bse/bse15_en.pdf; *Frequently Asked Questions About BSE*, at http://europa.eu.int/comm/food/food/biosafety/bse/m04_113_en.pdf.

429. *Id.*

430. See generally *TSE Forum, Frequently Asked Questions*, at http://www.tse-forum.de/tse_forum/englisch/offentlich/start_offentlich.htm (explaining how Germany has added restrictions, now requiring that all slaughtered cattle older than 24 months be examined by a meat hygiene examination). Cf. *Mad Cow Cases Increase to 62 in Italy*, XINHUA GEN. NEWS SERV., Apr. 30, 2002, available at LEXIS, News Library, XINHUA File; French Agriculture BSE webpage, at <http://www.agriculture.gouv.fr/esbinfo/esbinfo.htm> (France) (last visited Mar. 21, 2005).

431. Sandra Blakeslee, *Jumble of Tests May Slow Mad Cow Solution*, N.Y. TIMES, Jan. 4, 2004, §1, at 10.

432. *Id.*

433. Donald G. McNeil Jr., *Research in Italy Turns Up a New Form of Mad Cow Disease*, N.Y. TIMES, Feb. 17, 2004, at A9.

434. *Id.*; see also Debora MacKenzie, *New Form Of Mad Cow Disease Found*, NEW SCIENTIST, Feb. 17, 2004, available at <http://www.newscientist.com/article.ns?id=dn4689>.

435. Diedra Henderson, *USDA's Selective Screens Aren't Enough, Say Some Firms, Scientists*, DENVER POST, May 31, 2004, at 1E.

U.S. cattle population, but it is not driven by concerns for protecting human health from vCJD. Unless some fundamental problems with the program are fixed, however, merely expanding the number of animals tested for a brief interval will not yield an adequate testing program.

2. *The USDA's Inexplicable Prohibition on Privately Conducted Testing*

The USDA justifies its adamant refusal to allow companies voluntarily to engage in universal testing of their cattle at their own expense on the ground that universal testing is not “sound science.”⁴³⁶ As discussed above, scientific considerations simply cannot explain the Department’s obstinate opposition to an effort to gather more information about a little understood phenomenon. The USDA may, in its wisdom, have decided that universal testing would be a grossly inefficient use of its limited resources. It is, however, paternalistic in the extreme for the USDA to be so confident in its assessment that it is unwilling to abide by the possibility that Japanese consumers (or American consumers for that matter) might rationally decide that they would prefer to pay a little extra for the additional assurance that testing brings to their dinner tables.

One USDA official has argued that if a private slaughterhouse conducting individual testing came up with a “false positive” reading and the word got out to U.S. trading partners, the current import restrictions could be extended and new restrictions imposed.⁴³⁷ The companies advocating universal testing, however, are willing to allow the USDA or some other agency to confirm the tests to ensure against false positives.⁴³⁸ This should put to rest any fears about false positive results.

Another fear expressed by USDA spokespersons is that a company engaged in universal testing would quietly destroy cattle that tested positive for BSE without reporting the positive test to the USDA.⁴³⁹ This objection is especially unconvincing for several reasons. First, until the USDA’s universal animal identification program becomes effective in one or more years, a cattle producer can already destroy suspicious cattle, whether or not they test positive. Second, the USDA could easily promulgate regulations or guidelines holding slaughterhouses engaged in universal testing accountable for all tested animals. Finally, and most importantly, it would seem vastly preferable to destroy BSE-positive cows, quietly or otherwise, rather than have them enter the human food supply because they had not been tested at all.

436. Hileman, *supra* note 231, at 25 (quoting USDA spokesperson Jim Rogers); *see also* Marc Kaufman, *Company's Mad Cow Tests Blocked*, WASH. POST, Apr. 16, 2004, at A1 (stating that APHIS will “stick to the science”).

437. *See* Simon, *supra* note 386 (quoting USDA spokesperson Jim Rogers).

438. *Id.* (quoting John Tarpoff of Gateway Beef).

439. *Id.* (quoting USDA spokesperson Jim Rogers).

In the final analysis, it appears that the real reason that the USDA is unwilling to allow companies to test their own cattle has much more to do with the economic well-being of the four huge companies that control eighty percent of the meatpacking market than with the efficiency with which the USDA or consumers allocate their resources.⁴⁴⁰ The larger companies, which primarily serve domestic markets, did not see any drop in demand for their products and could therefore keep prices steady while at the same time paying less to producers for cattle in markets depressed by reduced exports.⁴⁴¹ They no doubt understood that as soon as smaller competitors were able to reestablish export markets, the windfall profits they were deriving from depressed cattle prices would dry up.

The large companies and the trade association that they dominate also expressed fear that universal testing by any company would result in consumer pressure on larger companies to engage in universal testing.⁴⁴² The dominant companies in any industry are, of course, always concerned about innovative competitors,⁴⁴³ and the big five meat processors had every reason to be concerned about Creekstone Farms, which was founded by a former head of the American Meat Institute.⁴⁴⁴ One way to prevent “upstart” companies like Creekstone Farms from intruding into a comfortable market is to pressure the USDA to prevent them from testing every animal for BSE. As Creekstone Farms lays off employees and careens toward bankruptcy as a result of the USDA’s inexplicable stance,

440. Hileman, *supra* note 231, at 23 (quoting John Stewart, CEO of Creekstone Farms, as stating that the companies would not pass the extra 4 to 5 cents per pound cost to test beef onto the consumer, but would try to reduce profits or pass costs along to cattle producers).

441. Alwyn Scott, *For Some in Beef Industry, Mad-Cow Disease “Almost a Windfall,”* SEATTLE TIMES, Feb. 29, 2004 at A1, A12 (finding that, contrary to what one might expect after the discovery of a cow with BSE in Washington, slaughterhouses and meat packing plants increased their profits because of the drop in price for cattle intended for processing; that restaurants, retailers, and dairy farms have prices similar to or higher than before the BSE cow; and that the short supply of cattle due to high pre-BSE demand downplayed export losses).

442. The CEO of the National Cattlemen’s Beef Association complained that “[i]f you let one company step out and do that, other companies would have to follow.” Donald G. McNeil, Jr., *Niche Meatpacker Is Cut Off From Its Best Markets*, N.Y. TIMES, Apr. 18, 2004, at A14. *But see* Hileman, *supra* note 231, at 25 (quoting North’s Dakota agriculture commissioner as stating that Creekstone’s desire to test would not result in testing across the industry and worrying that the United States will lose its share of the Japanese market).

443. As noted by a spokesperson for the American Meat Institute in 2002:

If you ask the CEOs of the four largest beef companies, one concern that they have is the upstart companies that are coming into the business, the small regional new entries that are coming into the beef industry, who one day may have the agility, the acumen, and the competitive instincts to achieve the market share levels that the larger companies have today.

Boyle Interview, *supra* note 88, at 4.

444. *See* McNeil, *supra* note 442 (focusing on Creekstone Farms, which was forbidden by the USDA from testing for BSE, and its CEO, a former chairman of the slaughterhouse industry trade group, which alleges the big meat packers that control 80% of the industry lobbied the USDA to stop Creekstone Farms from testing its animals).

Australian beef producers are rapidly establishing themselves, perhaps inextricably, as the dominant force in Japanese meat markets.⁴⁴⁵

D. The Downer Cattle Firewall

Assuming that the recently promulgated prohibition on the use of non-ambulatory cattle in human food is adequately enforced, it represents a reasonable and long overdue precautionary requirement that will help protect human health. Several states had already banned the sale for human consumption of meat from downer cattle. Many of the large restaurant chains (e.g., McDonald's and Wendy's) had eliminated meat from downer cattle from their product lines, and in 2001 the USDA decided not to use meat from downer cows in its school lunch program.⁴⁴⁶ In the two years prior to 2004, Congress considered and both houses approved a ban on downer cattle, but the cattle industry persuaded the leadership of the House Agriculture Committee to block both pieces of legislation in Conference Committee.⁴⁴⁷

While the USDA action should help ensure that meat from downer cattle does not wind up on the dinner table, it will by no means ensure that human beings do not consume proteins from mad cows. First, mad cow disease is not limited to nonambulatory cattle or even to cattle displaying signs of CNS disorders.⁴⁴⁸ Second, it is not always easy to identify a downer animal.⁴⁴⁹ Interpretational questions will inevitably arise at the margins in

445. See *Beef Exports to Japan on the Rise*, Australian Broadcasting Corporation (ABC Online), June 10, 2004 (reporting that Australia supplies 90% of Japan's imported beef because of the ban on U.S. beef exports); see also McNeil, *supra* note 442 (detailing the increase in price from \$17 to \$42 per tongue due to the stoppage of U.S. exports to Japan because U.S. beef is not tested for BSE, while Australian beef is tested).

446. Johanna Neuman & Edwin Chen, *Hunt on to Trace Diseased Animal*, L.A. TIMES, Dec. 27, 2003, at A20 (discussing proposed bans of downed animals from the food supply and Congress's failed attempts to pass such legislation); see also Judy Pasternak, *Disease Heightens Beef Debate*, L.A. TIMES, Dec. 26, 2003, at A1 (detailing arguments for and against the market ban on downer cows).

447. See Wald, *supra* note 5 (mentioning Congress's attempts to pass the bill as part of an omnibus spending bill after repeated but failed attempts to get the downer cow ban bill out of committees). Ironically, the most recent Conference Committee action to delete a ban on the use of downer cattle in human food came on the very day that the Mabton mad cow was discovered. Pasternak, *supra* note 446.

448. See McNeil, *supra* note 229 (listing behavioral signs of brain damage, such as twitching, aggression, stumbling or nervous animals). Tests in Japan and Italy, for example, have found healthy appearing animals to be BSE-positive. *Id.*

449. There is, in fact, an ongoing debate over whether the Washington Holstein was a downer cow. Sarah Linn, *Man Who Says He Killed Mad Cow Challenges USDA*, SEATTLE POST-INTELLIGENCER, Feb. 3, 2004, at B1 (comparing the story of the man who killed the mad cow, who alleges that he shot the cow to prevent it from trampling other animals, to the USDA's report that the cow was injured and lying down). The owner of Vern's Moses Lake Meats and the individual who stunned the BSE-positive cow steadfastly maintain that it was able to stand and walk. *Id.* The USDA's Chief Veterinary Officer has conceded that it is possible for a nonambulatory animal to "recover ambulation" prior to slaughter. Shankar Vedantam, *U.S. Recalls Meat Linked To Washington Slaughterhouse*, WASH. POST,

determining the “downer” status of suspect animals.⁴⁵⁰ Third, a strict ban, without more, does not solve the problem of what to do with the downer cattle once they are condemned.⁴⁵¹ It is generally lawful to dispose of dead cattle by burying them so long as sufficient cover is provided,⁴⁵² and in rural areas an unlawful, but not highly risky, option is to leave downed cows by the side of an isolated stretch of road.⁴⁵³ Fourth, the USDA rule keeping nonambulatory cattle out of human food failed to require that brains from all such animals be tested for mad cow disease.⁴⁵⁴ Finally, the ban still allows downer cattle to be sold to renderers for processing into feed for nonruminants and other products where cattle protein may find its way into cattle feed.⁴⁵⁵

E. The SRM Restrictions Firewall

The SRM firewall was an attempt to protect human food from especially risky materials. Unfortunately, the recently promulgated SRM rule defines

Dec. 25, 2003, at A1.

450. For example, male offspring of dairy cattle that are sent to slaughter within days of birth may technically be “downers” because they are still unable to walk, but they carry a very low risk of transmitting mad cow disease. Elizabeth Weise, *Cattle Slaughter Rules Yield Few Easy Answers*, USA TODAY, Feb. 10, 2004, at 8D (explaining that newborns too weak to walk after attempts to warm them up and cattle that cannot rise again due to a torn tendon are considered downers because non-ambulatory cattle must be condemned under the new ban on using downer cattle in human food).

451. See Pasternak, *supra* note 446 (quoting a professor of veterinary medicine at the University of California, Davis, who wondered: “If you ban all downer cows from the food chain, now what are you going to do with them? Are you going to put them in pet food? Bury them all in a toxic waste dump? You can’t burn it because there are air-quality rules.”).

452. An overview of the Minnesota animal disposal rules relates that burying dead animals is a lawful option: Carcasses must be buried “five feet above the seasonal high-water table and covered with dirt. Sandy or gravelly areas or areas within 10 feet of bedrock should be avoided.” Minnesota Board of Animal Health, *Carcass Disposal*, available at www.bah.state.mn.us/animals/carcass%20disposal/carcass_disposal.htm (last updated June 14, 2004). The Minnesota regulations also mandate that “[a]ll sites should be clearly marked for worker safety . . . do not place in or near lakes, ponds, rivers, streams, wetlands, ditches or wells” and qualify their recommendations by saying “[l]arge facilities or operations with catastrophic losses should not use this method” Minnesota Board of Animal Health, *Burial*, available at <http://www.bah.state.mn.us/animals/carcass%20disposal/burial.htm> (last updated June 14, 2004). See generally Charles D. Fulhage, *Dead Animal Disposal Laws in Missouri* (providing that “onsite burial” is an “acceptable method[] of dead animal disposal” for animal carcasses, but recommending against it “due to the potential for water pollution”), available at <http://muextension.missouri.edu/xplor/envqual/wq0216.htm> (last visited Apr. 3, 2005). When it is employed, “dead animals shall be immediately covered with a minimum of 6 inches of soil and a final cover of a minimum of 30 inches of soil.” *Id.*

453. Shannon Dinenny, *Mad-Cow Likely to Force Higher Rendering Costs: Carcass disposal may be too costly for some farmers*, SEATTLE TIMES, Jan. 26, 2004, at B2 (detailing the discovery of dozens of dead cattle along rural Washington roadside).

454. See *Testing All Beef*, BOSTON GLOBE, Jan. 3, 2004, at A10 (noting that the failure to require testing for all downer cattle “forfeits a chance to monitor the pervasiveness of the disease”).

455. See *supra* Part IV.A.4.

“specified risk material” far too narrowly, and it includes “flexible” performance standards that give the operators of slaughterhouses and meat processing establishments far too much leeway in deciding how to comply with its requirements. Consequently, the meat industry has quietly elected to implement the SRM Rule through “prerequisite” programs that do not require FSIS approval, do not establish and monitor quantitative limits for the risky material in meat product, require little documentation, have a high tolerance for failure, allow companies to shift responsibility to downstream processors who may not have sufficient expertise or resources to do the job, and are ultimately not very likely to attain the much flaunted “zero-tolerance” goal that FSIS established in its regulations.

1. Insufficiently Broad Definition of “Specified Risk Material”

As described above, the regulations prohibit the use of “specified risk material” in human food, which, among other things, includes brain, skull, eyes, trigeminal ganglia, and spinal cord of cattle more than thirty months old, and tonsils and lower intestines of all slaughtered animals.⁴⁵⁶ Although the USDA’s conclusion that BSE “infectivity has been confirmed” in these materials is incontestable, the regulations contain a significant loophole for cattle less than thirty months old that is not well supported in the existing scientific literature. The age at which potential infectivity is sufficient to warrant regulatory action is a topic for legitimate scientific debate, but not enough is known about TSE to determine the outcome of that debate. Policy considerations must therefore play a prominent role in drawing any age-based regulatory line.

BSE has been detected in many animals less than thirty months of age.⁴⁵⁷ In the preamble to the SRM Rule, the USDA attempted to explain away these inconvenient cows by suggesting that the incubation period for BSE is sufficiently lengthy and the 1997 FDA feed restrictions have been in place long enough that it is highly unlikely that an animal of less than thirty months in age will be BSE-positive.⁴⁵⁸ While it may be true that younger

456. See *supra* Part IV.A.1.

457. See USDA SRM Interim Final Rule, *supra* note 2, at 1863 (noting that “[t]he lower ranges of this age distribution include some cattle younger than 30 months of age”). In Japan, where all cattle are tested for BSE prior to slaughter, animals aging only 21 and 23 months have tested positive for BSE. See T. Ling Chwang, *Mad Cow Demands Respect*, DALLAS MORNING NEWS, Jan. 2, 2004, at 27A (reporting the popular belief is that only cows older than 30 months develop BSE). Other countries, including England and Slovakia, have also reported detecting BSE in cattle younger than 24 months. See Blakeslee, *supra* note 431 (finding that while the disease is found mostly in older cattle, one European cow was only 20 months old).

458. See USDA SRM Interim Final Rule, *supra* note 2, at 1863-64 (posturing that cattle younger than 30 months “are less likely to be in the later stages of BSE incubation than older BSE-infected cattle, and hence, are less likely to contain high levels of BSE infectivity”).

cattle pose fewer risks, however, they are by no means risk-free.⁴⁵⁹ TSEs are not sufficiently well-understood to draw firm conclusions about the length of the incubation period in any particular species. The very limited APHIS BSE surveillance program has not by any means established the true incidence of BSE in the United States, and the FDA's own monitoring indicates that compliance with its feed restrictions has been spotty.⁴⁶⁰ The preamble does not explain why U.S. consumers should be subjected to such a high-consequence risk, even if the probability is low.

FSIS appears to have engaged in an implicit cost-benefit analysis in deciding to draw the line at thirty months rather than at twelve or twenty-four months. The FMIA, however, does not allow the decision whether food is adulterated to be dictated by cost-benefit considerations. Under the statute, meat is adulterated if it contains a deleterious substance that “may render it injurious to health,”⁴⁶¹ or if it is “unhealthful, unwholesome or otherwise unfit for human food.”⁴⁶² The fact that some SRMs from younger cattle are less risky than SRMs from older cattle may be a relevant consideration in deciding where to draw the line, the added cost of removing SRMs from younger cattle is simply not relevant to the decision.

Similarly, FSIS's failure to include bone marrow in the definition of SRM is not well justified under the FMIA. The agency recognized that bone marrow had demonstrated infectivity thirty-eight months after exposure in one experiment, but it concluded that the findings of that study were “not conclusive.”⁴⁶³ The FMIA mandates a precautionary approach that manifestly does not require a “conclusive” demonstration that a meat food product will cause adverse health effects before regarding it as adulterated. The possibility that bone marrow is contaminated with mad

459. See Letter from Karen L. Egbert, Center for Science in the Public Interest, to Docket Clerk, Food Safety and Inspection Service 3-4 (Apr. 7, 2004) (taking the same position as the European Union that a 12-month age cut-off should be employed in defining SRM); see also Letter from Steven Roach, Food Safety Program Manager, Food Animal Concerns Trust, to Docket Clerk, Food Safety and Inspection Service 3 (Apr. 9, 2004) (arguing that a higher than 12-month age cut-off compromises human health and that the “FSIS should wait until better surveillance data is available before accepting the higher age”). Indeed, the USDA's 2002 “Current Thinking Paper” recognized that animals as young as 24 months old could harbor the disease, and one of the options that it recommended pursuing would have defined “special risk material” to include “brain and spinal cord from cattle aged 24 months and older and downer cattle regardless of age.” Bovine Spongiform Encephalopathy (BSE) Current Thinking Paper: Notice of Availability, 67 Fed. Reg. 2399, 2399-401 (Jan. 17, 2002).

460. See *supra* Part III.B.2.

461. 21 U.S.C. § 601(m)(1) (2000) (emphasis added).

462. *Id.* § 601(m)(3) (listing meat that “consists in whole or in part of any filthy, putrid, or decomposed substance” alongside the definition of unfitness).

463. See USDA SRM Interim Final Rule, *supra* note 2, at 1864 (detailing the results of a study where cattle were given a large dose of BSE when they were four months old and were determined to be infected 35 to 38 months after exposure to the BSE).

cow prions “*may* render it injurious to health.”⁴⁶⁴ Similarly, meat that may be contaminated with BSE prions may be “unhealthful, unwholesome or otherwise unfit,” even if it has not been shown conclusively to be infective. Given even a small risk of contracting BSE from bone marrow, the only plausible rationale for FSIS’s failure to include it in the definition of SRM is a legally irrelevant concern for the industry’s cost to remove bone marrow from processed meat.

2. *Zero Tolerance with Maximum Flexibility*

The HACCP concept has been well received among industry groups, consumer groups and the scientific community as a “science-based” alternative to outmoded organoleptic inspection techniques.⁴⁶⁵ The SRM Rule gives establishments “the flexibility to implement the most appropriate procedures that will best achieve”⁴⁶⁶ its zero-tolerance performance standard for SRM through HACCP plans, Sanitation SOPs, or prerequisite programs.⁴⁶⁷ The primary constraint on that flexibility is the rule’s insistence that the part of the plan devoted to SRM be committed to writing.⁴⁶⁸ It is doubtful, however, that a program with this much flexibility is capable of achieving a zero tolerance performance goal in the real world.

464. 21 U.S.C. § 601(m)(1) (2000).

465. See FOX, *supra* note 147, at 357 (noting that “the consensus is that food safety will be much improved by the institution of HACCP”). The NAS Ensuring Safe Food report concluded that HACCP approaches were generally “much more effective in ensuring the safety of foods than traditional visual inspection practices.” SAFE FOOD REPORT, *supra* note 140, at 30. The industry was attracted to HACCP because it assumed that individual companies would conduct the required monitoring at critical control points, and USDA inspectors would inspect monitoring reports rather than actual carcasses. See FOX, *supra* note 147, at 258 (finding the industry favored the deregulatory aspects of HACCP). Some consumer groups, like the Consumer Federation of America and the Center for Science in the Public Interest, were strong supporters of the HACCP concept in principle. See Caroline Smith DeWaal, FSIS Policy on E. Coli O157:H7: Reviewing the Role of Pathogen Testing in HACCP, Remarks at the Center for Science in the Public Interest (Feb. 29, 2000) (noting the testing system is more reactive than proactive and preventative), at http://www.cspinet.org/foodsafety/fsis_policy.html; see also CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at CRS-5-6 (Aug. 1, 2003) (noting support for the HACCP came from consumer advocacy organizations such as the Center for Science in the Public Interest and Safe Tables Our Priority).

466. USDA SRM Interim Final Rule, *supra* note 2, at 1869.

467. See Specified Risk Materials from Cattle and Their Handling and Disposition, 69 Fed. Reg. 1873 (Jan. 12, 2004) (to be codified at 9 C.F.R. pt. 310.22(d)(1)) (requiring slaughter houses and like establishments “that process the carcasses or parts of cattle . . . [to] develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials” as part of their HACCP plans, Sanitation SOPs or prerequisite programs).

468. See *id.* (requiring written procedures to be developed, implemented, and maintained).

3. Industry Reliance on Prerequisite Programs

The SRM Rule requires establishments to develop “written procedures” for “the removal, segregation, and disposition of specified risk materials” and to incorporate such procedures into their HACCP plans, their Sanitation SOPs or other prerequisite programs.⁴⁶⁹ Although the regulations appear to leave the choice among the three options (HACCP plans, Sanitation SOPs, or prerequisite programs) entirely up to the establishments, the HACCP regulations require establishments to base that choice on a “hazard analysis” of “food safety hazards reasonably likely to occur in the production process.”⁴⁷⁰ HACCP plans must specify control measures for every food safety hazard that the hazard analysis determines is “reasonably likely to occur.”⁴⁷¹

The preamble to the SRM Rule expresses FSIS’s expectation that meatpackers will “reassess their HACCP plans” to address SRMs under the rule’s zero-tolerance requirement.⁴⁷² A widely circulated FSIS Notice contemplates the possibility that an establishment’s hazard analysis will conclude that “SRMs are not a hazard reasonably likely to occur because of procedures in its Sanitation SOPs” or “because of procedures in a prerequisite program that the establishment has implemented.”⁴⁷³ The Notice does not, however, require the inspector to approve or otherwise verify that the establishment’s determination that a Sanitation SOP or a prerequisite procedure renders SRMs a hazard that is not reasonably likely to occur.

469. *Id.*

470. Hazard Analysis and HACCP Plan, 9 C.F.R. § 417.2(a)(1) (2004).

471. *Id.* § 417.2(b), (c); *see also* Food Safety and Inspection Service, Review of Establishment Data by Inspection Program Personnel, 69 Fed. Reg. 24,556-57 (May 4, 2004) [hereinafter USDA Establishment Data Review Notice] (“Whenever a hazard analysis reveals that a food safety hazard is reasonably likely to occur in the production process, establishments are required to develop and implement a written HACCP plan for each product that includes specified control measures for each hazard so identified.”). The regulations go on to specify that a food safety hazard that is “reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.” 9 C.F.R. § 417.2(a)(1).

472. USDA SRM Interim Final Rule, *supra* note 2, at 1863. Establishments must “reassess the adequacy” of their HACCP plans “whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.” 9 CFR § 417.4(a)(3) (2004). An FSIS Notice requires its inspectors to verify that each establishment dealing with SRMs “has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present a risk of transmitting BSE.” United States Department of Agriculture, Food Safety and Inspection Service, FSIS Notice 9-04, January 23, 2004 [hereinafter FSIS Notice 9-04], *available at* <http://www.fsis.usda.gov/Frame/FramRedirect.asp?main=/oppde/rdad/fsisnotices/9-04.pdf>.

473. *See* FSIS Notice 9-04, *supra* note 472, at 2 (stating that, in either case, the establishment must document this determination in its records, and FSIS inspectors are required to “verify that the procedures and supporting documentation are available for review”). *Id.*

It now appears that virtually all of the establishments subject to the January 2004 regulations are addressing SRMs in their Sanitation SOPs and prerequisite programs, rather than by amending their HACCP plans to establish scientifically monitored critical limits at critical control points.⁴⁷⁴ The companies have reassessed their HACCP hazard analyses, determined that a food safety hazard from the presence of BSE is not “reasonably likely to occur” with Sanitation SOPs and/or prerequisite programs in place, and concluded that it is therefore unnecessary to establish critical control points and critical control limits for SRMs in their operations.⁴⁷⁵ This, in turn, appears to reflect a general view that mad cow disease is primarily an animal safety problem and not a food safety threat. FSIS has apparently acquiesced in this response so long as the prerequisite programs are reduced to writing,⁴⁷⁶ and it currently has no plans to draft model HACCP plans identifying critical control points and suggesting critical limits for SRMs.⁴⁷⁷

Although the HACCP rule contains requirements for Sanitation SOPs, it does not directly address prerequisite programs.⁴⁷⁸ The preamble to an

474. See Telephone Interview by Thomas O. McGarity with Mr. Dennis Johnson, Olsson, Frank & Weeda, July 1, 2004 (on file with author) [hereinafter Johnson Interview, 7/1/04] (“[A]ll the companies that I know of are using prerequisite programs.”); see also Email from Jennifer Beasley-McKean, Staff Officer, Technical Assistance & Correlations, Technical Service, Food Safety and Inspection Service, Omaha, Nebraska to Elizabeth Duffy, March 24, 2004, at 2 (on file with author) [hereinafter Beasley-McKean/Duffy Email, 3/24/04] (“I would say more plants are addressing Sims in their hazard analysis through pre-requisite programs rather than SSOPs or CCPs.”).

475. Johnson Interview, 7/1/04, *supra* note 474; see also Email from Dennis Johnson to Elizabeth Duffy, March 31, 2004 (on file with author) [hereinafter Johnson/Duffy Email, 3/31/04] (“As regards BSE, the vast majority of my clients have not included a CCP for specified risk material (SRM) removal; rather such removal is handled as a ‘prerequisite program’ . . . because the BSE prion is not reasonably likely to occur given the various firewalls in place on live animal production.”).

476. Email from Jennifer Beasley-McKean, Staff Officer, Technical Assistance & Correlations, Technical Service, Food Safety and Inspection Service, Omaha, Nebraska to Elizabeth Duffy, May 3, 2004 (on file with author), at 2 [hereinafter Beasley-McKean/Duffy Email, 5/3/04] (“It would be acceptable for [establishments] to control SRM removal in an SOP, if the SOP was written, generated written documents, and was included in their hazard analysis as a pre-requisite program.”).

477. See Beasley-McKean/Duffy Email, 3/24/04, *supra* note 474, at 2 (noting that some industry organizations have issued their own compliance guidelines).

478. The preamble to the Notice of Proposed Rulemaking for the HACCP Rule notes that “[g]ood sanitation and basic good manufacturing practices (GMPs) are generally regarded as essential prerequisites for the production of safe food.” Food Safety and Inspection Service, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6774 (proposed Feb. 3, 1995) (to be codified at 9 C.F.R. pts. 308, 310, 318, 320, 325-27, and 381) [hereinafter HACCP Proposed Rule]. This suggests that the term “prerequisite” program is broader than Sanitation SOP, a term that is addressed explicitly in the HACCP regulations. USDA regulations, however, do not address the scope of “other prerequisite programs,” nor do they suggest how establishments should go about implementing them. See Food Safety and Inspection Service, E. coli O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62,325, 62,330 (Oct. 7, 2002) [hereinafter USDA E. coli O157:H7 Notice] (“Current regulations do not include specific requirements for prerequisite programs other than Sanitation SOPs.”).

FDA proposed regulation establishing HACCP requirements for juice provides some guidance on the meaning of “prerequisite program” in the HACCP context.⁴⁷⁹ According to the FDA, “prerequisite programs” come in two varieties: 1) Sanitation SOPs (of the sort directly addressed in USDA’s HACCP regulations) and 2) programs that provide “control over materials that are entering the plant.”⁴⁸⁰ If the USDA adheres to the FDA understanding of “prerequisite program,” then the “prerequisite programs” that are most relevant to mad cow disease are in fact the Sanitation SOPs provided for in the HACCP regulations. However, other prerequisite programs aimed at materials entering the plant are certainly imaginable, such as a restriction by a slaughterhouse on the age of cattle that the establishment will accept or a requirement by a beef grinder that all incoming meat be from carcasses of animals that have been tested negative for BSE.⁴⁸¹

The industry’s decision to address SRMs through Sanitation SOPs and prerequisite programs will undoubtedly affect the integrity of the SRM Rule’s zero-tolerance performance standard for SRMs in edible meat. Some of the crucial differences between HACCP plans with critical limits at critical control points on the one hand and Sanitation SOPs and prerequisite programs on the other are the following:

- *USDA Approval.* FSIS inspectors must approve HACCP programs; they do not approve Sanitation SOPs and prerequisite programs.⁴⁸² Moreover, if the establishment is following the procedures set out in the prerequisite program and the zero-tolerance requirement for SRMs is repeatedly violated, the FSIS inspector does not threaten to withdraw inspection and thereby shut the plant down. Instead, the inspector merely requires the establishment to revisit its hazard analysis determination that the relevant food safety hazard was not “reasonably likely to occur” under

479. See Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 63 Fed. Reg. 20,450, 20,465 (proposed Apr. 24, 1998) (to be codified at 21 C.F.R. pt. 120) [hereinafter FDA Juice NPRM, 4/24/98] (defining a prerequisite program as “an appropriate mechanism for a situation, such as sanitation, that does not lend itself well to HACCP controls”).

480. *Id.*

481. The latter prerequisite program, however, is currently not allowed by the USDA for dubious reasons discussed *supra* note 54.

482. See USDA HACCP Final Rule, *supra* note 140, at 38,818 (outlining how teams of USDA inspectors review and approve the HACCP plans upon initial promulgation and significant substantive amendments “to verify their scientific validity and ongoing adequacy for preventing food safety hazards”); see also Beasley-McKean/Duffy Email, 5/3/04, *supra* note 476, at 2 (“Inspectors do not ‘approve’ GMPs or other written pre-requisite programs.”); USDA HACCP Final Rule, *supra* note 140, at 38,832 (“FSIS will not approve Sanitation SOP’s . . .”); *id.* at 38,834 (“FSIS inspectors will not be tasked with directing an establishment’s sanitation procedures, nor with ‘approving’ the establishment’s Sanitation SOP’s.”).

the prerequisite program.⁴⁸³

- *Informality.* It appears that Sanitation SOPs and other prerequisite programs are, in the final analysis, whatever the establishments writing them want them to be. They consist primarily of various background procedures and practices that establishments have in place to protect against contamination of edible food by material that could cause it to become adulterated. They do not contain quantitative limits, like the critical limits that the HACCP regulations require at critical control points, and they can be limited to vague aspirational statements. Even industry-generated “good manufacturing practices” (GMPs) can constitute valid prerequisite programs, so long as they are contained in a written document and generate periodic written monitoring reports.⁴⁸⁴

- *Consequences of Failure.* Although the *Supreme Beef* opinion casts some doubt on the continuing vitality of the Salmonella goal for HACCP programs,⁴⁸⁵ it is a legally binding “standard” that establishments are required to meet “consistently over time as a condition of maintaining inspection.”⁴⁸⁶ Moreover, exceeding a critical limit at a critical control point may precipitate an FSIS enforcement action.⁴⁸⁷ For Sanitation SOPs and prerequisite programs, there are no legally enforceable performance standards, and any given failure to maintain sanitary conditions at a plant is not necessarily a violation of the law.⁴⁸⁸ As a practical matter, “[i]t is a lot harder to get closed under a Prerequisite program.”⁴⁸⁹

- *Documentation.* In administering an HACCP program, an establishment must document the monitoring that it undertakes at critical

483. See 9 C.F.R. § 417.2(a)(1) (2004) (defining “reasonably likely to occur” as those hazards that have occurred in the past or are likely to occur in the “particular type of product being processed”).

484. See Beasley-McKean/Duffy Email, 5/3/04, *supra* note 476, at 2 (“Written GMPs that generate written documents can be used as a pre-requisite program.”).

485. See *supra* Part II.A.1.f.

486. USDA HACCP Final Rule, *supra* note 140, at 38,838.

487. See 9 C.F.R. § 417.3 (requiring that a HACCP program identify a corrective action to respond to a deviation and listing how an establishment should respond when “a deviation not covered by a specified corrective action occurs”); see also Johnson Interview, 7/1/04, *supra* note 474, at 1 (stating that a violation of a critical limit at a critical control point under a HACCP program “means that my HACCP system has failed and I must take corrective action or an enforcement action might be brought”).

488. See USDA HACCP Final Rule, *supra* note 140, at 38,838 (providing performance “criteria” for E. coli contamination based on the prevalence of contamination of E. coli on carcasses produced nationwide). A failure to meet the criteria is merely an indication that greater sanitation efforts are necessary and not a violation of law. *Id.*

489. Johnson Interview, 7/1/04, *supra* note 474. The important difference in the legal consequences of a detected violation appears to be a significant factor in the industry’s choice of prerequisite programs over HACCP programs to address the SRM Rule. A prominent attorney for the beef industry relates that “[t]he reason you put it in a prerequisite program is that under the HACCP Plan, if you have a violation, it makes the food adulterated,” and the industry has concluded that “[a] little spinal cord does not . . . make it unsafe.” *Id.*

control points.⁴⁹⁰ Every incident of exceeding a critical control limit at any critical control point must be documented along with the required corrective action.⁴⁹¹ Establishments exceeding the critical control limit also require operators to undertake a written reassessment of the HACCP.⁴⁹² Sanitation SOPs and prerequisite programs do not require extensive documentation of deviations from the specified procedures and resulting corrective actions, and operators who rely upon these less formal programs may thereby avoid the paperwork “nightmare” that can result from the exceedence of a critical limit at a critical control point.⁴⁹³

After FSIS promulgated the SRM Rule in January 2004, specialists at the University of Nebraska prepared model Sanitation SOPs for controlling SRMs in some kinds of meatpacking facilities.⁴⁹⁴ Each document consists of two pages of text, a worksheet, and a checklist. Although written in mandatory terms, the requirements are actually highly discretionary. For example, the SOP for segregating older cattle provides that “[i]f possible, any beef animal(s) determined to be (>) 30 months of age will be held for slaughtering after young age documented animals are slaughtered.”⁴⁹⁵ Similarly, “grossly identifiable spinal cord material spread by the splitting process” on any carcasses of animals thirty months and older should “be trimmed from the carcass with a knife.”⁴⁹⁶ The suggested SOP does not require (or even suggest) any monitoring for SRMs in finished products beyond the requirement that “[v]isual observation will be conducted once per day during slaughter operations.”⁴⁹⁷ No quantitative testing of any sort for SRMs is required or suggested. Corrective actions are limited to

490. See 7 C.F.R. § 417.5(a)(3) (2004) (including times and temperatures, corrective actions, and verification procedures).

491. See *id.* § 417.3(c) (requiring that records meet verification and recordkeeping standards).

492. See *id.* §§ 417.3(b)(4), 417.4(a)(3) (ordering reassessment to determine whether a new deviation should be included in the HACCP plan or hazard analysis).

493. Johnson Interview, 7/1/04, *supra* note 474.

494. See Ryan R. Baumert & Dennis Burson, Cattle Slaughter Standard Operating Procedures (SOP) for Control of Specified Risk Materials (SRMs), Feb. 17, 2004 [hereinafter Nebraska Cattle Slaughter SRM SOPs] (outlining a seven step procedure for controlling SRMs). Although meat scientists are beginning to write suggested Sanitation SOPs for controlling SRMs in beef slaughter and processing establishments, there are no data on how many establishments have amended their prerequisite programs to incorporate some or all of these suggestions in an effort to prevent SRMs from entering meat. An attorney at some establishments relates that his clients have “adopted written procedures to identify the age of the animals (since the requirements are different depending on the age of the animal); written procedures for the removal of the SRMs; written procedures for segregation of various products; and dedicated space and equipment as well as training personnel on removal.” Johnson/Duffy Email, 3/31/04, *supra* note 475, at 1.

495. Nebraska Cattle Slaughter SRM SOPs, *supra* note 494, at 1.

496. *Id.*

497. *Id.* at 2.

retraining slaughter operators in SRM control procedures and properly disposing of SRMs.⁴⁹⁸

If the prerequisite programs that slaughterhouses are using follow the model SOPs described above, it seems highly unlikely that the zero-tolerance for SRM performance requirement of the SRM rule will be met in practice. Although FSIS has for years touted the virtues of quantitative tests at critical control points in HACCP programs, the industry's move to adopt prerequisite programs means that companies have opted for an essentially organoleptic approach in which the monitoring device is the human eye and the primary corrective action tool is a sharp knife. Indeed, since the entity ultimately responsible for writing prerequisite programs for an establishment is the company running that establishment, companies are entirely free to ignore even the rather minor suggestions contained in the recommended SOPs in writing their own Sanitation SOPs.

Although the HACCP regulations do not specifically require corrective action for failures of prerequisite programs, the agency has taken the position in connection with the other hazard for which it has adopted a zero-tolerance policy (*E. coli* O157:H7) that a single detection of the contaminant in finished product would require corrective action.⁴⁹⁹ FSIS is apparently adopting the same approach with respect to prerequisite programs that implement SRMs.⁵⁰⁰ The corrective action requirement provides some measure of comfort, but it does not alleviate all of the concerns that consumers might legitimately have about the industry's move away from HACCP to prerequisite programs. First, it still makes a difference that an HACCP plan is more quantitative and verifiable than prerequisite programs. Corrective action is not called for until failures are detected, and the probability of detection of program failures should be considerably higher for HACCP plans, for which critical control points and critical limits are established and periodically monitored, than for prerequisite programs under which no quantitative monitoring is required.

498. *Id.* The suggested SOPs for beef carcass receiving and fabrication plants are very similar and no more prescriptive. See RYAN R. BAUMERT & DENNIS BURSON, BEEF CARCASS RECEIVING AND FABRICATION STANDARD OPERATING PROCEDURES (SOP) FOR CONTROL OF SPECIFIED RISK MATERIALS (SRMs) (Feb. 17, 2004) (listing monitoring, corrective action, and recording requirements and providing receiving and fabrication SOP logs).

499. See USDA *E. coli* O157:H7 Notice, *supra* note 478, at 62,330 (stating that a finding of *E. coli* O157:H7 may require reassessment to determine if this new hazard should be incorporated into the HACCP plan); see also Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products, 68 Fed. Reg. 34,208, 34,214 (June 6, 2003) (to be codified at 9 C.F.R. pt. 430) [hereinafter USDA *Listeria* Rule] ("FSIS inspection program personnel are instructed to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan or of a Sanitation SOP or other prerequisite program.")

500. Beasley-McKean/Duffy Email, 5/3/04, *supra* note 474, at 2 ("Any noncompliance would be documented as an unforeseen hazard, and the establishment would be required to meet all parts of 9 CFR § 417.3(b).").

Second, the fact that HACCP programs must be verified and approved by FSIS in advance should result in fewer failures, and therefore less need for after-the-fact corrective action, than prerequisite programs that need no prior approval. Finally, the consequences of failure are considerably higher for programs aimed at keeping SRMs out of edible meat than for programs designed to control other pathogens because the ultimate “firewall” of adequate food preparation will destroy ordinary pathogens but not the mad cow prion.

4. *The Questionable Legal Rationale for Relying on Prerequisite Programs*

The industry’s legal rationale for failing to incorporate the SRM Rule into their HACCP plans is troublesome. The HACCP regulations require operators to establish critical control points for all “food safety hazards” that are “reasonably likely to occur,” and they further state that a hazard that is “reasonably likely to occur” is one “for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.”⁵⁰¹ The regulations define “food safety hazard” to be any “biological, chemical, or physical property that may cause a food to be unsafe for human consumption.”⁵⁰²

The industry has apparently concluded that the relevant “food safety hazard” is the presence of the mad cow prion, and not the presence of SRM.⁵⁰³ Given the various “firewalls” in place, including the FDA feed ban and the steps undertaken in individual Sanitation SOPs and/or prerequisite programs, the companies have concluded that mad cow prions are not reasonably likely to occur in finished product even if critical control points and critical control levels for prions or surrogates for prions are not established.⁵⁰⁴ The companies purport to comply with the zero-tolerance for SRM requirement in the SRM Rule through various sanitary measures contained in their Sanitation SOPs and/or prerequisite programs, but they have not established critical control points and critical control levels for

501. 9 C.F.R. § 417.2(a)(1) (2004).

502. *Id.* § 417.1.

503. See Johnson/Duffy Email, 3/31/04, *supra* note 475, at 1 (observing that “the BSE prion is not reasonably likely to occur given the various firewalls in place on live animal production”).

504. See Johnson Interview, 7/1/04, *supra* note 474 (stating that the “firewalls ensure that the mad cow prion will not be in the animals entering the plant, and it is therefore not a food safety hazard reasonably likely to occur”); see also Johnson/Duffy Email, 3/31/04, *supra* note 475, at 1.

SRMs because they have apparently concluded that SRMs *per se* are not “food safety hazards.”⁵⁰⁵

FSIS publications, however, adopt a very different view of the situation. The preamble to the Interim Final SRM Rule clearly states FSIS’s conclusion that SRMs, not just mad cow prions, “present sufficient risk of exposing humans to the BSE agent that it is prudent and appropriate to find that such materials are unfit for human food.”⁵⁰⁶ FSIS apparently concluded that SRMs are “unfit for human food” because they may present a “food safety hazard.”⁵⁰⁷ An FSIS Notice implementing the SRM Rule makes this crystal clear when it advises that “[i]f an establishment determines that SRMs are a hazard reasonably likely to occur in its process,” FSIS veterinary medical officers are to “verify that the establishment has designed controls and incorporated them into its HACCP plan.”⁵⁰⁸ It thus seems clear that FSIS considers the presence of SRMs in meat to be a “food safety hazard,” warranting the establishment of critical control points and critical levels requiring periodic monitoring and corrective action if SRMs are reasonably likely to occur in the food manufacturing process.⁵⁰⁹

Furthermore, it seems reasonably clear that the presence of SRMs in a finished product is “reasonably likely to occur” in slaughterhouses and meat processing establishments under the vague and wholly unenforceable requirements of typical Sanitation SOPs and prerequisite programs. Surely, no establishment could plausibly argue that daily visible inspections of finished product for the presence of SRMs will ensure that SRMs are not “reasonably likely to occur” in *any* finished product. The experience of AMR establishments, which have for several years been subject to a requirement that finished product contain no spinal cord material, indicates

505. See Johnson/Duffy Email, 3/31/04, *supra* note 475, at 1 (“To be sure, my clients are complying with the FSIS interim regulations requiring the removal of SRMs, but once again, this is not being handled under their HACCP plans.”).

506. USDA SRM Interim Final Rule, *supra* note 2, at 1869.

507. The FDA made this connection between safety risk and “unfitness” for human food in interpreting identical language in the FDCA when it promulgated its Interim Final Rule on the Use of Materials Derived from Cattle in Human Food and Cosmetics. In the “legal authority” section of the preamble to that rule, the FDA stated that “a food can be ‘otherwise unfit for food’ based on health risks.” FDA Food and Cosmetics Rule, *supra* note 368, at 42,264. It further stated that:

Because of the discovery of a BSE positive cow in the United States and the possibility of disease transmission to humans from exposure to material from infected cattle, [SRMs and other materials] may present a risk to human health. Under our interpretation of section 402(a)(3) [of the FDCA], these materials are unfit for food.

Id.

508. FSIS Notice 9-04, *supra* note 472, at 2 (emphasis added).

509. See Beasley-McKean/Duffy Email, 5/3/04, *supra* note 476, at 3 (“The program must adequately support in the hazard analysis why SRMs are a food safety hazard not reasonably likely to occur.”).

the poor performance of visual inspection as a technique for ensuring that SRMs do not wind up in finished product. As described above, AMR systems have consistently produced beef product that has tested positive for spinal cord and DRG.⁵¹⁰

An industry attorney suggests that FSIS may have meant merely to allow companies electing to implement the SRM Rule through HACCP programs to use SRMs, which the industry believes to be nonhazardous, as an easily measurable “surrogate” for the hazardous mad cow prion, in much the same way that fecal matter is used in establishing critical control points as a surrogate for dangerous bacteria that might be found in fecal matter.⁵¹¹ This interpretation of the agency’s intent would leave companies with the option of implementing the SRM rule through prerequisite programs on the theory that SRMs are not reasonably likely to contain mad cow prions. This interpretation, however, does not square with the above-quoted language in the preamble to the SRM rule. Indeed, since companies typically do address fecal matter in HACCP programs by establishing critical control points,⁵¹² the argument may prove too much.

5. HACCP’s High Tolerance for Contamination

Given the HACCP’s historical focus on controlling bacteria,⁵¹³ FSIS’s conclusion that the HACCP is capable of controlling mad cow prions involves a considerable leap of faith. The preamble to the SRM Rule did not explain how a system designed to ensure that Salmonella levels in finished product did not exceed the national average would be capable of ensuring that SRM levels in finished product could meet a zero-tolerance performance standard. Whether companies continue to implement the SRM Rule through Sanitation SOPs and prerequisite programs, there are many good reasons to conclude that a flexibly administered performance-based regime of the sort envisioned by the HACCP regulations cannot effectively address the wholly different issue of mad cow prions.

The Salmonella testing and performance requirements of the HACCP regulations were not designed to ensure that the number of disease-causing microorganisms on any given piece of beef was sufficiently low to make

510. See Aaron Zitner, *Bovine Disease Surfaces in U.S.*, L.A. TIMES, Dec. 24, 2003, at A1 (reporting on a cow in Washington State that tested positive for mad cow disease); see also USDA AMR Interim Final Rule, *supra* note 25, at 1876 (stating that a 2002 beef survey concluded that seventy-six percent of AMR establishments whose products were tested “had positive laboratory results for spinal cord, DRG, or both in their final beef AMR products”).

511. Johnson Interview, 7/1/04, *supra* note 474.

512. *Id.*

513. The primary goal of the HACCP regulations is “to build into food production processes, and into the system of FSIS regulation and oversight, effective measures to reduce and control harmful bacteria on raw meat and poultry products.” USDA HACCP Final Rule, *supra* note 140, at 38,811.

that piece of beef edible.⁵¹⁴ Any piece of meat that flunks the Salmonella test is, in fact, long gone by the time that the testing is completed and the report of the testing is delivered to the operator. Rather, the testing requirement is designed to ensure that the prevalence of Salmonella-contaminated end product does not exceed the national average.⁵¹⁵ This goal may be acceptable from a public health perspective, because the agency can reasonably assume that any contaminated meat will be cooked prior to consumption.⁵¹⁶ A reasonable assumption in the context of microorganisms like Salmonella, however, may be a reckless gamble in the context of mad cow disease. Cooking meat containing the mad cow prion will not destroy the prion, and the risk of contracting vCJD will remain. Since the food preparer cannot be the “final line of defense” against mad cow disease, greater efforts will be necessary earlier in the process.

6. *A Verification Vacuum*

Like any performance-based approach to safety regulation, the HACCP approach depends upon the assumption that performance can be monitored with dependable monitoring tools that are capable of bright-line distinctions between outcomes that meet the performance standard and outcomes that do not meet the standard and therefore indicate the need for corrective action.⁵¹⁷ The FSIS Guidebook for preparing HACCP plans

514. The agency made it clear in the preamble to the HACCP regulations that “[t]he pathogen reduction standard for Salmonella requires testing of products not for purposes of determining product disposition . . . but rather as a measure of the effectiveness of the process in limiting contamination with this particular pathogen.” *Id.* at 38,848.

515. See FOX, *supra* note 147, at 356 (observing that the overall percentage of contaminated beef creeping downward “may not instill the confidence the USDA is hoping for in consumers, who cook individual [pieces of meat], not percentages”).

516. See *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 439 (5th Cir. 2001) (agreeing with the USDA that Salmonella is “not an adulterant per se, meaning its presence does not require the USDA to refuse to stamp such meat ‘inspected and passed,’” 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’”).

517. A 2002 Report of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) articulated five powerful reasons for preferring quantitative over qualitative approaches to food safety monitoring:

1. The use of quantitative data to determine the concentration of a specific organism in a specific product may be more relevant to public health than the use of qualitative data.
2. Quantitative data better define the public health outcomes as determined through risk assessments (especially important for exposure assessment).
3. Quantitative data obtained from various points on the production line provide more specific information on pathogen reduction than qualitative data. . . .
4. Quantitative data can help monitor changes in the concentrations of organisms in relation to variables such as the time of the year and the source of the raw material.
5. Considerations and technical challenges to the acquisition of quantitative baseline data are not substantially different from those associated with qualitative

states that “[m]onitoring is essential to a HACCP system.”⁵¹⁸ It is the feedback provided by accurate monitoring that, in the words of the current USDA Undersecretary for Food Safety, “has added [an] element of science” to the inspection process under the HACCP regulations.⁵¹⁹ In addition, the promise of quantitative monitoring persuaded consumer advocates to support the HACCP approach when the USDA initially proposed it.⁵²⁰ By allowing companies to implement the prohibition of SRMs in edible meat through Sanitation SOPs and prerequisite programs that require no monitoring whatsoever, the SRM Rule has violated this important HACCP principle.

Although the SRM Rule declares SRMs to be “inedible” and provides that SRMs “shall not be used for human food,”⁵²¹ it does not provide even a hint as to how establishments and the USDA should go about determining whether or not otherwise edible meat has become contaminated with SRMs. A zero-tolerance policy is easily prescribed and popular with the citizenry, but it may be impossible to achieve in practice.⁵²² It is, at best, an ideal to be strived for but perhaps never completely achieved.⁵²³ In the context of the only other contaminant for which FSIS has specifically adopted a zero-tolerance approach, the very dangerous pathogen *E. coli* O157:H7, the agency has taken the position that it “considers an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level.”⁵²⁴

data, except that laboratory methods for quantification may be more time and resource intensive for certain pathogens.

518. USDA, FOOD SAFETY AND INSPECTION SERVICE, *NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, RESPONSE TO THE QUESTIONS POSED BY FSIS REGARDING PERFORMANCE STANDARDS WITH PARTICULAR REFERENCE TO GROUND BEEF PRODUCTS* (Oct. 8, 2003), available at http://www.fsis.usda.gov/OPHS/nacmcf/2002/rep_stand2.pdf.

519. USDA, FOOD SAFETY AND INSPECTION SERVICE, *GUIDEBOOK FOR THE PREPARATION OF HACCP PLANS* (April 1997), at C-18 [hereinafter *FSIS HACCP PLAN GUIDEBOOK*].

520. Frontline Interview with Elsa Murano, Undersecretary for Food Safety, USDA, at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/murano.html> (last visited Apr. 3, 2005).

521. See Frontline Interview with Carol Tucker Foreman, [hereinafter *Foreman Interview*] at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/foreman.html> (last visited Apr. 3, 2005) (explaining that the HACCP regulations “were developed with the idea that there needed to be some objective measures for determining whether or not a company was actually producing a product that met a public health standard”); see also *id.* (“The key change that was made that made it possible for us to support HACCP was the creation of an objective measure.”).

522. Prohibition of the Use of Specified Risk materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862, 1873 (Jan. 12, 2004) (to be codified at 9 C.F.R. pt. 310.22(b)).

523. See *SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT*, *supra* note 128, at 25 (explaining that scientists “recognize the inability to ensure, in most situations, the complete absence of pathogens and contaminants and the limitations of any feasible sampling plan to check for their total absence”).

524. See *id.* at 25 (recognizing that “zero-tolerance is a regulatory and lay concept that specifies an ideal, but that science can strive for but never meet that ideal”).

524. USDA *E. coli* O157:H7 Notice, *supra* note 478, at 62,329.

Whether a particular establishment complies with the SRM Rule's zero-tolerance requirement depends upon the monitoring tool's ability to detect SRM in the final product, a matter that the rule leaves up to the establishment. As a result, the Department delegated the critical determination of how hard to look for SRM to the operators of establishments that have every reason not to find it.

The preferred form of monitoring under the FSIS HACCP regulations is to take continuous quantitative measurements for the relevant characteristic(s) at the critical control points.⁵²⁵ When continuous monitoring is not feasible, non-continuous monitoring is appropriate if it is undertaken with sufficient frequency.⁵²⁶ The regulations further envision the possibility of "visual examination" as a form of non-continuous monitoring.⁵²⁷ In the case of SRMs, the industry has apparently rejected continuous quantitative monitoring for SRMs at critical control points in favor of visible inspection for the presence of SRMs on meat with a monitoring frequency of as low as "once per day during slaughter operations."⁵²⁸

Quantitative tests are readily available for at least some of the most important and most prevalent SRMs in meat. Chemical testing procedures are available to detect the presence of spinal cord in meat tissue, and companies stand ready to provide testing services to slaughterhouses and meat processors.⁵²⁹ Because the USDA prohibits spinal cord in AMR

525. FSIS HACCP PLAN GUIDEBOOK, *supra* note 518, at C-18 ("Continuous monitoring is better because it results in a permanent record that you can review and evaluate to ensure that the CCP is under control.").

526. *See id.* at C-19 ("Non-Continuous monitoring can include: visual examinations; monitoring of ingredient specifications; measurements of pH, water activity . . . and product temperatures; attribute sampling; and the like"); *see also* NAS SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 22 (complaining about the "lack of a generally accepted approach to setting regulatory controls and performance standards that result in a reduction of human disease"). The report further noted that "much of the data needed to develop science-based strategies are often incomplete, nonexistent, or require extensive resources to generate." *Id.* at 1.

527. FSIS HACCP PLAN GUIDEBOOK, *supra* note 518, at C-19.

528. Nebraska Cattle Slaughter SRM SOPs, *supra* note 494, at 2. The FSIS has apparently acquiesced in this response to the SRM Rule. A January 23, 2004, FSIS Notice providing "verification instructions" to its inspectors for the SRM Rule tells them to "perform the verification activities related to SRM removal in conjunction with other food safety concerns by reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verifying adequacy of Sanitation SOP procedures)." *See* FSIS Notice 9-04, *supra* note 472, at 3 (requiring that since establishments that rely entirely upon prerequisite programs will have no "HACCP monitoring records," the FSIS inspectors must rely upon physical observations).

529. *See* E-mail from Gregorio Rivera, ABC Research, to Elizabeth Duffy (Apr. 5, 2004), at 1 ("As part of all the services ABC offers the industry, CNS testing is performed to detect Glial Fibrillary Acidic Protein in beef as an indicator of contamination with SRM."); *see also* David Kelly, *For Some, Mad Cow Disease All in a Day's Work*, L.A.

product, it promulgated guidelines for conducting Glial Fibrillary Acidic Protein Analysis for CNS tissues in the product of AMR operations.⁵³⁰ In fact, some large meatpacking companies routinely test their products for the presence of minute amounts of brain and spinal cord material and keep any contaminated material off the market.⁵³¹ Their competitors are free, however, to rely upon visual inspections for SRMs by company employees.

7. *Technological Torpidity*

In promulgating the original HACCP Rule, FSIS went to some effort to list and discuss various technologies that were capable of achieving the Salmonella standard.⁵³² The agency was careful, however, not to prescribe any particular technology, leaving those critical decisions up to the establishments. The HACCP, Sanitation SOP, and prerequisite programs were not, however, designed with zero-tolerance policies in mind.⁵³³ Indeed, they seem to be quite tolerant of failure so long as steps are taken to correct those failures after-the-fact. As discussed above, this tolerance for failure is probably a consequence of FSIS's assumption that the person who ultimately prepares meat for consumption is the primary defense against foodborne illness. The much higher likelihood that any mad cow prions in meat leaving a slaughterhouse will be consumed and the high consequences of contracting vCJD suggest that a strictly "performance-based" approach may be inappropriate for addressing the human health risks posed by mad cow disease. If technologies and techniques are available for removing SRMs from meat destined for human consumption, it may be foolhardy to give meatpacking establishments the option of ignoring them.

The USDA has in fact departed from the performance-based approach in other important aspects of the mad cow regulatory regime. For example, the January 2004 regulations feature outright bans on the use of "air-injection captive bolt stunning" devices for killing cattle⁵³⁴ and on

TIMES, Jan. 4, 2004, at A16 (explaining that the tests can find a half billionth gram of brain or spinal tissue in meat and quoting Kim Hossner, a biochemist for the Center for Red Meat Safety at Colorado State University, "[i]f we can detect it, it's unacceptable").

530. See USDA TESTING GMPs, *supra* note 123, at 3 (noting that the objective of the guidelines is to "assure uniform sample collection for detection of the presence of Glial fibrillary acidic proteins").

531. See Kelly, *supra* note 529 (quoting Dell Allen, Vice President for Technical Services at Excel Corporation, as stating that "[w]e now have labs in all of our facilities where we test all the tissue").

532. See Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806, 38,846 (July 25, 1996) (stating that antimicrobial treatments and spray-vacuum devices could be used to achieve the Salmonella standard).

533. See SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 8 (noting that "[w]hen zero tolerance is used as a performance standard, unique methodology issues need to be considered").

534. Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle

mechanical separation technologies for removing meat from bones.⁵³⁵ Similarly, the preamble to the SRM Rule is quite prescriptive in specifying how FSIS inspectors must go about making the critical age determination.⁵³⁶ Nevertheless, the agency was quite reluctant to specify or even identify what techniques and technologies establishments should use to remove SRMs from meat, and subsequent FSIS notices have thus far provided very little additional guidance in this regard.⁵³⁷

8. *Sticky Enforcement Triggers*

Under the general HACCP regulations, failure to meet the Salmonella standard results not in an enforcement action, but in a company-implemented “corrective action[] to lower the incidence of Salmonella on all such product” that the establishment produces.⁵³⁸ Variations from the national baseline prevalence of Salmonella only trigger a withdrawal of inspection if the variations are repeated. Similarly, individual violations of Sanitation SOPs do not result in the shut down of a facility or a recall of any potentially contaminated meat, so long as the establishment takes appropriate steps to correct the insanitary conditions resulting from the violation “in a timely manner” and makes “proper disposition of any affected product.”⁵³⁹

A January 23, 2004, FSIS enforcement directive for the SRM Rule tells on-line FSIS inspectors to notify a USDA veterinary medical officer (VMO) or other off-line personnel “when there is evidence that an establishment’s SRM control program is ineffective (for example, when repeated presentation of contaminated heads or carcasses for post-mortem inspection at the rail and head inspection station indicates failure to control SRM contamination).”⁵⁴⁰ Only when the VMO or other off-line official

During Slaughter, 69 Fed. Reg. 1885, 1891 (Jan. 12, 2004) (to be codified at 9 C.F.R. pt. 313.15).

535. USDA SRM Interim Final Rule, *supra* note 2, at 1862, 1865. This hard-line technology prohibition was, of course, easy to impose because both technologies had already been abandoned by the industry.

536. In cases where establishments presented accurate and reliable records documenting the age of cattle to be slaughtered or from which meat is to be processed, the inspectors may take the documents at face value. But in the absence of accurate and reliable records, reliable records, inspectors at slaughterhouses must verify the age of cattle through the specific technique of dental examination. USDA SRM Interim Final Rule, *supra* note 2, at 1869. An FSIS Directive specifies that inspectors are to consider cattle to be thirty months and older “when the examination of the dentition of the animal shows that at least one of the second set of permanent incisors has erupted,” and it provides an illustration in an attached chart. See FOOD SAFETY AND INSPECTION SERVICE, USDA, FSIS NOTICE 5-04, 4 (2004) (detailing these rather prescriptive instructions to inspectors).

537. See *supra* note 54.

538. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806, 38,848 (July 25, 1996).

539. *Id.* at 38,834.

540. FSIS Notice 9-04, *supra* note 472, at 4.

determines that “the process failed to prevent SRMs from adulterating product,” are they to take action, and that action is limited to the issuance of a Noncompliance Record (NR).⁵⁴¹ An NR is “an official letter of noncompliance with one or more regulatory requirements” that “could result in additional regulatory and administrative action.”⁵⁴²

The consequences of an establishment’s repeated failure to keep SRMs out of finished product are even more limited when the establishment elects to address SRMs through prerequisite programs. The Notice to inspectors provides that when they find that the procedures under a prerequisite program have “failed to prevent SRMs from adulterating product,” they need only “verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.”⁵⁴³ Thus, the consequence of a repeated failure to keep SRMs out of meat for those establishments that rely upon prerequisite programs is not even a Noncompliance Record, but merely an obligation to revisit the conclusion that SRMs (or, in the industry’s view, mad cow prions) are “food safety hazards reasonably likely to occur in the production process.”⁵⁴⁴

FSIS’s tolerance for repeated violations, such as “repeated presentation of contaminated heads and carcasses for post-mortem inspection,” is consistent with the performance-based HACCP approach, which gives each producer three opportunities to correct violations of the regulations before the producer faces any real threat of civil or criminal prosecution,⁵⁴⁵ but it is wholly inconsistent with the zero-tolerance policy articulated in the SRM rule. There are no techniques that the preparer of the food can employ to destroy or remove disease-causing prions from contaminated meat. Hence, if beef leaves the meat processing establishment contaminated with SRMs and if those SRMs contain mad cow prions, then consumers will be exposed to those prions and the associated risk of contracting vCJD. Revisiting the establishment’s hazard analysis will not protect the consumers of the beef that has already exited the facility.

9. *Shirking Responsibility*

A commercial slaughterhouse rarely sells meat directly to consumers to be cooked and eaten. There is usually an intermediary processor or butcher

541. *Id.*; see also USDA, FOOD SAFETY AND INSPECTION SERVICE, FSIS DIRECTIVE 5000.1 41 (n.d.) (“When inspection program personnel conducting these procedures determine there has been a failure or failures to comply with regulatory requirements, they are to document their findings on a NR.”).

542. USDA, FOOD SAFETY AND INSPECTION SERVICE, FSIS DIRECTIVE 5400.5, 9-10 (n.d.).

543. FSIS Notice 9-04, *supra* note 472, at 4.

544. 9 C.F.R. § 417.2(a)(1) (2004).

545. USDA HACCP Final Rule, *supra* note 140, at 38,849.

that also handles the meat before consumers purchase it. Although the SRM Rule declares meat contaminated with SRM to be inedible and therefore adulterated, a notice that FSIS circulated in January 2004 to its inspectors suggests that a slaughterhouse may avoid responsibility for removing SRMs from meat that it sells to downstream processors if it determines that “the SRMs are removed at the receiving establishment.”⁵⁴⁶ At least one state Department of Agriculture has read this FSIS Notice to allow “an official establishment” to “ship out carcasses which contain SRMs.”⁵⁴⁷

The suggestion that FSIS inspectors should tolerate the shipment of SRM-contaminated meat upon a determination that some downstream customer will detect the SRM and remove it will virtually guarantee that human beings consume SRM contaminated food. Although the keen eye of a trained inspector may be able to detect small amounts of SRM on raw meat, it does not have a special glow or other characteristic that makes it obvious to the untrained eye. A giant slaughterhouse should not be allowed to evade legal responsibility for providing edible meat to consumers by passing off that responsibility to the local butcher.

10. The USDA's Limited Legal Authority

The *Butz* and *Supreme Beef* cases raise serious questions concerning USDA's legal authority to enforce requirements that operators include in their HACCP or prerequisite programs to ensure that meat is free of SRM.⁵⁴⁸ The *Butz* case, which was decided in 1974, long before the discovery of prion-based diseases, ratified the USDA's position that meat is not *per se* adulterated merely because it contains pathogenic organisms.⁵⁴⁹ The court agreed with USDA's decision to place the ultimate responsibility for removing pathogens from meat on the person who prepares the food, reasoning that “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.”⁵⁵⁰ The *Supreme Beef* opinion reaffirmed the *Butz* conclusion in the HACCP context, concluding that so long as there was a credible possibility that *Salmonella*-contaminated the

546. FSIS Notice 9-04, *supra* note 472, at 5.

547. Letter from Gus R. Douglass, West Virginia Department of Agriculture, to FSIS Docket Clerk 1 (Apr. 5, 2004) (on file with author).

548. See SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 5 (noting that “[l]egal challenges to actions taken by regulatory agencies in response to violations of established food safety criteria have cast doubts on the agencies' authority to enforce [HACCP] criteria”).

549. See *American Public Health Ass'n. v. Butz*, 511 F.2d 331, 333-34 (D.C. Cir. 1974) (holding the labels placed on raw meat are not misleading when they do not warn consumers about salmonellae and other bacteria).

550. *Id.* at 334; see also *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 439 n.21 (5th Cir. 2001) (reaffirming the *Butz* holding that *Salmonella* is not a *per se* adulterant).

meat entering a facility, FSIS could not insist that meat leaving the facility met the HACCP nationwide average prevalence test for Salmonella.⁵⁵¹

Although there is no reason to believe that twenty-first century housewives are less informed than twentieth century housewives, it is clear that their methods of preparing and cooking meat will not remove mad cow prions, because prions are not destroyed at normal cooking temperatures.⁵⁵² Since there is virtually nothing, including cooking, that the consumer can do to reduce the risk of contracting vCJD from meat contaminated with the mad cow prion, the *Butz* rationale is inapplicable to FSIS's regulatory efforts to protect consumers from foodborne TSEs. If FSIS cannot assume that the preparer will remove mad cow, it must ensure that steps are taken upstream in the meat production process to remove any material that may contain mad cow prions. Although the *Supreme Beef* court made it clear that the USDA has no authority to "regulate the levels of non-adulterant pathogens," the agency clearly does have the authority to regulate adulterants in meat. If the USDA can successfully defend the proposition that SRMs are "unfit for human food" and are therefore adulterants,⁵⁵³ then it should be able to defend its zero-tolerance policy for SRMs as a legal matter.

Supporting a conclusion that SRMs are adulterants may not, however, be an easy matter. The preamble to the regulations states that "[g]iven the way that infectivity occurs in BSE-infected cattle, and the fact that a case of BSE has been detected in the United States, FSIS has determined that [SRMs] present sufficient risk of exposing humans to the BSE agent that it is prudent and appropriate to find that such materials are unfit for human food."⁵⁵⁴ FSIS concluded that SRMs presented "a persistent risk of exposing humans to the BSE agent because, in pre-clinical BSE-infected cattle, infectivity in most of these tissues is not readily ascertainable" and humans could therefore "unknowingly be exposed to the BSE agent through consumption of these materials."⁵⁵⁵

The primary legal obstacle to the agency's approach to SRM is its conclusion that because there is a risk of exposing humans who consume SRMs to the BSE agent, SRMs are "otherwise unfit for human food."⁵⁵⁶

551. See *Supreme Beef*, 275 F.3d at 442 (noting that the presence of Salmonella does not imply the presence of other pathogens); see also Lassiter, *supra* note 370, at 454 (explaining that there is an expanding list of pathogens that may cause food poisoning, however presence of those pathogens "do not necessarily render the meat 'adulterated'").

552. See HCRA BSE REPORT, *supra* note 30, at 38 ("TSE agents are known for their capacity to survive severe environmental conditions such as desiccation, thermal extremes and UV exposure.").

553. 21 U.S.C. § 601(m)(3) (2000).

554. USDA SRM Interim Final Rule, *supra* note 2, at 1869.

555. *Id.*

556. 21 U.S.C. § 601(m)(3) (2000).

First, SRM is clearly not a complete proxy for prion-containing tissue. The Secretary of Agriculture and Department spokespersons have gone to great lengths to assure the public that the Mabton mad cow is unique and that numerous firewalls exist to ensure against additional cases of mad cow disease in the United States. If the USDA is correct in its assessment of the incidence of mad cow disease in this country, then the presence of SRM is a poor surrogate for tissue contaminated with the mad cow prion. Furthermore, even if SRM is likely to be contaminated with mad cow prions, not every human being that consumes meat containing the mad cow prion will contract vCJD.⁵⁵⁷ Otherwise, a much larger proportion of the population of England would have contracted vCJD.⁵⁵⁸

On the other hand, it is abundantly clear that consuming meat that is infected with the mad cow prion poses a high risk of contracting vCJD, which is an exceedingly debilitating and ultimately fatal disease. Given the very high risk to human health attributable to the mad cow prion and given a small, but non-trivial probability that SRMs will be contaminated with those prions, FSIS may be able to persuade a reviewing court that SRMs are unfit for human food. Still, it may be unwise to assume that the court that decided *Supreme Beef*, a case that did not adopt an especially precautionary view of the FMIA, would accept this interpretation of that statute. As discussed below, Congress should remove any doubt about this by amending the FMIA to provide clear authority to the USDA to regulate SRMs.⁵⁵⁹

V. FAULTY RESPONSES TO FIREWALL FAILURE

No firewall designed and implemented by human beings can be one-hundred percent effective one-hundred percent of the time. Sadly, the previous analysis of new, existing, and recently enhanced firewalls strongly suggests that firewall failure is not only possible, but highly likely. The federal government should therefore be prepared to deal with firewall failure by minimizing the amount of contaminated meat that enters the food supply and by identifying and tracing the animals that caused the contamination. Unfortunately, the Mabton mad cow experience

557. See 2002 GAO MAD COW REPORT, *supra* note 225, at 32 (“Many experts believe that vCJD is difficult to contract and, therefore, that relatively few people would develop the disease.”).

558. See FDA Food and Cosmetics Rule, *supra* note 368, at 42,263 (“Despite widespread exposure in the United Kingdom to BSE-contaminated meat products, only a very small percentage of the exposed population has been diagnosed with vCJD to date.”).

559. See *infra* Part VII.C.2 (raising the concern that meat industry resistance is likely to impair the FSIS’s authority to impose serious sanctions for HACCP violations, and further suggesting that congressional action will be necessary to provide the USDA the pose to mandate and enforce HACCP regulations).

demonstrates that the USDA is not fully prepared to address firewall failure with effective recalls and a universal cattle identification program.

A. A Perverse Recall Policy

One frequently mentioned impediment to effective protection from food-borne disease is the USDA's lack of authority to order manufacturers to recall contaminated beef and beef products.⁵⁶⁰ Although companies are sufficiently concerned about the public relations impacts of a failure to recall potentially adulterated meat that they are generally willing to recall it voluntarily,⁵⁶¹ a firm is entirely free to decline a request if it decides not to go to the expense and effort of a recall.⁵⁶² If it does so, the government's only recourse is to seek a court order to seize and detain adulterated products in a proceeding in which the government has the burden of proving that the product is adulterated and that seizure is the appropriate remedy.⁵⁶³ As a practical matter, a company can minimize the adverse economic impact of a voluntary recall by contesting it for several days as the meat becomes so thoroughly integrated into interstate commerce that a recall is unlikely to produce a very high yield.⁵⁶⁴

According to the Deputy Director of FSIS's Recall Management Division, the bulk of the financial burden of all recalls is ultimately borne by the slaughterhouse that produced the recalled meat and the companies that processed and sold it.⁵⁶⁵ FSIS bears only the costs of issuing the voluntary recall statement, informing the public of the recall, and ensuring

560. See USDA, FOOD SAFETY AND INSPECTION SERVICE, FACT SHEET: FSIS FOOD RECALLS (Oct. 2004), at http://www.fsis.usda.gov/fact_sheets/fsis_food_recalls/index.asp (last visited Feb. 11, 2004) (explaining that a food recall is a "voluntary" action by a manufacture).

561. See Boyle Interview, *supra* note 88 (stating that the USDA "cannot point to a single instance where, at their suggestion, a company refused to initiate a voluntary recall").

562. CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 10 (noting that a court order is required to force compliance when a firm refuses to issue a voluntary recall).

563. See *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 410-11 (1914) (explaining that the government has the burden of establishing a product is adulterated in order to warrant seizure); see also *United States v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds*, 516 F. Supp. 321, 326 (D.C. Kan. 1981) (stating "the concept of due process, in the Court's view, imposes the burden of persuasion on the proponent, here the government, and this burden does not shift."); CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 10 (noting that "the Secretary must go to the courts to obtain an order to seize and detain suspected contaminated products if a firm refuses to issue a recall voluntarily.").

564. See Foreman Interview, *supra* note 520 (explaining that by the time the meat gets around to being recalled much of it has been eaten); see also Frontline Interview with Eric Schlosser [hereinafter Schlosser Interview] (advising that "when the government starts asking for a recall, there's a negotiation process," and "while they're negotiating how much meat should be recalled, people are eating that meat"), available at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/schlosser.html> (last visited Apr. 3, 2005).

565. Michelle Avallone, Telephone Interview with Jane Johnson and Hany Sidrak, Deputy Director of Recall Management Division, Food Safety and Inspection Service, (June 15, 2004).

its effectiveness by inspecting the facilities subject to the recall.⁵⁶⁶ Although this policy may appear sensible in the context of huge operations that can easily afford the expense of a recall, the significant expense of product recalls and the USDA's unwillingness to defray the entire costs of a recall may dissuade small companies from participating voluntarily.⁵⁶⁷ More importantly, forcing the slaughterhouse to assume financial responsibility for recalls provides a strong economic incentive to avoid the recall risk entirely by ignoring or improperly handling suspicious animals.

B. Lack of a Universal Animal Identification Program

The task of locating the origin of the Mabton mad cow would have been much more difficult were it not for fact that a plastic tag identifying the farm that arranged for the cow's slaughter remained in an ear of its severed head.⁵⁶⁸ This was fortuitous because there is currently no legal requirement that cattle be tagged, and there is no requirement that slaughterhouses retain those tags for identification purposes.⁵⁶⁹ Even with the fortunate find of the tag, the search for the Mabton cow's herd of origin was greatly complicated by the absence of a national animal tracking system.⁵⁷⁰ By the time the USDA halted its investigation, only 29 of the 81 cows in the birth herd had been accounted for.⁵⁷¹ A functioning animal ID program would no doubt have increased that number dramatically. As it was, the effort was entirely unconvincing to the Japanese, whose agricultural attaché opined that "[t]he investigation is not completed; it just failed."⁵⁷²

When Secretary Veneman promised on December 30, 2003, to "begin immediate implementation of a verifiable system of national animal identification,"⁵⁷³ the Department was not prepared to put a system of national animal identification into place in the immediate future or even in the fairly distant future.⁵⁷⁴ The USDA had been working with state

566. *Id.*

567. See American Meat Institute, *AMI Product Recall Insurance*, at <http://www.meatami.com/Content/NavigationMenu/CrisisCenter/AMICrisisManagementResources/AMIProductRecallInsurance/AMIProductRecallInsurance.htm> (last visited Apr. 3, 2005) (detailing insurance the American Meat Institute offers to companies to cover recall costs).

568. See Gugliotta & Morgan, *supra* note 394 (quoting Stan Painter, FSIS federal meat inspector and chairman of the National Joint Council of Food Inspection, as stating: "If it hadn't had a tag, or the tag came off, they would never have known.").

569. *Id.*

570. See Vedantam & Harden, *supra* note 5 (stating that the lack of an organized system makes it difficult to identify the source of the infection).

571. *U.S. Ends Its Hunt for More Cases of Mad Cow Disease*, L.A. TIMES, Feb. 10, 2004, at A15.

572. Vedantam, *supra* note 242, at A1.

573. Press Release, USDA, Veneman Announces Additional Protection Measures To Guard Against BSE (Dec. 30, 2003).

574. See generally Grady, *supra* note 291 (noting that it would take a number of years to get the system that the USDA planned to implement immediately after the U.S. mad cow incident in place and operational).

agencies and industry groups since 2002 to come up with an acceptable Animal Identification Plan.⁵⁷⁵ The Department had, in fact, only earlier that month announced that it would “in the next few months” issue a notice of *proposed* rulemaking to establish such a program, and it predicted that it would be phased in over time so that livestock would not receive identification numbers until at least July 2005.⁵⁷⁶ Several critical issues must be resolved before an effective animal identification program can go into effect.

One unresolved issue is whether animal identification will be voluntary or mandatory.⁵⁷⁷ A related issue is who will be responsible for assembling and implementing an animal identification program. Easily available microchip devices “the size of a grain of rice” providing identification information can be implanted in cattle at a cost of about “\$2 apiece.”⁵⁷⁸ Cost estimates for workable identification devices range from \$5 to \$20 per head.⁵⁷⁹ Startup costs for the program would be about \$600 million, and annual costs are estimated to range from \$70 to \$122 million annually.⁵⁸⁰ Although these aggregate costs are nothing to be sneezed at, the cost to consumers of such a program would be pennies per pound of meat.⁵⁸¹

Another industry concern has been the potential of an identification program to decrease protections for confidential business information and thereby increase the risk of tort liability.⁵⁸² It is very difficult, however, to find a legitimate privacy or trade secrecy interest in the identity of an animal that a producer has sold to someone else. The short answer to the industry’s confidentiality concerns is probably the one accepted by Canadian producers when that country implemented a comprehensive cattle

575. See *supra* Part III.A.2.d (describing the Cattle Identification and Tracking Program under USDA Mad Cow Efforts Prior to December 2003).

576. See *USDA Creating National Livestock ID System*, AGONLINE, Dec. 8, 2004, at http://www.fass.org/fasstrack/news_item.asp?news_id=1730. But see Hileman, *supra* note 231, at 24 (stating that other estimates have the identification system in place by July 2006).

577. Charles Abbott, *After Mad Cow, U.S. Farmers Warily Back Animal ID*, REUTERS HEALTH, Jan. 9, 2004.

578. Michelle Cole, *Reliable Tracking of Cattle Could Be Years Away*, NEWHOUSE NEWS SERVICE (Mar. 8, 2004), at <http://www.newhousenews.com/archive/cole030804.html>; see also Margaret Webb Pressler, *Cattle-Tracing System Will Face Obstacles*, WASH. POST, Jan. 3, 2004, at E1; Wald, *supra* note 5 (discussing the microchips).

579. Arlene Weintraub & Janet Ginsburg, *A High-Tech Race To Corral Mad Cow*, BUSINESS WEEK, Mar. 1, 2004, at 108.

580. See *Draft U.S. Animal Identification Plan*, *supra* note 244, at 45; see also Pressler, *supra* note 578, at E1 (discussing the program’s potential costs).

581. See Stephanie Simon, *USDA Plans to Beef Up Livestock ID System*, L.A. TIMES, Jan. 11, 2004 (noting the negligible cost to consumers in comparison to the expense likely to be borne by ranchers).

582. See *id.* (“Many ranchers worry that farm-to-plate tracking will leave them vulnerable to consumer lawsuits.”).

identification program: “We have lost the right to anonymity if we’re food producers.”⁵⁸³

Many countries already have operational animal identification systems in place. The European Union, Canada, and Japan all have mandatory systems in place to track animals from birth to the meat retailer.⁵⁸⁴ Compliance is apparently high, perhaps because EU agricultural subsidies are contingent upon maintaining accurate producer records.⁵⁸⁵ Some EU countries have cattle identification systems run by private companies and funded by farmers.⁵⁸⁶ In Denmark, for example, a farmer-owned private company manages a national database that is funded by an annual fee paid by farmers.⁵⁸⁷ Canada’s animal identification system has been in place since 2001 and is run jointly by the Canadian Cattle Identification Agency, an industry group, and the Canadian Food Inspection Agency.

VI. WHY THE FIREWALLS ARE FAILING—UNDERLYING CAUSES OF INADEQUATE REGULATION

Although many of the underlying reasons for firewall failure were addressed in the analyses of the individual firewalls, several broader underlying causes are endemic to the existing regulatory regime and are therefore common to all of the firewalls. Although robust public debates might have helped avoid many of the problems that plague the current firewalls, the USDA has frequently shielded the industry and its own deliberations from public scrutiny and criticism. Both the FDA and the USDA face numerous legal and resource constraints that impede effective enforcement of the regulatory requirements out of which the firewalls are built. Finally, several institutional and structural deficiencies in the current regulatory regime greatly hamper the government’s efforts to maintain adequate firewalls against the spread of mad cow disease.

A. Lack of Transparency

At several critical junctures, the regulatory regime currently in place for protecting the public health from mad cow disease (and other meat-borne diseases as well) lacks transparency. Industry representatives and government officials work out critical matters of great public concern without any participation by representatives of the supposed beneficiaries of the regulatory protections—American consumers. One meat industry

583. Pressler, *supra* note 578.

584. See generally Drew, *supra* note 240.

585. See National Audit Office, IDENTIFYING AND TRACKING LIVESTOCK IN ENGLAND 14 (Nov. 2003) at http://www.nao.gov.uk/publications/nao_reports/02-03/02031144.pdf (outlining the tracking specifications for EU cattle).

586. *Id.*

587. See *id.* at 49 (providing details about Denmark’s process for tracking cattle).

observer concluded that the regime “maintains a level of secrecy that far exceeds that of nuclear power plants.”⁵⁸⁸ And the federal government has frequently aided and abetted the industry’s passion for secrecy.

1. *Lack of Transparency in the Import Restriction Program*

Restrictions on imports from countries in which BSE has been reported provide the first firewall in the defense against an outbreak of mad cow disease in the United States. Given the acknowledged importance of this critical first line of defense, the public has every reason to expect it to be an especially transparent process. Those expectations were sorely tested in April 2004 by reports that the USDA had quietly informed Canadian companies and U.S. companies with facilities in Canada that it would immediately lift many of the import restrictions that the USDA had put in place after the discovery of a mad cow in Canada in May 2003.⁵⁸⁹ Although a public outcry forced the USDA to back away from that proposal, trust in the transparency of its import program was shattered when a lawsuit revealed that for months APHIS had allowed imports of up to 33 million pounds of restricted beef products, including hamburger meat and processed meat containing offal, from Canada under a secretly administered “exemption” process.⁵⁹⁰ The USDA even refused to name the U.S. meat producers that had received the secret permits.⁵⁹¹

2. *Lack of Transparency in the Administration of HACCP and Prerequisite Programs*

The USDA has gone to great lengths to ensure that HACCP plans, FSIS verification efforts, and individual tests conducted by establishments at critical control points are invisible to the public.⁵⁹² It declined to require establishments to submit their written HACCP plans and Sanitation SOPs to FSIS for its files. Worse, it promised not to make copies of *any* operator-generated documents for its files (where they would be subject to Freedom of Information Act requests), except in cases where the inspector suspected that the HACCP program was operating incorrectly. Even in those situations, in which the public would seem to have an intense interest, FSIS made it clear that it would be very receptive to operator trade secrecy claims.⁵⁹³ The result of all of this secrecy is a closed system in which the public must trust the agency to do its job and has no significant access to

588. FOX, *supra* note 147, at 357.

589. See *supra* Part V.B.1.

590. See Kaufman & Skrzycki, *supra* note 378 (discussing the reasons Canadian beef could be imported to the U.S.); see also *supra* Part V.B.1.

591. Kaufman, *supra* note 382.

592. See *supra* Part III.A.1.d.

593. USDA HACCP Proposed Rule, *supra* note 125, at 6,818.

documents that might indicate that the agency is not doing its job. Performance-based systems like HACCP provide regulatees with a certain degree of flexibility to meet performance goals without having to adopt any government-mandated technology or methodology. The public is asked to trust the regulatees to implement measures that will attain the goals. The quid pro quo should be some vehicle for assuring the public that the performance goals are in fact being met. In the case of the USDA's HACCP program, the government is not fulfilling its side of the bargain.

3. *Lack of Transparency in the Animal Identification Program*

The nationwide animal identification program that Secretary Veneman promised would be forthcoming may be years away. And there are already discouraging signs that the agency or Congress may yield to demands of cattle producers to keep the information produced by that program away from the general public. The USDA's General Counsel recently acknowledged that information produced by a mandatory identification program would ordinarily not be protected as confidential business information, but she offered that if the program were voluntary the information might well be protected from release under FOIA.⁵⁹⁴ It did not take long before a bill was introduced in Congress to exempt animal identification information from FOIA disclosure altogether.⁵⁹⁵ Neither of these developments suggests that the animal identification that results from the USDA's current initiative is likely to be highly transparent.

4. *Lack of Transparency in the Recall Process*

To encourage industry participation in recalls, the USDA has implemented a policy of keeping the details and results of recalls secret.⁵⁹⁶ This policy came under sharp criticism in California Senate hearings probing why the public never learned that a batch of beef that may have contained meat from the Mabton mad cow had been quietly sold or recalled in as many as nine California counties without any public announcement of the fact that it was even present in those counties and no indication of how much had been recalled and how much had been eaten by unsuspecting

594. See Nelson Antosh, *Tracking of Cattle Becomes Key Goal/ Mad Cow Issue Prods USDA*, HOUSTON CHRONICLE, Mar. 5, 2004, at Business 1 (explaining that the agency is subject to FOIA, but that if information was "gained during a mandatory program, the test [for determining whether FOIA applies] would be harder").

595. See *id.* (advising at least one bill had already been filed to exempt animal identification information).

596. See Andrew LePage, *Beef Recall Secrecy Fought*, SACRAMENTO BEE, Feb. 25, 2004, available at <http://www.sacbee.com/content/business/agriculture/story/8333772p-9263870c.html> (detailing a "memorandum of understanding" between California's Department of Health Services and the USDA that prevents public access to details about the beef recall that occurred after the first known mad cow disease case).

consumers.⁵⁹⁷ The California Department of Agriculture, which was in charge of administering the (only partially successful) recall, admitted that it was sworn to secrecy by a memorandum of understanding (MOU) with the USDA. Under that MOU, which the USDA demands of all states participating in such recalls, federal officials agree to share with the state agency the names of stores and restaurants to which recalled meat has been shipped, and the state agency agrees not to reveal those names to the public.⁵⁹⁸ Interpreting the memorandum broadly, California agricultural officials refused to reveal critical recall information even to the counties in which the meat had been sold.⁵⁹⁹ Worse, the State Department of Health Services did not find out about the recall until a week later.⁶⁰⁰

B. Practical Enforcement Difficulties

Although any regulatory regime must depend heavily upon voluntary compliance by regulated entities, “governmental action is only as good as the enforcement mechanism used to ensure compliance.”⁶⁰¹ Food safety advocates generally supported the USDA’s adoption of a HACCP-based approach to meat safety, but they were concerned that its “performance-based” requirements would not be enforceable.⁶⁰² This general concern was shared by the authors of a recent National Academy of Sciences (NAS) report, which noted that “[i]mplementation problems, including questions about the authority of regulatory agencies to enforce performance standards, have contributed to diminishing the effectiveness of new regulatory measures aimed at controlling old and emergent foodborne hazards and have prompted many to question the effectiveness and appropriateness of the current system.”⁶⁰³ The capacity of FSIS inspectors to uncover instances of adulteration and cases of fraud is far too limited. The pressures on those inspectors to ignore potentially serious violations of USDA regulations are far too pervasive, and the options available to FSIS inspectors to require companies to address serious problems are far too few

597. Sabin Russell, *Mad Cow Censoring Gets Legislators’ Goat*, S.F. CHRONICLE, Feb. 25, 2004, at A15 (emphasizing the need for full disclosure to protect public safety).

598. *See id.* (recognizing that 38 states have not signed such MOUs, and at least one has retained recall information in the past).

599. *See id.* (showing strict adherence to their MOU and living up to their bargain with the USDA).

600. *See* Jon Ortiz, *State Hit A Wall on Beef Recall*, SACRAMENTO BEE, May 10, 2004, at D1 (reporting that despite signing the MOU, the State Department of Health Service did not receive critical up to date information on the recall).

601. Lassiter, *supra* note 370, at 444. Professor Lassiter concluded that the HACCP regulations “are significantly flawed because the imposed enforcement mechanisms are weak and inadequate.” *Id.* at 445.

602. USDA HACCP Proposed Rule, *supra* note 125, at 6,784.

603. SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 2.

to yield a great deal of confidence in the current mad cow regulatory regime.

1. The Limited Capacity of USDA Inspectors

In theory, an FSIS on-line inspector observes the removal and subsequent slicing of cheeks and tongues from every head, the splitting of every carcass, and the removal of every spinal cord from every spinal cavity. In theory, that same inspector also observes the cleaned carcass at the end of the process and is on the lookout for the presence of any SRM material on the carcass. In practice, it is not possible for inspectors to be everywhere at the same time. Even multiple inspectors have great difficulty observing all possible sources of contamination in large facilities operating at line speeds of more than 300 animals per hour.⁶⁰⁴ One inspector at a large plant in which 25-30 downer cattle were slaughtered on any given day reported that cattle were lawfully marched past him in groups of six, thereby rendering it impossible to observe all of the animals carefully.⁶⁰⁵

One of the primary purposes of adopting the 1996 HACCP regulations was to place the primary responsibility for ensuring safe food on the operators of the establishments, rather than on the FSIS inspectors. Thus, in the last few years, company employees and quality control officials have assumed a much larger role in ensuring the safety of the resulting meat, and FSIS inspectors have been increasingly relegated to the role of inspector of paper records prepared by the establishments.⁶⁰⁶ As part of their HACCP inspection duties, in-plant FSIS Consumer Safety Inspectors regularly review the plant's hazard analysis, HACCP Plan, pre-requisite programs, and all supporting documentation.⁶⁰⁷ The regulations assume that meat producers will keep accurate records of quantitative and qualitative testing done at critical control points, and they do not provide for an independent audit of the accuracy of those records. Thus, a dishonest operator that falsifies its records (e.g., by failing to report observations of the presence of SRMs on edible meat) will suffer no adverse regulatory consequences unless the fraud otherwise comes to the agency's attention.⁶⁰⁸ It is always possible that a company "whistleblower" will bring such fraud to the

604. See Schlosser Interview, *supra* note 564, at 3 (indicating the speed at which cattle is processed is at least twice as fast as anywhere else in the world).

605. See McNeil, *supra* note 229 (quoting an inspector as saying: "I'm lucky if I see the second or third . . . [t]he sixth? Forget about it.").

606. See FOX, *supra* note 147, at 356 (signaling a shift in philosophy on the part of the USDA).

607. Beasley-McKean/Duffy Email, 5/3/04, *supra* note 476, at 2.

608. See Lassiter, *supra* note 370, at 445 ("HACCP does not contain any mechanism to detect and confront fraudulent recordkeeping by the meat producer as a means to compel compliance with the program.").

agency's attention, but the fact the FMIA fails to provide whistleblower protections greatly reduces the likelihood of that ever happening.⁶⁰⁹

FSIS inspectors do conduct unannounced inspections during which they undertake their own testing at critical points.⁶¹⁰ The industry's decision to address SRMs through prerequisite programs, however, has had an impact on this process as well. Because the facilities have not established critical limits for SRMs at critical control points, unannounced inspections are limited to spot checks for visually observable SRMs on edible meat. A January 23, 2004, FSIS Notice providing "verification instructions" to its inspectors for the SRM Rule tells inspectors to "perform the verification activities related to SRM removal in conjunction with other food safety concerns by reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verifying the adequacy of Sanitation SOP procedures)."⁶¹¹ On-line inspections of individual carcasses or heads should attempt to "observe visible (readily identifiable) SRMs on edible portions of the product."⁶¹²

It is not at all clear that the USDA has the resources to conduct the inspections and follow-up necessary to make the performance-based HACCP approach work in the context of mad cow disease. The agency added the HACCP program "on top of the traditional carcass-by-carcass inspection duties" and has therefore had to stretch pre-existing resources to cover additional HACCP enforcement obligations.⁶¹³ The NAS report discussed above concluded that "[a]dequate resources have not been provided to enable the implementation of HACCP-based inspection effectively, efficiently, and without disruption."⁶¹⁴ Nevertheless, Congress has not significantly added to the USDA's appropriation for inspection activities, and it has steadfastly refused to allow FSIS to charge establishments user fees to cover the cost of inspections.⁶¹⁵

609. See *id.* at 453 ("[T]o date, Congress has not granted whistle-blower protection to meat industry employees.").

610. See 9 C.F.R. §§ 310.25(b)(2), 381.94(b)(2), 417.8 (2004) (stating that the frequency of unannounced inspections, however, depends upon the number of violations reported in the producer's records).

611. FSIS Notice 9-04, *supra* note 472, at 3.

612. *Id.* at 4 (noting that if such SRM material is found on edible portions of the product the establishment has an opportunity to recondition the entire carcass or head by knife trimming).

613. See CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 6 (explaining the current difficulties the FSIS is experiencing with having sufficient staff to meet their obligations).

614. SAFE FOOD REPORT, *supra* note 140, at 31.

615. CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 7 (speculating that such user costs would be no more than one cent per pound).

2. Pressures on USDA Inspectors

Even if USDA inspectors could be everywhere, they face strong pressures from the facilities they inspect and sometimes from their superiors at the USDA to overlook problems that they encounter. Inspectors and slaughterhouse workers have reported that FSIS inspectors have been pressured to approve near-dead downer animals that have to be dragged or carried into facilities to be stunned.⁶¹⁶ Numerous reports exist of inspectors who did their jobs so effectively that they became targets of complaints from facility operators and were ultimately transferred to different facilities.⁶¹⁷

FSIS inspectors can theoretically exercise the option of shutting down facilities that fail “to ensure that product is not adulterated” or fails to maintain sanitary conditions, even if the failure in question is not specifically prohibited in the regulations.⁶¹⁸ The FSIS instructions for inspectors, however, make it clear that stopping a moving production line is a drastic measure involving considerable economic loss to the facility operator. The instructions put inspectors on notice that their superiors at FSIS will support a decision to stop a line only if “a product that is going into the food supply has been directly contaminated and you can justify the production loss that will prevent its entrance into the food supply.”⁶¹⁹ The instructions warn inspectors that “[s]topping production for ‘possible’ cross contamination is unjustifiable unless you can verify that there is direct product contamination.”⁶²⁰ Clearly, FSIS inspectors face pressure from upstairs to keep the lines moving, even in the face of serious safety concerns.

3. Lack of Enforcement Options

Under the FMIA, the only enforcement options available to the government for violations of FSIS regulations are to request the Justice Department to file a criminal enforcement action or to threaten to withdraw FSIS inspection, thereby effectively closing the facility. The former option takes a great deal of time and effort and requires the government to prove beyond a reasonable doubt that the defendant knowingly violated the law. The latter is the regulatory equivalent of dropping the atomic bomb, because the economic consequences of an FSIS withdrawal for a large meatpacker are so high that the agency is necessarily very reluctant to

616. See McNeil, *supra* note 229 (recognizing that the real role of an FSIS inspector is not to slow the process down).

617. See *id.* (reporting the complaints of Dr. Lester Friedlander, a former USDA veterinarian).

618. USDA Sanitation Requirements Final Rule, *supra* note 177, at 56,402.

619. *It's What's For Dinner*, HARPER'S MAGAZINE, Apr. 2003, at 20.

620. *Id.*

consider it. Since the establishments know that withdrawal is not a serious option, most detected violations lead at most to the filing of a Noncompliance Record in the establishment's file. Enforcement thus becomes a matter of negotiation between the inspectors and the facility operator as to how many violations will be tolerated before FSIS threatens to pull the plug, and even after the threats are delivered, enforcement can still be an exercise in brinkmanship. Notably, the USDA does not have an option to issue citations and enforce them by seeking civil penalties in administrative proceedings where the burden of proof would be to show by a preponderance of the evidence that the violation occurred and that the penalties were warranted.⁶²¹

C. Institutional Conflict of Interest

A fundamental underlying problem with the USDA's approach to mad cow disease is its narrow view of its primary mission. Many USDA officials see the agency's primary role as the preeminent governmental protector of animal health. Protecting human health is all too often a secondary consideration for an institution so devoted to animal health and, consequently, the economic health of the industry that raises and markets meat from those animals. An APHIS spokesperson was refreshingly candid about this when he observed that "APHIS is not a human-health agency. The APHIS is an animal-and-plant agency."⁶²² Despite the FMIA's explicit focus on food safety, there are few indications that FSIS views its role any differently.

This elevation of animal health over human health is at least partly attributable to the fact that the USDA suffers from an "institutional conflict of interest" of the sort that characterized the old Atomic Energy Commission.⁶²³ The USDA's primary task has always been to advance the interests of American agriculture.⁶²⁴ As such, the USDA has been the country's chief spokesperson, advocate and apologist for agricultural economic interests. At the same time, Congress has charged the USDA with responsibility for protecting the consuming public from foodborne diseases such as vCJD. The same governmental entity is both a promoter and regulator of a single industry.⁶²⁵ On those relatively rare occasions

621. See CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 10 (indicating that at past hearings consumer groups and food safety advocacy groups have testified in favor of giving the USDA such enforcement power).

622. Henderson, *supra* note 435, at 2E.

623. See generally, K.S. Shrader-Frechette, NUCLEAR POWER AND PUBLIC POLICY (D. Reidel Publishing Company 1980); Elizabeth S. Rolph, NUCLEAR POWER AND THE PUBLIC SAFETY (Lexington Books 1979).

624. See NESTLE, *supra* note 124, at 63 (following the USDA's overall goal of making sure there is enough food available at all times to feed the population).

625. See Eric Schlosser, *The Cow Jumped Over the U.S.D.A.*, N.Y. TIMES, Jan. 2, 2004,

when the USDA considers taking a position strongly opposed by U.S. agricultural interests, the Department can expect criticism from the House and Senate Agriculture committees that oversee all of its programs.⁶²⁶ Professor Marion Nestle observes that “for decades, food producers, USDA staff, and members of the House and Senate agriculture committees constituted what was universally understood to be the ‘agricultural establishment.’”⁶²⁷

The USDA’s institutional bias was revealed in its reaction to the discovery of the Mabton mad cow. Although Department officials met frequently with representatives from the beef industry during the week between the announcement of the discovery and the press conference at which it announced its regulatory response, it did not meet with representatives of consumer groups at all during that period.⁶²⁸ Further evidence of institutional bias is observable in FSIS’s willingness to go to great lengths to ensure that HACCP plans and monitoring reports do not wind up in agency files where they might be subject to FOIA requests and in its adamant refusal to allow a small specialty company to test all of the animals it slaughters for BSE.⁶²⁹ The strong tendency to elevate “flexibility” over protection in its promulgation and administration of the SRM regulations also suggests institutional bias.⁶³⁰

D. The Revolving Door

The USDA’s institutional bias is further indicated by the career path of many upper-level USDA officials. Individuals with expertise in the arcane interface between government and agriculture tend to flow freely among the institutions that form the agricultural establishment.⁶³¹ A young political appointee with a mid-level supervisory job at the USDA may, with a change in Administrations, leave to work for an industry trade association. A young Hill staffer may, after acquiring expertise in complex agricultural legislation and accumulating many useful contacts, decide to

at A17 (“The Agriculture Department has a dual, often contradictory mandate: to promote the sale of meat on behalf of American producers and to guarantee that American meat is safe on behalf of consumers.”); *see also* Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J. L. REFORM 1089 (1987).

626. NESTLE, *supra* note 124, at 64 (elaborating on one instance in which opposition to the agricultural interests developed from health officials recommending restrictions on fat intake including dairy).

627. *Id.*

628. *See* Daly, *supra* note 341 (illustrating consumer group complaints).

629. *See supra* Part III.A.1.d (discussing public access to information).

630. *See supra* Part V.E.2 (stating that the SRM rule provides establishments with the flexibility to implement procedures that will best achieve its zero-tolerance performance standard for SRM).

631. *See* NESTLE, *supra* note 124, at 64 (establishing a revolving door between government and industry including heavy job exchange between lobbyist and the USDA).

abandon the cramped quarters and low salary of the legislative branch for a large office in the USDA or the considerably more lucrative lifestyle of a corporate lobbyist. On rare occasions, consumer advocates have been appointed to high positions in the USDA,⁶³² and once in awhile champions of consumer interests have served on one of the congressional agriculture committees.⁶³³ These people, however, are exceptions to the rule.

The “revolving door” tends to spin especially rapidly at the change of Administrations. Secretary Ann Veneman, for example, served on the Board of Directors for Calgene, Inc, a pioneer in agricultural biotechnologies until it was purchased by Monsanto Corporation, the nation’s leading biotechnology company. Veneman also served on the International Policy Council on Agriculture, Food, and Trade, a group funded by Cargill, Nestle, Kraft, and Archer Daniels Midland.⁶³⁴ Her predecessor as Secretary of Agriculture, Dan Glickman, left USDA to join a law firm that lobbies for the food and agriculture industries.⁶³⁵ Veneman appointed a lobbyist for the National Cattleman’s Beef Association, Dale Moore, to be her chief of staff.⁶³⁶ Moore served as the legislative director of the House Agriculture Committee from 1995-96, and he worked as the minority legislative coordinator for the House Agriculture Committee from 1993-94.⁶³⁷ Charles Lambert, Deputy Under Secretary for Marketing and Regulatory Programs at the USDA, had been a lobbyist for the National Cattleman’s Beef Association for fifteen years before joining the USDA.⁶³⁸

632. See Carole Tucker Foreman, *Biography*, Pew Initiative on Food and Biotechnology, available at <http://pewagbiotech.org/events/1121/bios/foreman.php> (last visited Apr. 2, 2005) (providing that Carole Tucker Foreman, now a spokesperson for the Consumer Federation of America, was appointed by President Carter to be the head of the Food Safety and Inspection Service).

633. See Press Release, House Science Committee, Statement by Marth Macias Brown on the Passing of the Honorable George E. Brown, Jr., (July 16, 1999), available at http://www.house.gov/science_democrats/releases/99jul16.htm (last visited Apr. 2, 2005) (noting Congressman George Brown, who chaired the House Agriculture Committee from 1991 to 1994, was generally regarded as a friend to consumer and environmental groups).

634. See Press Release, Center for Responsive Politics, The Bush Administration: Ann M. Veneman, available at <http://www.opensecrets.org/bush/cabinet/cabinet.veneman.asp> (last visited Apr. 2, 2005) (illustrating the fast-paced change from the position Agriculture Secretary to meat industry positions and visa versa).

635. See Press Release, Kennedy School’s Institute of Politics, Former Agriculture Secretary to Direct the Kennedy School’s Institute of Politics (Apr. 25, 2002), available at http://www.ksg.harvard.edu/press/press%20releases/2002/pr_glickman_iop_042502.htm (restating the Agricultural Secretary’s connection to the food and agricultural industry rather than consumer advocates).

636. See NESTLE, *supra* note 124, at 65 (demonstrating the process of the changes in administration in 2001).

637. See *Editor’s Roundup: USDA People in the News*, USDA NEWS, Jan – Feb 2001, available at <http://www.usda.gov/news/pubs/newslett/old/vol60no1/moore.htm> (last visited Feb. 15, 2005) (stating the professional history of Dale Moore and his expertise in agricultural matters).

638. See Anne C. Mulkern, *Watchdogs or Lap Dogs? When Advocates Become Regulators*, DENVER POST, May 23, 2004, at A1 (showing how even a lobbyist for this

VII. SUGGESTIONS FOR CHANGE

The foregoing analysis of the federal government's regulatory response to the discovery of the Mabton mad cow strongly suggests that changes are in order. The agencies themselves have sufficient legal authority to implement some of the necessary changes, and they should do so as quickly as possible. The following two subsections outline changes that the USDA and the FDA can implement administratively with little or no assistance from Congress other than supplying much needed additional resources. The next subsection suggests reforms that will probably require legislation and are therefore properly addressed to Congress.

A. *USDA Reforms*1. *Ensure that Imported Beef Complies with U.S. Requirements*

The USDA's secret grant of exemptions for 33 million pounds of beef imports from Canada, which circumvented its otherwise applicable import restrictions on Canadian beef, proved to be an embarrassment to the Department, and it will no doubt feel compelled to take steps to see that it does not happen again. The USDA should dismantle its covert process for granting exemptions from import bans on the basis of unpublished petitions from U.S. meat processors who agree to vague "mitigation" measures. The very existence of such covert processes undermines the public trust in the import "firewall" that is the first line of defense against mad cow disease. The Department should promulgate regulations providing for an open exemption process in which the public receives notice of exemption requests and is provided an opportunity to comment on those requests.

2. *Increase Surveillance*

Although testing all cattle for BSE might provide additional information on the incidence of mad cow disease, it is probably not worth the considerable resources required to test every animal. The USDA should, however, follow the example of the EU and test all cattle of greater than thirty months in age for BSE prior to slaughter for human consumption.⁶³⁹ Failing that, APHIS should at the very least radically revise its current "see no evil" policy. First, FSIS inspectors should continue to take samples from downer and suspect cattle, and APHIS laboratories should not have the option of declining to test those samples for BSE. Second, APHIS should, with the help of an expert advisory committee, design a

association was mistaken when he stated that mad cow disease was not a threat to the US), available at <http://proquest.umi.com> (last visited Feb 14, 2005).

⁶³⁹ See *supra* note 54; see also Letter from Steven Roach to Docket Clerk, *supra* note 459 (recommending testing of all cattle above thirty months).

comprehensive random sampling program under which APHIS personnel simply show up at slaughterhouses and rendering facilities and randomly select cattle brains for sampling. The random selection program should include three categories: 1) less than 24 months, 2) between 24 and 30 months, and 3) above 30 months. The proportion of total cattle randomly tested should increase as the age category gets higher.⁶⁴⁰ The USDA clearly has the authority under the FMIA to implement a program of mandatory testing, and it should do so forthwith.⁶⁴¹

3. *Permit Voluntary Testing*

The USDA's adamant refusal to allow private companies to test their cattle for BSE is simply inexplicable. The only plausible explanation for the USDA's position is an apparent desire to protect the big five beef processors from competition. Nothing in the USDA's statutes suggests that protecting dominant companies from competition is one of the tasks assigned to that Department. It should therefore grant any petitions from companies that express a desire to engage in universal testing and demonstrate the ability to do so. Any concerns about the efficacy of the testing can be addressed through frequent inspections of company testing laboratories.

4. *Deal with the Disposal of Downer Cattle*

Having determined to condemn almost 200,000 downer cattle per year, rather than allow them to enter the human food supply, the government must finish the job and prescribe what must be done with the condemned animals. Technologies are available that will guarantee the destruction of prions in infected tissue. The USDA favors a process, called alkaline hydrolysis, in which carcasses are dissolved in vats of lye under conditions of high pressure and temperatures in excess of three-hundred degrees.⁶⁴²

640. See *International Panel Report*, *supra* note 340, at 7. The International Panel urged the USDA to consider testing a random sample of healthy slaughter cattle over 30 months of age. Because mad cow disease has been detected in cattle younger than 24 months of age, the program suggested here would include all age categories in the random selection process but provide for proportionally less testing in lower age categories.

641. See Animal and Plant Health Inspection Service, Blood and Tissue Collection at Slaughtering and Rendering Establishments, 69 Fed. Reg. 10,137 (Mar. 4, 2004) (to be codified at 9 C.F.R. pt. 71) (requiring slaughterhouses and rendering plants to grant access to APHIS personnel for the purpose of collecting samples for BSE testing and other purposes).

642. See Waste Reduction by Waste Reduction, Inc., *Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species*, Comments on Proposed Rule, Mar. 24, 2004 [hereinafter *Waste Reduction*]; see also Denise Grady, *With Diseased Animals, Disposal Isn't Simple*, N.Y. TIMES, Jan. 6, 2004, at F6. This process leaves about 76 pounds of bone and 375 gallons of a sterile solution, both of which can be used for fertilizer. *Id.* An Indiana company is ready and willing to produce digesters using this process that can process up to 40,000 pounds of potentially contaminated tissue in a single batch for about \$1.5 to 2 million apiece. *Id.*

Although this process may be relatively expensive at this point, costs should decrease as production of alkaline hydrolysis tissue digestors increases to meet increased demand.⁶⁴³ Scientists are also working on a promising technology for cheaply disposing of downer cattle through composting.⁶⁴⁴

One of the serious disadvantages of the ban on the use of downer cattle for human food is the perverse incentive it provides to producers to destroy and improperly dispose of such cattle in ways that could lead to transfer of mad cow disease to other animals. This incentive will dramatically increase if the FDA implements, as it should, a ban on feeding proteins from mammals to farm animals, thereby completely destroying the rendering market for downer cattle. A partial solution to this problem is for the USDA to establish a program for compensating producers for cattle that must be condemned under the January 2004 regulations. Illinois has already established a financial incentive program under which producers presenting cattle that appear to be suffering from CNS disorders to state inspectors are compensated \$300 for the animal and reimbursed the cost of transporting the animal to the state laboratory for testing.⁶⁴⁵ USDA officials have indicated that the Department is willing to consider a similar option, but it has not yet implemented it.⁶⁴⁶

The USDA should follow the Illinois lead and establish a program under which it will pay up to \$300 plus travel costs for downer cows that are taken to a designated location for BSE testing. If the determination that the cow was suffering from a CNS disorder was a reasonable one (e.g., based upon a veterinarian's assessment), then the government should further reimburse any disposal costs. If compensation does not solve the problem of improper disposal of downer and otherwise suspect cattle, the USDA should seek authority from Congress to regulate the disposal of downer and

643. See Waste Reduction, *supra* note 642 (explaining that "alkaline hydrolysis Tissue Digestor manufacturing has not yet benefited from the significant cost reductions that will accompany high volume requirements for these machines").

644. See *Mad Cow Ban Could Prompt More Cow Composts*, ASSOCIATED PRESS, Apr. 11, 2004 (stating that officials at Iowa State University are urging farmers to utilize this composting technique, because the cost is minimal). The effectiveness of composting in destroying mad cow prions, however, has not been demonstrated scientifically. See Waste Reduction, *supra* note 642 ("[T]here is no evidence that composting destroys the infectivity of BSE prions.").

645. See *New Incentive Offered for Mad-Cow Vigilance*, CHI. TRIB., Mar. 15, 2004, at C3 ("This plan will expand our surveillance of farms and make sure we continue to work aggressively to monitor for the disease and protect our food supply.").

646. See Randy Fabi & Charles Abbott, *U.S. May Pay Farmers to Test for Mad Cow*, REUTERS, Jan. 2, 2004 (pointing out this is the only option under consideration), available at http://foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum=1012000 (last visited Apr. 2, 2005).

other cattle that die from diseases that pose a threat to human and animal health.⁶⁴⁷

5. *Establish an Effective Animal Identification and Tracking Program*

With the help of state agencies and industry groups, the USDA has been slowly working its way toward a system for universal animal identification that, if implemented, would begin on a voluntary basis some time in the not-too-distant future.⁶⁴⁸ Most observers recognize that a comprehensive animal identification system is necessary to track animals, protect animal and human health, stem economic disruption from lost export markets, and restore lost consumer confidence in the safety of U.S. meat.⁶⁴⁹ Syringe-injectable radio-frequency and digital data chips about the size of a grain of rice are readily available on the U.S. market.⁶⁵⁰ In fact, such chips have already been implanted in millions of wild salmon to facilitate tracking them around hydroelectric dams in the Northwest.⁶⁵¹ Another technology that scans the retinas of cattle is also available for universal identification purposes.⁶⁵² The latter technology would avoid the risk of a microchip winding up in someone's hamburger.⁶⁵³

The USDA should implement an effective mandatory animal identification system as expeditiously as possible. The Department should reject suggestions that the program remain voluntary. Noting that Canada's

647. See Letter from Steven Roach to Docket Clerk, *supra* note 459 (urging the USDA to exercise its existing authority to "require licensing of all entities including farms and ranches that dispose of cattle").

648. See Simon, *supra* note 241 (responding to a discovery of a Holstein infected with mad cow disease); see also *supra* Part III.A.2.d. (stating that while the other countries have mandatory animal testing systems, the United States has yet to adopt a system largely due to producer concerns over costs, legal liability, and privacy).

649. See generally Jill E. Hobbs, *Traceability and Country of Origin Labeling* (2003), at <http://www.farmfoundation.org/farmpolicy/hobbs.pdf> (last visited Feb 15, 2005) (describing the process and history of tracking and labeling on food products and livestock). In a 2002 report evaluating the risk of foot and mouth disease, the U.S. General Accounting Office (GAO) identified animal tracking as an area in need of improvement stating "the United States does not have a system to identify and track animal movements in the event of an outbreak, and it is unclear how this information would be gathered in a timely manner." GENERAL ACCOUNTING OFFICE, FOOT AND MOUTH DISEASE: TO PROTECT U.S. LIVESTOCK, USDA MUST REMAIN VIGILANT AND RESOLVE OUTSTANDING ISSUES, GAO-02-808, 5 (July 2002).

650. See Cole, *supra* note 578 (emphasizing that even though an ID system should be used, it may take several years before it is operational); see also Sherrie Gossett, *Spy Chips for Nation's Livestock?*, WORLDNET DAILY, Feb. 28, 2004 (stating that this ID and chip can be read from just a few feet away and is wirelessly writeable), at http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=37347 (last visited Apr. 2, 2005).

651. See Simon, *supra* note 241 (indicating that veterinarians also put these chips in dogs, cats and pet birds).

652. See Weintraub & Ginsburg, *supra* note 579 (inventing the device to track every step of the beef production process).

653. See *id.* (stating that all this procedure entails is taking a scan of the retina and nothing is put into the cow, so there is no extra burden on slaughterhouses to make sure they do not migrate any devices into the meat).

initial voluntary testing program attained a poor seventy-five percent compliance, the chairman of the Canadian agency responsible for that country's cattle identification program reported that compliance climbed to ninety-nine percent once the program became mandatory. The USDA has sufficient legal authority to establish a mandatory nationwide cattle identification system. The Animal Health Protection Act (AHPA)⁶⁵⁴ empowers the USDA to regulate interstate movement of animals for purposes of detection, control, and eradication of disease.⁶⁵⁵ Animal identification and tracking for BSE (and other diseases) should easily fall within this authority to "detect" and "control" livestock disease.⁶⁵⁶

6. Eliminate the Specified Risk Material Loopholes

Although BSE has undeniably been found in cattle much younger than the thirty month cut-off that the SRM Rule establishes for many categories of risky tissues, FSIS decided to allow such risky materials from younger cattle to be used in human food and animal feed in spite of the risk of spreading mad cow disease.⁶⁵⁷ An International Panel appointed by Secretary Veneman after the discovery of the Madton mad cow recommended that FSIS redefine SRM to include skull, brain, spinal cord, and vertebral column of all cattle over twelve months of age and lower intestines of all cattle.⁶⁵⁸ The panel noted that the suggested twelve month cut-off represented "a recognition of the fact that some cattle under thirty months of age may be slaughtered with infectivity present in the tissues."⁶⁵⁹ The European Union has defined SRM to include risky tissues of animals

654. See generally Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 10,401 *et seq.* (emphasizing the importance of this issue).

655. See *id.* §§ 10,406-07 (clarifying that the Secretary can "hold, seize, quarantine, threat, destroy, dispose of, or take other remedial action" when dealing with animals moving interstate); see also APHIS, ANIMAL IDENTIFICATION, available at http://www.aphis.usda.gov/vs/ nahps/animal_id/ (last visited Apr. 2, 2005) (relying upon the APHA, the USDA has, for many years, employed animal identification tools, such as tattoos, ear tags, and other comparatively crude identification devices, to trace diseased animals as part of its ongoing outbreak and eradication programs).

656. In addition, the FMIA empowers the USDA to ensure meat safety through inspection and recordkeeping requirements. 21 U.S.C. § 601 *et seq.* (2000). The statute requires slaughterhouses, meat brokers and wholesalers, renderers, and others to maintain records to "disclose all transactions involved in their businesses." *Id.* § 642. This would appear to provide authority for the USDA to require participants throughout the animal production process to keep and produce such business records. Insofar as such records are necessary for an adequate nationwide animal identification program, the USDA rather clearly has the authority to promulgate regulations requiring companies to keep such records and to make them available to the USDA inspectors.

657. See *supra* Part VIII.A.6 (stating that the FSIS decided to allow risky materials from younger cattle to be used in human food and animal feed despite the potential risk of spreading mad cow disease).

658. See *International Panel Report, supra* note 340, at 5 (stating that this should be done unless surveillance proves the BSE risk in the U.S. is minimal).

659. *Id.*

imported from the U.K. and Portugal greater than six months old and of all animals from other EU countries greater than twelve months old.⁶⁶⁰

If risky materials can be removed from older cattle, they can likewise be removed from younger cattle, and the only reason for declining to do so is the added expense of disposing of such materials and a very slight loss of protein to the food supply. The FMIA, however, does not permit FSIS to engage in this sort of balancing of the costs and benefits of safety measures in determining whether meat containing SRMs is adulterated.⁶⁶¹ FSIS should follow the lead of the European Union and the advice of its own International Panel and broaden the definition of “specified risk material” to the relevant tissues from all animals over twelve months of age.⁶⁶²

Furthermore, FSIS should not simply walk away from its decision to exclude bone marrow from the definition of “specified risk material.” The USDA recognizes that bone marrow has demonstrated infectivity thirty-eight months after exposure in one laboratory experiment, but it has concluded that the findings of that study were “not conclusive.”⁶⁶³ Although it is not clear why the public should have to wait for a “conclusive” study before it can expect protection from this potentially risky material, the USDA should immediately fund studies to determine whether and to what extent bone marrow from BSE-positive cattle is infective. If the previous study is confirmed, FSIS should promulgate an interim final rule expanding the definition of SRM to include bone marrow.

7. Remove the Option of Relying upon Prerequisite Programs

FSIS’s passive acquiescence in the industry’s decision to rely upon Sanitation SOPs and/or prerequisite programs, rather than establishing and monitoring critical limits for SRMs at critical control points, effectively neuters the SRM Rule. Unlike HACCP programs, prerequisite programs do not require FSIS approval. In addition, FSIS treats a violation of a prerequisite program as an indication that the establishment’s hazard analysis should be revisited, rather than as a legally enforceable violation of the law. Also, much more documentation is required for HACCP programs than for prerequisite programs. Finally, the industry’s wholesale reliance upon prerequisite programs to implement the SRM Rule ensures that they are not engaged in scientific testing for SRMs in meat and meat

660. *Specified Risk Material from November 2004* (November 23, 2004), at <http://www.food.gov.uk/multimedia/webpage/srmnov04>.

661. See *supra* Part VIII.A.6 (explaining the risks of establishing a thirty month cut-off for testing risky tissues).

662. See Letter from Karen L. Egbert, *supra* note 459 (taking the position that a 12-month age cutoff should be employed in defining SRM).

663. See USDA SRM Interim Final Rule, *supra* note 2, at 1864 (disregarding the fact that bone marrow is not designated as SRM, FSIS announced requirements to limit bone marrow in meat produced).

products. Not only does this hinder the effectiveness of the establishment's own efforts to ensure that it does not violate the zero-tolerance standard for SRMs in final product, it also hampers the efforts of FSIS inspectors to conduct unannounced inspections for the presence of SRMs on meat.⁶⁶⁴ FSIS should amend its SRM rule to eliminate the option of relying upon Sanitation SOPs or other prerequisite programs as a means to implement the rule's zero-tolerance for SRMs standard.

8. *Require Quantitative Testing for SRMs in Implementing any Performance-Based Requirements*

Whether or not it continues to allow establishments to implement the SRM rule through prerequisite programs, FSIS should not allow establishments to rely upon visual inspection for SRMs, conducted at a frequency of as low as "once per day during slaughter operations," to monitor for SRMs in meat and meat products.⁶⁶⁵ Anything less than a scientific test for the presence of actual SRMs in meat will not ensure adequate detection of the presence of SRMs in meat. While tests for the presence of some, if not all, SRMs are readily available,⁶⁶⁶ the industry's sorry experience in keeping spinal cord out of the finished product of AMR systems indicates that SRMs will be present in a distressingly large proportion of finished meats if frequent tests of the kind envisioned for HACCP programs are not periodically undertaken.⁶⁶⁷

FSIS should amend the SRM Rule to require testing for SRMs at critical control points and at the time that the product exits the facility. Even if it continues to allow establishments to rely upon Sanitation SOPs and prerequisite programs, it should mandate testing for SRMs at appropriate points in the manufacturing process. FSIS certainly has the authority to require quantitative testing for contaminants in Sanitation SOPs and prerequisite programs, and it did just that in its 2003 Interim Final Rule for Listeria.⁶⁶⁸ In addition, FSIS should modify its own testing program to require FSIS inspectors periodically to test random samples of final product

664. See *supra* Part VII.B.1 (discussing the limited capacity of USDA inspectors).

665. See Nebraska Cattle Slaughter SRM SOPs, *supra* note 494, at 2 ("[R]ecords will be a visual observation of the SRMs control procedures to ensure proper performance.").

666. For example, in connection with its AMR regulations, FSIS has written guidelines for using Glial Fibrillary Acidic Protein Analysis to test for CNS material, and some large meatpacking companies already routinely test their products for the presence of minute amounts of brain and spinal cord material. See *supra* Part III.A.1.a. (discussing the lack of a monitoring requirement).

667. See *id.*

668. See USDA Listeria Rule, *supra* note 499, at 34,215 ("[The] FSIS regards testing as an essential means of verifying the effectiveness of sanitation procedures to control L. monocytogenes, whether the procedures are incorporated in a HACCP plan, a Sanitation SOP, or another prerequisite program."); see also Johnson Interview, 7/1/04, *supra* note 474 (stating that the FSIS "could test for SRMs at the rail under either HACCP or Prerequisite programs").

for the presence of SRMs. This program could be modeled on the existing program for testing AMR product for spinal cord and other CNS materials.⁶⁶⁹ This second layer of testing would provide a much-needed level of redundancy while at the same time serving as a vehicle for detecting fraud or incompetence in company-administered testing programs.

9. Write Protective Standards for SRM Removal

The most effective environmental laws often articulate high health and environment goals, but also charge the implementing agencies with promulgating standards aimed at inducing regulatees to install the best available technologies.⁶⁷⁰ Although the aspirational goals may be achievable over that long haul, the “technology-based” approach ensures that progress is made in the near term in pursuit of the long-term goals. SRM regulation is a very good candidate for this overall approach. A zero-tolerance policy is a worthy, if potentially unattainable goal. The regulatory requirements enacted in pursuit of that goal should at the very least insist that companies do the best that they can with the most effective tools available, even if that means sacrificing efficiency for the sake of safety.

Although the relevant establishments have only just begun to implement the new regulations, it is already clear that the high degree of discretion that the SRM Rule’s “flexible” approach affords to those establishments virtually guarantees that SRMs will enter the food supply. Overworked USDA inspectors, who have no authority to pre-approve operator-established prerequisite programs and face considerable pressure not to hold up production lines, cannot possibly take on the added responsibilities entailed in effectively enforcing a performance-based approach that depends exclusively upon visual detection to ensure that SRMs do not wind up in finished product. Consequently, consumers will not receive the regulatory protection to which they are entitled under federal law.

The USDA should therefore reconsider the extent to which it relies upon performance-based standards to regulate mad cow risks. Tried and true technologies and techniques for reducing mad cow risks are easily

669. See Letter from Steven Roach to Docket Clerk, *supra* note 459 (suggesting that FSIS create a “regulatory sampling program to verify that edible portions are not contaminated by central nervous system tissue from cattle over 12 months of age”).

670. See Wendy Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83 (2000) (finding that the most important environmental innovation over the past 30 years is the technology-based standards); see also Rena Steinzor, *Reinventing Environmental Regulation: The Dangerous Journey from Command to Self-Control*, 22 HARV. ENVTL. L. REV. 103, 104 (1998) (considering and discussing “experiments in reinventing the system that controls pollution through the encouragement of industry self-regulation as an alternative to traditional rules”).

available, but are not being implemented at all of the nation's slaughterhouses and meat processing facilities. For example, FSIS could prohibit the use of any tissue from the head of untested cattle in meat for human consumption and require slaughterhouses to remove the entire vertebral column of all animals during the slaughter operation.⁶⁷¹ FSIS should undertake a comprehensive survey of safety technologies and techniques, identify additional feasible techniques and technologies for reducing mad cow risks, and promulgate regulations requiring the installation and use of the best available technologies and techniques. To fulfill its statutory obligation to protect the public health, the USDA must ensure at the very least that companies are doing the best they can to keep mad cow prions out of the food supply.

10. Less Tolerance for Repeated Violations

As FSIS is currently implementing the SRM Rule, a facility can repeatedly produce SRM-contaminated meat and suffer no adverse legal consequences.⁶⁷² This degree of flexibility seems wholly unwarranted for regulating potentially dangerous SRMs. Since the mad cow prion is not destroyed by cooking at ordinary temperatures, it is not sufficient to focus exclusively upon process failure in regulating SRMs in meat. If the agency is serious about its zero tolerance goal for SRMs in edible meat, it should require its inspectors to stop a production line any time SRM-contaminated meat is observed on otherwise edible meat and ensure that the contaminated meat is either destroyed or fully reconditioned and that the cause of the contamination is identified and corrected before allowing the line to resume. If SRM is detected in final product, a Noncompliance Record should be issued automatically, and a recall should be implemented if it appears that the deficiency caused additional meat to become similarly contaminated. There should not be a three-strike rule for SRMs in meat destined for human consumption.

11. Prevent Shifting of Responsibility to Downstream Establishments

A recently issued FSIS Directive contains a subtle suggestion that slaughterhouses may avoid responsibility for shipping SRM-free meat to downstream customers if they determine that the customers will detect and remove the SRMs prior to human consumption.⁶⁷³ This highly questionable signal to large slaughterhouses to shift their responsibility for keeping SRMs out of meat to their customers should be immediately

671. See *supra* Part IV.A.1.b. (stating that the FSIS allows establishments decide how to institute procedures for removal subject to limited oversight).

672. See *supra* Part V.E.5. (discussing the HACCP's high tolerance for contamination).

673. See *supra* Part IV.A.1.b. (discussing the locus of responsibility for removing SRMs).

withdrawn. FSIS should either amend the SRM Rule or issue a revised notice to its inspectors informing them that SRM-contaminated meat may not leave the slaughterhouse, whether or not downstream processors are capable of identifying such meat and removing it from the food supply.

12. Increase Transparency

The USDA's frequent attempts to make made cow regulation a matter of private negotiations between its officials and the industry are inconsistent with modern administrative law concepts of "open government" and depart drastically from the way other agencies, like the EPA, implement their statutes.⁶⁷⁴ The USDA should promulgate procedural regulations ensuring that future requests for "exemptions" from health-related import restrictions are published in the *Federal Register* and that the public has an opportunity to comment on such requests before the USDA grants them. FSIS should amend its HACCP regulations to require that establishments submit all written HACCP plans and prerequisite programs to FSIS for its files where they will be available for public inspection. Like NPDES discharge permits that the EPA issues under the Clean Water Act,⁶⁷⁵ HACCP plans are legally enforceable documents, and they should be available to members of the public who are interested in evaluating how well meat processing establishments and the USDA inspectors are doing their jobs. If the USDA has a serious concern about whether such plans contain legitimate trade secrets, it should seek legislation specifying that such plans are not trade secrets and are fully disclosable to the public.

13. More Effective Enforcement

Effective enforcement is necessary for any regulatory program, but it is especially critical for the integrity of "performance-based" regulatory regimes that give regulatees a great deal of flexibility to achieve agency-mandated goals. The USDA has in the last few years added both the new HACCP program and the new mad cow regulations "on top of the traditional carcass-by-carcass inspection duties."⁶⁷⁶ In addition to seeking authority to levy civil penalties, the USDA should seek additional resources

674. For example, all industry-generated pollution control data generated pursuant to NPDES permits under the Clean Water Act are easily available for public inspection. See 33 U.S.C. § 1318 (b) (2000) (providing that any records regarding effluent data "shall be available to the public, except that upon a showing satisfactory to the Administrator by any person that records, reports, or information, or particular part thereof (other than effluent data), to which the Administrator has access under this section, if made public would divulge methods or processes entitled to protection as trade secrets of such person").

675. See *id.* (requiring certain documents to be "available to the public" but excluding documents related to trade secrets).

676. CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at CRS-6; see also *supra* Part VII.B.1. (discussing the limited capacity of USDA inspectors).

from Congress for enforcing its January 2004 regulations and future mad cow-related regulatory requirements. More importantly, upper-level USDA officials should not put pressure on inspectors to keep production lines running even when they have doubts about products contaminated with SRMs or other unsafe material. To the contrary, upper-level supervisors should support their inspectors in the field and thereby send a message to the regulated establishments that FSIS takes its public health responsibilities seriously.

B. FDA Reforms

1. Expand the Feed Ban

On January 26, 2004, the FDA announced that it would amend the feed ban rule to eliminate the exemptions for mammalian blood, poultry litter, and plate waste and to require any feed manufacturing facilities using prohibited protein to be dedicated to non-ruminant feed.⁶⁷⁷ For reasons known only to its leaders, the agency decided instead to solicit more information on feed restrictions and thereby effectively postpone any additional regulation until after the 2004 elections. The agency should publish a Notice of Proposed Rulemaking (NPRM) requesting public comment on the changes that it promised in January.

The NPRM should, however, go beyond the rather timid steps mentioned in the January 26th announcement. Because of the considerable real-world risk of misfeeding pig or chicken feed to cattle, the best way to prevent improper feeding on the farm is to prohibit the addition of any animal protein to any feed consumed by animals that may be eaten by humans or rendered into cattle feed.⁶⁷⁸ The U.K. learned this lesson the hard way when feed restrictions virtually identical to the current U.S. restrictions were openly flouted by some farmers and feed manufacturers and inadvertently violated by others.⁶⁷⁹

677. See News Release, United States Department of Health and Human Services, Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), available at <http://www.hhs.gov/news/press/2004pres/20040126.html> (last visited Feb. 10, 2005) (noting the presence of BSE in blood, the presence of "bedding, spilled feed, feathers, and fecal matter" in poultry litter, and the existence of "uneaten meat and other meat scraps" in plate waste).

678. See *supra* Part V.B.1; see also RAMPTON & STAUBER, *supra* note 37, at 5 ("Simple common sense tells most people that this practice of animal cannibalism is a bad idea.").

679. See *International Panel Report*, *supra* note 340, at 8 ("The current [FDA Feed Rule] ban reflects the situation in Europe early in the outbreak where, with the benefit of hindsight, it can be concluded that propagation of BSE infectivity continued, albeit to a lesser extent than would have occurred in the absence of any controls."); see also Doughton, *supra* note 392 ("Some farmers and feed manufacturers flouted the rules, while others inadvertently contaminated cattle feed in plants that also produced feed in which cow parts were allowed.").

The European Union (EU) prohibits the use of any processed animal protein in the feed of any farm animal that is raised for food production,⁶⁸⁰ and it includes a much narrower list of exceptions.⁶⁸¹ An EU Council Directive further bans the use of plate waste as feed for pigs and poultry.⁶⁸² In addition, the EU has a cannibalism ban that prohibits any intra-species recycling except for fish and fur animals.⁶⁸³ Consumer groups in the United States have long urged the FDA to expand its Feed Rule to “ban the feeding of all rendered animal remains to food animals.”⁶⁸⁴ The USDA’s own International Panel recommended that “the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds.”⁶⁸⁵ A broader prohibition would considerably enhance the FDA’s enforcement arsenal, which contains no vehicle for testing animal feed for the presence of banned proteins because of the difficulty of distinguishing prohibited ruminant proteins from allowable pig proteins.⁶⁸⁶

According to a representative of the National Cattlemen’s Beef Association, expanding the Feed Rule to prohibit using animal protein in animal feed would not have a large impact on the beef industry, because that industry’s “need for animal protein byproducts has never been high.”⁶⁸⁷ It could, however, adversely affect the dairy industry, which relies more heavily upon protein supplements to sustain high levels of milk production.⁶⁸⁸ It could also have a negative impact on the rendering industry, which would have to limit rendered animal materials to markets for tallows that are used in soaps and lubricants or other products that

680. See Official Journal of the European Union, Commission Regulation (EC) No 1234/2003, Jul. 10, 2003, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_173/l_17320030711en00060013.pdf (last visited Mar. 27, 2005) (amending Regulation (EC) No 999/2001).

681. See *id.* (including exceptions for feeding fishmeal to non-ruminants; using non-ruminant protein for gelatin for coating feed additives; dicalcium phosphate and hydrolysed protein; milk and milk products; and egg and egg products).

682. See 2003 Council Directive on Swine Fever, Official Journal of the European Communities, Regulation (EC) No. 1774/2002 at L. 273/2, 19 (Oct. 3, 2002), available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_273/l_27320021010en00010095.pdf (last visited Feb. 14, 2005) (defining “catering waste” as “all waste food originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens,” and prohibiting the feeding of catering waste to any animals other than “fur animals”).

683. See *id.* at L.273/1-2 (prohibiting the practice of feeding an animal species with proteins from the same species as it “presents a risk of spreading disease” but acknowledging possible exceptions for fish and fur animals “if justified by scientific advice”).

684. See Press Release, Consumers Union, Consumers Union: USDA Proposals to Prevent Spread of Mad Cow Disease Inadequate to Protect Public Health (Jan. 8, 2004), available at http://www.consumersunion.org/pub/core_food_safety/000726.htm.

685. International Panel Report, *supra* note 340, at 9.

686. See *supra* Part V.B.2.

687. See Denise Grady, *Mad Cow Quandary: Making Animal Feed*, N.Y. TIMES, Feb. 6, 2004, at A22 (quoting Dr. Gary Weber).

688. See *id.* (noting that soy protein is a poor substitute).

would not be consumed by humans or farm animals.⁶⁸⁹ These economic impacts, however, seem insignificant when measured against the considerable risk of both economic damage and harm to human health posed by a breach of the critically important animal feed firewall.

2. *Better Enforcement of the Feed Ban*

The FDA's Feed Rule got off to a bad start, and, despite the agency's protestations to the contrary, it is not clear that it is functioning properly even now. After finding that the FDA and the states had done a very poor job of enforcing the 1997 feed ban, the U.S. General Accounting Office recommended that the FDA develop "a strategy, working with states, to ensure that the information it needs to oversee compliance is collected and that all firms subject to the feed ban are identified and inspected in a timely fashion."⁶⁹⁰ It further recommended that the FDA develop "an enforcement strategy with criteria for actions to address firms that violate the ban and time frames for reinspections to confirm that firms have taken appropriate corrective action."⁶⁹¹ The USDA's International Panel recommended that the feed ban "be strongly enforced" through "an inspection program including sampling and testing of feed."⁶⁹² The FDA should adopt a feed ban enforcement strategy providing for a sophisticated inspection program that includes sampling and testing of the actual feed produced and used at the inspected facilities.

C. *Statutory Reforms*

Although many of the reforms suggested here can easily be implemented by the USDA and the FDA, some of them do not clearly come within the scope of those agencies' authorizing statutes. These reforms will require congressional attention. Without attempting to prescribe the contents of specific legislation, the following section of this Article outlines some of the reforms that Congress should consider in light of the failure of existing firewalls to keep mad cow disease out of this country.

1. *Require Testing of all Downer Cattle*

Since downer cattle are the most at risk for mad cow disease, it is critical that all downer cattle are tested for mad cow disease. The International Panel that Secretary Veneman appointed in January 2004 recommended that all downer cattle be tested for BSE,⁶⁹³ and the USDA has decided to

689. *See id.* (discussing the possible impact on the rendering industry).

690. 2002 GAO MAD COW REPORT, *supra* note 225, at 37.

691. *Id.* at 38.

692. *International Panel Report, supra* note 340, at 9.

693. *See id.* at 6 (stating that goals for downer cattle measures would be to test the cattle and prevent infective tissue from entering the feed and food chains).

test as many downer cattle as possible during the next year-and-a-half. Because downer cattle may no longer be slaughtered for human consumption, however, the sampling for the testing will have to take place at rendering facilities or at the ranches and other production facilities where the animals first attain downer status. The USDA's authority to require ranchers to sample the brains of downer cattle before burying them or sending them to a landfill is not at all clear.⁶⁹⁴ Congress should therefore amend the FMIA to require any owner of an animal that becomes nonambulatory to notify the USDA of that fact within 24 hours and to hold that animal for sampling for up to an additional 48 hours before sending the animal to a rendering establishment or otherwise disposing of the animal. Renders that are presented with downer cattle should have an equivalent obligation to notify and hold downer cattle if such notification has not already been provided.

The universal animal identification program that the USDA hopes to establish within the next few years should help ensure that ranchers do not simply destroy downer cattle in violation of the requirement that they first be tested, because all cattle will ultimately have to be accounted for. The USDA International Panel on BSE believed that it was "imperative that the USDA take additional steps to assure that facilitated pathways exist for dead and non-ambulatory cattle to allow for collection of samples and proper disposal of carcasses."⁶⁹⁵ The panel recognized that this "most likely would involve expending resources to assist with costs associated with sampling, transport and disposal."⁶⁹⁶ Congress should provide such "facilitated pathways" for testing downer cattle by providing appropriate economic incentives for farmers to present downer cattle for inspection and testing before destroying them.⁶⁹⁷

2. Clarify USDA Authority to Enforce HACCP Programs for SRMs

The USDA's authority to enforce its recently imposed ban on SRMs in meat for human consumption may be open to question in light of the Fifth Circuit's opinion in *Supreme Beef*. Although a court more sympathetic to the need for federal regulation to protect the public health could easily have reached a different result, the *Supreme Beef* case has highlighted a central weakness with the current statutory regime for meat safety. A more recent

694. See USDA HACCP Proposed Rule, *supra* note 125, at 6829 (stating that the USDA does "not currently have and does not anticipate on-farm inspectional authority"); see also CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 3 (revealing that FSIS' inspectional authority does not arise until "animals arrive at slaughterhouses").

695. *International Panel Report*, *supra* note 340, at 6.

696. *Id.*

697. See *id.* (invoking the concept of "facilitated pathways," which includes sampling, transport and disposal of carcasses).

aggressive challenge to the USDA's authority to close down a plant that supplied ground beef containing the deadly pathogen *E. coli* O157:H7 suggests that the meat industry will likely challenge FSIS's authority to enforce the HACCP regulations when FSIS contemplates more serious enforcement action than a slap on the wrist.⁶⁹⁸

The basic underlying premise of the FMIA, and to a somewhat lesser extent the FDCA, is a century-old scientific theory that "equated filth with disease."⁶⁹⁹ Today, we know that diseases like vCJD are caused by infectious agents.⁷⁰⁰ While some of these agents, like prions, remain poorly understood, the proper regulatory approach is to focus on the agents and the pathways through which they spread, enter the food supply, and ultimately affect human beings. A statute that requires the agency to prove that meat has become "adulterated" because it is likely to cause disease in the same way that meat contaminated with fecal matter is likely to cause disease is not likely to be an effective tool for regulating the spread of mad cow prions.

A recent report issued by the National Academy of Sciences noted that "[l]egal challenges to actions taken by regulatory agencies in response to violations of established food safety criteria have cast doubts on the agencies' authority to enforce [HACCP] criteria," and it recommended that the situation "be promptly addressed through Congressional action."⁷⁰¹ This is very good advice. Congress should amend the FMIA to authorize the USDA to mandate and enforce HACCP programs under which scientific testing for SRMs must be undertaken at critical control points and at the point at which product exits the plant.

3. Recall Legislation

Although companies generally comply with FSIS requests to recall potentially adulterated product, they are under no obligation to do so. There is little reason to doubt that a company would be willing to refuse a recall request and force FSIS to its judicial seizure remedy if it seriously disputed the need for a recall. The perverse FSIS policy of forcing the companies asked to conduct voluntary recalls to bear the bulk of the costs incurred makes it even more likely that small facilities will resist voluntary compliance in the future.⁷⁰² The USDA's insistence upon keeping the

698. See CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 9 (describing Nebraska Beef's settlement with FSIS after the *E. coli* discovery but noting that the settlement merely reflects a "restatement of existing regulations").

699. SCIENTIFIC CRITERIA TO ENSURE SAFE FOOD REPORT, *supra* note 128, at 19.

700. See *id.* (stating our "current understanding that infectious diseases are caused by specific pathogenic microorganisms").

701. *Id.* at 5.

702. See *supra* Part VI.A.

recall process secret has also been driven by its need to secure the voluntary cooperation of the companies engaged in the recall. If the USDA had mandatory recall authority, privacy would no longer be necessary.

Consumer groups have for many years strongly advocated legislation giving the Department mandatory recall authority, but so far to no avail.⁷⁰³ Congress should, as quickly as possible, supply FSIS with adequate legal authority to order recalls of contaminated meat and poultry products.⁷⁰⁴ Mandatory recalls should be conducted at the expense of the companies ordered to participate in the recalls, but the USDA should have a fund available for small companies that can demonstrate that they are not able to afford available recall insurance.⁷⁰⁵ Congress should not wait until a company has refused to recall meat potentially contaminated with mad cow prions before giving the USDA the authority to issue mandatory recall orders.⁷⁰⁶

4. Country of Origin Legislation

Congress enacted legislation requiring retailers of certain imported foods to feature the country of origin on food labels so that consumers can ascertain where the food came from in deciding whether to purchase it.⁷⁰⁷

703. Consumer advocacy organizations promoting recall legislation include: *Support HR 1612 and S. 908 – The Consumer Food Safety Act of 1999*, Center for Science in the Public Interest, at <http://www.cspinet.org/foodsafety/hr1612.html> (last visited Mar. 25, 2005); see also Robert Roos, *USDA Hears Suggestions for Improving Product Recall Procedures*, Consumer Federation of America, at <http://www.cidrap.umn.edu/cidrap/content/fs/food-disease/news/recallmeet.html> (last visited Mar. 27, 2005); Sabin Russel, *Beef Recall Process Draws Criticism*, Consumers Union, at <http://inspectorsunited.com/beefrecall.htm> (last visited Mar. 27, 2005); *Comments on Recall Policies and Procedures*, Safe Tables Our Priority (STOP), at http://www.safetables.org/Policy_&_Outreach/Public_Comments/pc_98029n_recall_10_1998.html (last visited Mar. 25, 2005).

704. See Statement, Carol Tucker Foreman of Consumer Federation of America, Statement of CFA's Carol Tucker Foreman on USDA's Additional Protections to Prevent Bovine Spongiform Encephalopathy (Dec. 31, 2003), available at <http://www.consumerfed.org/usdarelease123003.html> (last visited Feb. 10, 2005) (listing various concerns, including the USDA's failure to seek "mandatory recall authority" which received support from the "previous Administration").

705. See generally American Meat Institute, *supra* note 567 (providing information on the American Meat Institute's offer for recall insurance to companies to cover recall costs).

706. A recall bill introduced by Representative Tom Udall (D-NM) is pending in the 108th Congress, but the House leadership has not seen fit to allow it to go forward. See *Unsafe Meat and Poultry Recall Act*, H.R. 2273, 108th Cong. (2003) (authorizing the Secretary of Agriculture to order the recall of adulterated, misbranded, or otherwise unsafe meat and poultry).

707. The 2002 Farm Bill (P.L. 107-171) requires retailers to provide country of origin labeling for fresh fruits and vegetables, red meats, seafood, and peanuts starting September 30, 2004. See Geoffrey S. Becker, *Country-of-Origin Labeling for Foods*, CRS Report for Congress, available at www.ncseonline.org/nle/crsreports/03Feb/97-508.pdf (last visited Mar. 25, 2005). Beef, pork, and lamb must be labeled unless they are an ingredient in a processed food. A food is processed if it has undergone a physical or chemical change in character, or if it is combined with other substantive food components. For example, pork belly that is cured and smoked to make bacon is excluded. See *Country of Origin Labeling*, at <http://www.ams.usda.gov/cool> (last visited Mar. 25, 2005) [hereinafter *Country of Origin*].

Had the unnamed meat processors who secretly imported 33 million pounds of otherwise banned beef from Canada pursuant to special exemptions been forced to comply with that law, the fact that the massive importation of Canadian beef was taking place would have been obvious to U.S. consumers.⁷⁰⁸ Unfortunately, those processors did not have to comply with the law, because Congress enacted a rider in January 2004 that made the program voluntary until 2006.⁷⁰⁹ It is now time to eliminate the rider and allow previously enacted mandatory country of origin labeling to go into effect.

5. *Civil Penalty Power*

The USDA currently lacks authority to levy civil penalties for violations of its regulations.⁷¹⁰ The only remedies available are resource-intensive and difficult to win criminal actions and the “atomic bomb” of withdrawal of inspection authority. FSIS is therefore very reluctant to take any enforcement action at all in the absence of serious and repeated violations of its regulations. Knowing this, facility operators have every incentive to play “hardball” with FSIS inspectors. An intermediate option is needed under which the USDA can assess a civil penalty sufficiently large to make firms sit up and take notice without threatening them with economic calamity. Congress should enact legislation granting the USDA the authority to collect penalties in civil proceedings subject to judicial review.

6. *User Fees*

Although most administrations during the last twenty years have sought legislation empowering FSIS to charge establishments reasonable fees to cover the cost of USDA inspections, Congress has steadfastly refused to enact such legislation.⁷¹¹ Thus, even though HACCP program responsibilities have been added to the ordinary carcass-by-carcass inspection duties of FSIS inspectors, the resources available for performing these critical tasks are woefully lacking. Enforcement of the new mad cow

Labeling] (providing country of origin labeling details).

708. See Barrie McKenna, *Canada Fears Fallout Over U.S. Beef Gaffe*, GLOBE AND MAIL, May 21, 2004, at B4 (revealing that the enormous amount of meat that entered the U.S. between September 2003 and February 2004 included “hamburger patties and pepperoni”).

709. The 2002 Farm Bill requires retailers to provide country of origin labeling on covered commodities starting September 30, 2004. See Becker, *supra* note 707 (including fruits, vegetables, red meats, seafood and peanuts). However, Public Law 108-199, signed by President Bush on January 27, 2004, further delays implementation of mandatory country of origin labeling for all covered commodities except fish and shellfish until September 30, 2006. Until then, the program is voluntary. Country of Origin Labeling, *supra* note 707.

710. See *supra* Part VIII.C.5.

711. See CRS ISSUE BRIEF AUG. 1, 2003, *supra* note 155, at 7 (citing Congress’ reason for rejecting such proposals as the government should bear responsibility for food safety).

regulations will only make matters worse. Congress should enact legislation enabling USDA to charge user fees to FSIS-inspected establishments of sufficient magnitude to cover the costs of inspections and oversight of HACCP programs.

7. Greater Transparency

If the USDA does not act on its own to increase the transparency of the HACCP process, Congress should amend the FMIA to make it crystal clear that HACCP plans, Sanitation SOPs, prerequisite programs, and FSIS inspection reports are fully accessible to the public. The claim that these documents are somehow “proprietary” and therefore not subject to public inspection should be rejected out of hand. Likewise, if the USDA neglects to make the process of granting import exemptions more transparent, Congress should do that for the Department. Congress should enact legislation that ensures that legitimate public requests for animal identification information are honored. Since animal identification information could conceivably be used by competitors to the economic disadvantage of the provider of the information, Congress should allow the USDA to shield commercially valuable information from competitors. The general public, however, should have access to information that is relevant to assessing the risks of food-borne diseases. Finally, Congress should require the USDA to make the terms and conditions of all recalls a matter of public record.

D. Whistleblower Protections

FSIS takes the position that it lacks authority to protect private sector whistleblowers from retaliation by their employers. Given the wholesale reliance of the FSIS HACCP rule on company-prepared reports, it is difficult to imagine how FSIS inspectors will be able to detect violations by corrupt companies that are willing to falsify those documents to avoid fines or heavy regulatory costs. The most likely source of information on falsification is the employee who has done the falsifying. Yet few employees will risk loss of employment and potential blackballing by unscrupulous employers in the absence of effective whistleblower protections. Although such protections are by no means a panacea, Congress should enact strong protections for those employees who have the integrity and courage to blow the whistle on companies that falsify documents or otherwise fail to comply with their regulatory obligations.⁷¹²

712. See Lassiter, *supra* note 370, at 458 (suggesting that Congress take an additional step toward encouraging whistleblowers by vesting them with a *Qui Tam* action on behalf of the federal government when they detect fraudulent recordkeeping under the HACCP regulations). The federal government could be given the right to take over the enforcement

CONCLUSION

The USDA told the American public that an outbreak of mad cow disease would never happen in the United States, but it did. After the outbreak, the USDA told the American public that it will never happen again, but it almost certainly will.⁷¹³ To calm consumer fears, the USDA promulgated a set of regulations built on the assumption that mad cow disease is primarily an animal health problem, but it is also a serious public health problem. It should be painfully apparent that forceful governmental action is absolutely necessary to protect the American public from the tragedy that befell the United Kingdom in the 1990s. If the same “pernicious, pervasive and deeply corrupt antigovernment fanaticism that [took] hold in Britain”⁷¹⁴ in the mid-1990s is allowed to prevail in the United States, the results could be equally devastating. It is time for the USDA and the FDA to stop using “science-based” excuses for failing to take strong regulatory action to protect the public from mad cow disease and to start following the protective policies of the existing statutes. If those agencies do not soon demonstrate a new commitment to protective regulatory action, Congress should intervene with sufficient vigor and precision to send a clear message that public health must trump production efficiency.

action so long as it continued to prosecute that action vigorously, but the whistleblower would be entitled to a preestablished percentage of any fines. *Id.* at 459.

713. Secretary Ann Veneman admits that the ameliorated meat inspection methods will likely uncover additional cases of mad cow disease in the United States. See “*We Expect Further Cases of BSE*” - Veneman, USAgNet, May 27, 2004 (discussing the impact on America’s trading partners), available at <http://www.rense.com/general53/esven.htm> (last visited Feb. 11, 2005).

714. RHODES, *supra* note 35, at 231.