Flimsy Firewalls:

The Continuing Triumph of Efficiency Over Safety in Regulating Mad Cow Disease Risks

Thomas O. McGarity
with Frank Ackerman

July 22, 2004

Acknowledgements

This report is a project of the Center for Progressive Regulation. Founded in 2002, the Center for Progressive Regulation is a nonprofit research and educational organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment. CPR supports regulatory action to protect health, safety, and the environment, and rejects the conservative view that government's only function is to increase the economic efficiency of private markets.

CPR President, Thomas O. McGarity is the primary author of the report. Professor McGarity holds the W. James Kronzer Chair at the University of Texas School of Law. He teaches and writes in the areas of Food Safety Law, Environmental Law, Torts and Administrative Law.

CPR Scholar Frank Ackerman prepared much of the analysis of the Harvard Center for Risk Analysis Study. Dr. Ackerman is the Director of the Research and Policy Program at the Global Development and Environment Institute at Tufts University. He is an economist with experience in analyzing the economics of waste, pollution, and energy.

This Report 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 Prof. Thomas O. McGarity in 2002 and 2004. The authors would also like to express their appreciation to Michelle Avalone and Katherine Baer for their diligent research assistance.

CPR is very grateful to the Deer Creek Foundation for the generous support that it has provided for this project and for all of CPR's efforts.

Direct media inquiries to Matthew Freeman at mfreeman@progressiveregulation.org.
Visit CPR's website at www.progressiveregulation.org.

Table of Contents

Flimsy Firewalls:
The Continuing Triumph of Efficiency over Safety in Regulating Mad Cow Disease Risks.

> [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.
>
> -- Nichols Fox, food safety expert[1]

I Introduction.

On December 23, 2003, Secretary of Agriculture Ann Veneman interrupted afternoon television programming to report that the United States Department of Agriculture (USDA) had received word that a Holstein cow slaughtered on December 9 in Washington state had 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 had 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 had 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, told the media that 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]

---

1 Nicols Fox, *The Case Against Efficiency*, Washington Post, February 15, 2004, at B1.

2 Shankar Vedantam, *Mad Cow Case Found In U.S. for First Time*, Washington Post, December 24, 2003, at A1; USDA, 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, 1863 (2004) [hereinafter cited as USDA SRM Interim Final Rule].

3 Vedantam, *Mad Cow Case Found In U.S. for First Time* , *supra*; Aaron Zitner, *Bovine Disease Surfaces in U.S.*, Los Angeles Times, December 24, 2003.

4 Vedantam, *Mad Cow Case Found In U.S. for First Time* , *supra*.

5 *Id.*

6 Zitner, *Bovine Disease Surfaces in U.S.*, *supra*.

7 *Id*. A spokesperson for the Harvard Center for Risk Analysis confirmed this assessment. *Id.*

At the December 23 briefing, Secretary Veneman offered the American public strong assurances that any risk to public health was "extremely low."[8] In fact, she still planned to have beef with her Christmas dinner.[9] Four days later the White House announced that President Bush continued to eat beef.[10] In highly publicized hearings before the Senate Agriculture Committee, Secretary Veneman testified that mad cow disease posed "virtually no risk to public health."[11] FDA's Deputy Commissioner told the same committee that "the risk of exposure to BSE through products FDA regulates remains extremely low in the U.S."[12] 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."[13] The American Meat Institute announced that "[f]irst and foremost, the U.S. beef supply is safe."[14]

These confident assurances apparently had their desired effect on American consumers. Belying early fears that U.S. beef consumption would plummet,[15] polls conducted in mid-January showed that consumers continued to eat beef at about the same levels.[16] Although wholesale beef prices steeply declined by 15 percent because of lost export markets, domestic demand for beef kept retail prices high.[17] Secretary Veneman reported to a congressional committee on January 22 that "retailers and food service outlets are reporting virtually no adverse effects on consumer demand."[18]

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,[19] and within a day countries representing two-thirds of the U.S. export marked had followed suit.[20] More than two dozen countries initially

---

8 *Id.*

9 Vedantam, *Mad Cow Case Found In U.S. for First Time* , *supra*.; Julian Borger, *First Case of Mad Cow Disease in US*, The Guardian, December 24, 2003.

10 Shankar Vedantam & Blaine Harden, *Probe of Infected Cow Spreads, So Does Worry*, Washington Post, December 27, 2003, at A1.

11 Testimony of Ann M. Veneman, Secretary, Department of Agriculture before the Senate Committee on Agriculture, January 21, 2004.

12 Testimony of Lester M. Crawford, Deputy Commissioner, FDA before the Senate Agriculture Committee, January 27, 2004 [hereinafter cited as Crawford Testimony, 1/27/04].

13 Zitner, *Bovine Disease Surfaces in U.S.*, *supra*.

14 Steve Mitchell, *USDA Refused to Release Mad Cow Records*, United Press International, December 24, 2004.

15 Margaret Webb Pressler, *Beef Businesses May Be Hit Hard*, Washington Post, December 24, 2003, at A3 (citing predictions that beef producers, beef retailers and restaurants would lose business because of the discovery of the Washington state mad cow).

16 *Mad Cow Could Keep Cattle Prices Lower for Months*, Los Angeles Times, January 12, 2004.

17 Jake Thompson, *Mad Cow Scare Didn't Turn U.S. Against Beef*, Omaha World-Herald, May 20, 2004; Steve Raabe, *No Mad-Cow Bargains*, Denver Post, January 13, 2004; *Mad Cow Could Keep Cattle Prices Lower for Months*, *supra*.

18 Marc Kaufman, *Cattle IDs to Combat Mad Cow*, Atlanta Journal-Constitution, January 22, 2004.

19 Pressler, *Beef Businesses May Be Hit Hard*, *supra*; Zitner, *Bovine Disease Surfaces in U.S.*, *supra*.

20 Matthew L. Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, New York Times, December 25, 2003.

banned imports of U.S. beef,[21] although a few have lifted or modified their bans in the intervening months.[22] This was a matter of no small importance to an industry that exported $3.5 billion in beef and beef products during 2002.[23] The immediate impact of the import restrictions was to strand 1,800 to 2,000 containers of American beef and beef products worth more than $200 million in foreign ports or at sea."[24]

The discovery of the Mabton mad cow should have been a much-needed, if belated wake up call to a sleeping federal regulatory establishment. Instead, the Bush Administration treated it as a trivial annoyance that demanded a symbolic, but unintrusive regulatory response and an aggressive public relations initiative. After USDA determined that the Mabton Holstein had been imported into the United States from Canada,[25] it 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.[26]

Within a week after announcing the discovery of the Mabton mad cow, 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.[27] 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."[28] Soon thereafter, 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.[29]

---

[21] David Willman & Jube Shiver, *Diseased Cow Traced to Canada, U.S. Says*, Los Angeles Times, December 28, 2003.

[22] *See Mexico Further Relaxes Its Ban on U.S. Beef*, Los Angeles Times, April 14, 2004 (reporting Mexico's easing of U.S. beef import restrictions).

[23] Margaret Webb Pressler, *Meat Industry Feels Fallout*, Washington Post, December 25, 2003, at A12.

[24] Johanna Neuman & Evelyn Iritani, *USDA Defends Its 'Mad Cow' Disease Efforts*, Los Angeles Times, January 1, 2004.

[25] *See infra* Section VI.B.

[26] United States Department of Agriculture, Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Release No. 0451.03, December 30, 2003 (remarks of Ron DeHaven).

[27] USDA, Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, 69 Fed. Reg. 1885 (2004) [hereinafter cited as USDA Stunning Device Interim Final Rule]; USDA, Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, 69 Fed. Reg. 1874 (2004) [hereinafter cited as USDA AMR Interim Final Rule]; USDA SRM Interim Final Rule, *supra*; Food Safety and Inspection Service, Bovine Spongiform Encephalopathy Surveillance Program, Notice, Docket No. 03-048N, undated.

[28] USDA Transcript of Agriculture Secretary Ann M. Veneman Announcing Additional Protection Measures to Guard Against BSE, Washington, D.C., December 30, 2003.

[29] Food and Drug Administration, Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission, Press Release, January 26, 2004, [hereinafter cited as FDA Statement 1/26/04].

The Center for Progressive Regulation (CPR) has undertaken an investigation into the federal government's regulatory activities since the discovery of the Mabton mad cow. This Report contains the detailed results of that investigation. CPR has concluded that the Bush Administration's modest efforts to address the very real risk that mad cow disease poses to the health of U.S. citizens do not match its confident rhetoric. Administration officials have consistently pointed to three regulatory "firewalls" that the federal government erected years ago to protect the public health from the risk of mad cow disease. First, USDA had established import controls prohibiting U.S. companies from purchasing cattle and feed from countries experiencing BSE outbreaks. Second, USDA had initiated a surveillance program in which suspect cattle were identified at the slaughterhouse and some were tested for BSE. Third, FDA had enacted restrictions on the kinds of protein that could be included in feed to cattle and other ruminants (mammals, like cattle, that chew cud and have multi-chambered stomachs).[30] After the discovery of the Mabton mad cow, the federal government announced that it was enhancing two of the three pre-existing 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.

CPR's investigation has discovered 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 for why these firewalls are so flimsy, the primary underlying flaw with the current system, even has 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.[31] Consequently, 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 entirely useless ban on technologies that have not been used for years, the new USDA regulations created an unenforceable and otherwise wholly inadequate "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,[32] stymied by cattle industry fears of increased liability risks. Furthermore, USDA neutered the one effective action that it took, a guideline requiring companies to hold carcasses of animals designated for testing off the market, by tolerating an attitude in the field that discouraged the testing of suspect cattle in the first place. The anemic program that USDA announced for expanding testing of "downer" cattle, even as greatly 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 USDA has

---

30 *Id.* (describing the three "firewalls").

31 Thomas O. McGarity, Telephone Interview with Dennis Burson, Meat Science Extension, University of Nebraska-Lincoln, May 4, 2004 [hereinafter cited as Burson Interview 5/4/04].

32 USDA, Veneman Announces Additional Protection Measures To Guard Against BSE, Press Release No. 0449.03, December 30, 2003 (Secretary of Agriculture promises to "begin immediate implementation of a verifiable system of national animal identification.").

reportedly threatened to criminally prosecute any company that attempts at its own expense to test its animals for mad cow disease.

FDA's response has, if anything, been even less inspiring of public confidence. Although it announced that it would be taking stringent new steps to prevent the spread of mad cow disease, FDA did precisely nothing for the next five months because it was paralyzed by complaints from special interests in the poultry and rendering industries. When it finally did act, in July 2004, FDA merely mimicked USDA's restrictions for foods, cosmetics and dietary supplements and reneged on its promise to shore up the cattle feed firewall.

In the final analysis, these flimsy firewalls are doomed to failure. 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 will not keep infected animals and contaminated meat out of the country. They will not ensure that the federal government identifies the BSE-positive cattle that almost certainly exist in this country at the moment. They are 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.

II Background.

A. Mad Cow Disease and Other TSEs.

Bovine Spongiform Encephalopathy (BSE), or mad cow disease, is a member of a larger family of chronic, degenerative diseases called transmissible spongiform encephalopathies (TSEs).[33] After a prolonged incubation period of months or even years, TSEs cause a progressive debilitating neurological illness that is always fatal.[34] 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.[35] Hence, an accurate diagnosis of BSE in a cow is only possible by examining the brain tissue of slaughtered cattle, and the

---

[33] Joshua T. Cohen, *et al.*, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States (2003) [hereinafter cited as Harvard Center for Risk Analysis BSE Report]; United States Department of Agriculture, Bovine Spongiform Encephalopathy (BSE) Overview, available at http://www.aphis.usda.gov/lpa/issues/bse/bse-overview.html (last visited on July 8, 2004), at 1 [hereinafter cited as USDA BSE Overview]. Other TSEs include scrapie in sheep and goats, transmissible mink encephalopathy, feline spongiform encephalopathy, and chronic wasting disease (CWD) in deer and elk. *Id.* at 4.

[34] Harvard Center for Risk Analysis BSE Report, *supra*, at 4; USDA BSE Overview, *supra*, at 1.

[35] USDA BSE Overview, *supra*, at 1.

most accurate diagnoses examine that tissue microscopically for the telltale "spongiform" changes that uniquely characterize TSEs.[36]

BSE was first discovered in cows in Great Britain in 1986.[37] 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 was the probable culprit.[38] 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.[39]

B. The Cause of TSEs.

Although there is still some disagreement within the scientific community,[40] most scientists believe that TSEs are caused by an abnormally configured protein called a "prion."[41] While much remains to be learned about prions (or whatever other microorganism 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.[42] 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.[43]

C. The Incidence of Mad Cow Disease.

After hitting a peak of about 3,500 cases per month in 1993,[44] 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.[45] As of late 2003, about 178,000 total cases of mad cow disease had been confirmed in England on

---

36 *Id*.

37 Harvard Center for Risk Analysis BSE Report, *supra*; USDA BSE Overview, *supra*, at 1.

38 Richard Rhodes, *Deadly Feasts: The Prion Controversy and the Public's Health* (1997), at 174 [hereinafter cited as Rhodes, *Deadly Feasts*].

39 *Id*.

40 Sheldon Rampton & John Stauber, *Mad Cow U.S.A.* (1997), at 115-22 [hereinafter cited as Rampton & Stauber, *Mad Cow U.S.A.*]; Jennifer Mckee, *Science Studies Clues to Mad Cow*, Billings Gazette, January 25, 2004 (relating uncertainties cited by scientists at Rocky Mountain National Laboratories); Tom Paulson, *Lab Challenges Usual Theory on Mad Cow*, Seattle Post-Intelligencer, January 23, 2004 (quoting Dr. Bruce Chesebro) ("Most scientists think this question (of causation) has been answered, the problem solved," but "[w]e don't think so.").

41 USDA SRM Interim Final Rule, *supra*, at 1863; Harvard Center for Risk Analysis BSE Report, *supra*, at 5; USDA BSE Overview, *supra*, at 1. For a fascinating description of the discovery of prions and the scientific debate surrounding these strange infective agents, *see* Rhodes, *Deadly Feasts*, *supra*, at ch. 10.

42 USDA SRM Interim Final Rule, *supra*, at 1863; USDA BSE Overview, *supra*, at 1.

43 Harvard Center for Risk Analysis BSE Report, *supra*, at 1, 38.

44 *Id.* at 14.

45 European Commission, Commission Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001, available at http://europa.eu/int/comm/food/food/biosafety/bse/ban_en.htm and www.defra.gov.uk/animalh/bse/animal-health/feedban-legislation.html#euro [last visited June 3, 2004].

35,275 farms.[46] In addition to the recently discovered U.S. mad cow, the disease has been detected in cattle in Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Japan, Luxembourg, Liechtenstein, the Netherlands, Northern Ireland, Poland, Portugal, Slovakia, Slovenia, Spain and Switzerland,[47] As of April 2004, more than 180,000 case of BSE have been reported worldwide.[48]

D. Detection of BSE in Cattle, Cattle Feed and Food.

Animals infected with TSEs frequently display clinical manifestations of the disease, including "changes in temperament, such as nervousness or aggression; abnormal posture; incoordination and difficulty in rising; decreased milk production; or loss of body condition despite continued appetite."[49] Because BSE has an incubation period of 2 to 8 years from exposure to the clinical manifestation, an infected cow may show none of these signs.[50] It is also possible, of course, that an animal that manifests one or more clinical symptoms is not in fact suffering from the disease.[51]

Because accurate tests do not exist for determining the presence of TSEs in live animals,[52] 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.[53] Historically, testing procedures for BSE have taken weeks to complete. The tissue from the Mabton mad cow, for example, was taken from the slaughtered animal on December 9, 2003, but the test results were not reported until December 23, 2003.[54]

Scientists have recently developed post-mortem chemical tests that "have a high sensitivity and specificity for detecting and confirming BSE" and yield results within 24 hours.[55] The accuracy of such tests, however, is still disputed, and is not clear that they are effective until near the end of the incubation period.[56] Although they are regularly used in the European Union and Japan, USDA did not approve any "rapid" tests until Spring 2004.[57] Although no tests for BSE in feed or food currently exist, tests are available for detecting high risk tissues from cattle (frequently referred to as "Specified Risk Materials") in food and food products.[58]

---

46 Harvard Center for Risk Analysis BSE Report, *supra*, at 14.

47 USDA SRM Interim Final Rule, *supra*, at 1863; USDA BSE Overview, *supra*, at 2.

48 USDA BSE Overview, *supra*, at 1.

49 *Id*.

50 *Id*.

51 *Id*.

52 USDA SRM Interim Final Rule, *supra*, at 1871; USDA BSE Overview, *supra*, at 1.

53 Harvard Center for Risk Analysis BSE Report, *supra*, at 36; Sandra Blakeslee, *Expert Warned That Mad Cow Was Imminent*, New York Times, December 25, 2003 (quoting Dr. Stanley Pruisner).

54 USDA SRM Interim Final Rule, *supra*, at 1863.

55 Harvard Center for Risk Analysis BSE Report, *supra*, at 37.

56 *Id*.

57 *See* Section VII.H

58 Harvard Center for Risk Analysis BSE Report, *supra*, at 37. See infra Section XI.F.2.c.3.

USDA has taken the position that the cattle most likely to be infected with BSE are among the population of nonambulatory or so-called "downer cattle," so named because they cannot regain their feet once they have keeled down or become prone.[59] Not all downer cattle suffer from mad cow disease, but USDA has based its past surveillance efforts on the assumption that the probability of BSE in cattle that are not downer cattle (and not otherwise demonstrating clinical symptoms) is so low that testing such cattle is not worth the cost.[60]

E. TSEs in Humans.

TSEs were first discovered in humans in 1913 by the German physician Hans Gerhard Creutzfeldt, a former student of Alois Alzheimer, the discoverer of Alzheimer's disease. His first subject, an emaciated woman named Bertha Elschker, displayed several obvious signs of neurological disease along with an odd additional symptom that Creutzfeldt reported as "unmotivated outbursts of laughter." In 1920, a University of Hamburg professor, Dr. Alfons Jakob, read Creutzfeldt's belatedly published paper and recognized the symptoms as similar to those he had encountered in four of his patients. In time, the relatively rare disease became known as Creutzfeldt-Jacob Disease (CJD), but its cause remained elusive. In the late 1950s, an American research physician named Carleton Gajdusek discovered a similar disease in an indigenous population of a remote area of New Guinea. Over time, Gajdusek demonstrated at least one causal mechanism, the consumption by humans of the brains of other humans.[61]

CJD is a slowly degenerative disease of the central nervous system with an apparently spontaneous incidence of about one-in-one-million in humans.[62] Prior to the mid-1980s, the disease was diagnosed almost exclusively in persons more than 50 years old.[63] That fact helped epidemiologists uncover the connection between mad cow disease and a new form of TSE called variant Creutzfeldt-Jacob Disease (vCJD).

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) and human consumption of certain human hormones.[64] A recent British study suggests that CJD can be transmitted from human to human through blood transfusions.[65]

---

59 The Harvard Center Risk Assessment defines nonambulatory or downer cattle to include "animals that are unable to rise." Harvard Center for Risk Analysis BSE Report, *supra*, at 118.

60 *Id*. at 45.

61 Rhodes, *Deadly Feasts*, *supra*, at ch. 2; Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 37-52.

62 Harvard Center for Risk Analysis BSE Report, *supra*, at 21; USDA BSE Overview, *supra*, at 2.

63 Harvard Center for Risk Analysis BSE Report, *supra*, at 21.

64 *Id*. at 7.

65 Sandi Doughton, *Panel Studies Mad-Cow Risk From Blood Transfusions*, Seattle Times, February 13, 2004; Audrey Woods, *Transfusion, Mad Cow May Be Linked*, Atlanta Journal-Constitution, February 5, 2004.

Four years after the discovery of mad cow disease in England, the British government, in what it perceived to be an abundance of caution, banned the sale for human food of especially risky materials (i.e., brain, spinal cord, spleen, thymus, intestines, and tonsils) from cattle known to be suffering from mad cow disease. The government, however, ensured that meat from mad cows would remain on the market by agreeing to pay only 50 percent of market value to owners of condemned animals. A government-appointed expert committee, chaired by Oxford zoologist Richard Southwood, 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." The government's chief veterinary officer then went on television to assure the public that "we are fairly confident that BSE does not transmit to man." Later, the Minister of Agriculture himself "assured himself a place in British history" by feeding his daughter Cordelia a hamburger on national television.[66]

Things began to unravel for the British government in 1993 when a fifteen-year-old schoolgirl named Victoria Rimmer was diagnosed with CJD.[67] By early 1996 a clearly identifiable cluster of eight cases of CJD in young people inspired the Secretary of State for Health to announce in the House of Commons that BSE was capable of causing CJD in humans after all.[68] In March 1996, a high-level U.K. advisory committee concluded that 10 cases of vCJD had apparently been caused by human consumption of meat from cows suffering from BSE.[69]

With this disturbing revelation, the British began to purchase and slaughter all cattle of more than 30 months old. However, it soon halted the program after concluding that previously imposed feeding restrictions would cause BSE to "die out in 2000 or 2001."[70] The scientific community and the public were in no position to second-guess that assessment, because the government refused to disclose the data underlying the prediction.[71] The prediction, however, proved disastrously wrong as the incidence of mad cow disease continued to increase. The European Union then imposed much more stringent animal feed restrictions.[72]

---

66 Rhodes, *Deadly Feasts*, *supra*, at 179-86. *See also* Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 93-97, 131-32.

67 Rhodes, *Deadly Feasts*, *supra*, at 187; Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 9-11.

68 Rhodes, *Deadly Feasts*, *supra*, at 189, 209-12; Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 182-84.

69 USDA BSE Overview, *supra*, at 3. Although similar to classic CJD, the variant form, vCJD, appeared to differ in several regards. First, it affected much younger individuals. Second, it took more than twice as long from the onset of the disease until death. Third, the electroencephalographic (EEG) activity in the brain differed from that of classic CJD. Fourth, the brain pathology was also somewhat different. *Id.*

70 Rhodes, *Deadly Feasts*, *supra*, at 218.

71 *Id*. at 219-20.

72 European Commission, Commission Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001, available at http://europa.eu/int/comm/food/food/biosafety/bse/ban_en.htm and www.defra.gov.uk/animalh/bse/animal-health/feedban-legislation.html#euro [last visited June 3, 2004].

As of mid-2004, 150 cases of vCJD have been reported worldwide.[73] 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.[74] The case in the United States was probably caused by consumption of meat in England because the victim was a U.K. citizen currently living in Florida.[75]

Although there have been no reported cases of vCJD in the United States due to the consumption of U.S. cattle, it is not clear how hard the experts have looked for vCJD among the 300 or so people who die each year from naturally occurring, or "sporadic" CJD.[76] 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 by doctors as Alzheimer's disease.[77] One especially troubling statistic is that five people under 30 died of a disease diagnosed as sporadic CJD between 1997 and 2001, whereas only one case of the disease in a person under 30 was reported prior to 1996.[78] 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."[79]

F. How TSEs are Communicated.

The mad cow prion can be communicated through consumption of the brain, spinal cord, and eyes of cattle.[80] In experimental studies, frequently involving direct injection of contaminated material into the brain, infectivity has been confirmed in the brain, trigeminal ganglia,[81] tonsils, spinal cord, dorsal root ganglia (DRG),[82] and the distal

---

73 *Id*. at 1863.

74 USDA BSE Overview, *supra*, at 3.

75 *Id*. at 3.

76 Linda A. Johnson, *Have Scientists Missed Mad Cow in Humans?*, Associated Press, January 7, 2004.

77 Andrew Nikiforuk, *North Americans Haven't Tested Rigorously Enough For Mad-Cow Disease*, Boston Globe, January 8, 2004, at A21; Michael Greger, *Could Mad Cow Disease Already be Killing Thousands of Americans Every Year?,* CommonDreams.org, January 7, 2004 (citing Folstein, M., *The Cognitive Pattern of Familial Alzheimer's Disease*, Biological Aspects of Alzheimer's Disease. Ed. R. Katzman. Cold Spring Harbor Laboratory, 1983).

78 Greger, *Could Mad Cow Disease Already be Killing Thousands of Americans Every Year?, supra* (citing Yam, P., *The Pathological Protein: Mad Cow, Chronic Wasting, and Other Deadly Prion Diseases*. New York: Springer-Verlag Press, 2003). The single reported case of vCJD in the U.S. was a Florida woman who grew up in the UK. Nicholas K. Geranios, *Canadians Irked by U.S. Blame for Mad Cow*, Seattle Post-Intelligencer, January 11, 2004.

79 Johnson, *Have Scientists Missed Mad Cow in Humans?*, *supra*. 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*, Philadelphia Inquirer, January 16, 2004.

80 USDA SRM Interim Final Rule, *supra*, at 1862.

81 Trigeminal ganglia are "clusters of nerve cells connected to the brain that lie close to the exterior of the skull." *Id*. at 1864.

ileum of the small intestine of cattle.[83] USDA has concluded that "BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with the disease."[84] Scientists are not, however, entirely confident that consumption of muscle tissue, which does contain some tissue from the nervous system, cannot communicate TSEs.[85] The USDA conclusion is based primarily upon a single long-term British study, and other experiments, not involving beef, have shown some transmissibility of TSE via muscle tissue.[86] Since no TSEs have been identified in pigs and poultry, transmission to humans or cattle through consumption of those species seems unlikely.[87]

Studies of clinical manifestation of BSE-infected cattle in England lead USDA to conclude that clinical BSE "has rarely been reported in cattle younger than 30 months of age." 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." Moreover, "tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent." 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.[88]

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 agent increases over the two-to-eight year incubation period from initial exposure to the onset of the clinical disease.[89] Thus, USDA has concluded 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."[90] This is significant for the cattle industry, because approximately 80 percent of the cattle slaughtered at federally inspected facilities are less than 30 months of age.[91]

---

82 DRG are "clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column." *Id*.

83 *Id*. at 1862.

84 *Id*. at 1865.

85 *See* David Brown, *Scientists Weigh Risks of Beef*, Washington Post, January 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.").

86 *Id*.

87 Harvard Center for Risk Analysis BSE Report, *supra*, at 28-32.

88 USDA SRM Interim Final Rule, *supra*, at 1862.

89 *Id*. at 1863.

90 *Id*.

91 United States Department of Agriculture, 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 (2004), at 5 [hereinafter cited as FSIS BSE Interim Rules Preliminary Analysis].

G. 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 sales of cattle.[92] In 2003 beef production in the United States was about 26.3 billion pounds from the slaughter of 36 million cattle.[93] Beef production yielded gross farm income of $44.1 billion in 2003.[94] Exports of 2.6 billion pounds of beef, veal, and variety meats in 2003 produced $3.8 billion in income.[95] The beef sector is the "largest single agricultural enterprise" in the United States,[96] and, prior to the Mabton mad cow, was the world's largest producer of beef for export markets.[97] 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 80 percent of the output of those facilities is controlled by only five large companies -- Tyson, Excel, Swift, National Beef Packing and Smithfield.[98]

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,[99] further discoveries may have a more dramatic impact. The 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.[100] The discovery of a case of vCJD caused by consumption of a domestic mad cow could have a devastating impact on the beef industry.

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

Because the U.S. market for beef is extremely competitive, modern agribusiness has for the last several decades devoted much of its attention to efficiency in the production, slaughter, processing, and distribution of meat and meat products. In its obsession for efficiency, the industry is inclined to consign safety considerations to a secondary role.

---

92 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 May 6, 2004), at 1 [hereinafter cited as Otto & Lawrence, *Economic Impact*].

93 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 5.

94 *Id*.

95 *Id*.

96 Otto & Lawrence, *Economic Impact*, *supra*, at 1.

97 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 4-5.

98 Michael Moss, Richard A. Oppel, Jr. & Simon Romero, *Mad Cow Forces Beef Industry to Change Course*, New York Times, January 5, 2004; *Frontline* Interview with Patrick Boyle, American Meat Institute, undated, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews, at 4 [hereinafter cited as Boyle Interview] (four companies account for more than 80 percent of the beef capacity in the United States).

99 *See supra* Section I.

100 Lewis Kamb, *QFC Sued over Mad Cow Case*, Seattle Post-Intelligencer, March 5, 2004.

Consequently, several modern agribusiness practices have the potential to open the door to mad cow disease in this country.

A. 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. USDA has since 1989 banned the importation of ruminants and certain ruminant products from countries where BSE is known to exist.[101] Although USDA has 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.[102] In December 2000, USDA expanded its import restrictions to prohibit all imports of rendered protein products from BSE-restricted countries because of concerns that feed intended for cattle may become cross-contaminated with the BSE agent.[103] The discovery of a mad cow in Canada in May 2003 brought cattle and meat from that country under the import restrictions.[104]

B. Communication from Animal to Animal.

The original source of BSE may have been protein from sheep suffering from a TSE called scrapie, or it may have come from cattle suffering from a spontaneous BSE.[105] Although BSE does not appear to be transmissible through inhalation or incidental contact, it can 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 into concentrated protein could fatten animals more quickly and get them to market faster.[106] 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.[107]

---

101 Harvard Center for Risk Analysis BSE Report, *supra*, at 22; USDA BSE Overview, *supra*, at 4.

102 Harvard Center for Risk Analysis BSE Report, *supra*, at 22.

103 USDA SRM Interim Final Rule, *supra*, at 1863.

104 *See infra* Section IV.A.2.a.

105 USDA BSE Overview, *supra*, at 2.

106 See Harvard Center for Risk Analysis BSE Report, *supra*, at 32; Lewis Kamb, *Cattle Feed Is Often a Sum of Animal Parts*, Seattle Post-Intelligencer, January 28, 2004.

107 Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 63-64; Kamb, *supra*.

Currently, about 265 rendering plants in the United States convert about 50 billion pounds of tissue from dead animals into protein for animal feed.[108] The following graphic description of the inputs for a Baltimore rendering plant illustrates that rendered protein 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 yards, 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.[109]

Rendering is obviously not a business for people with weak stomachs.

During the rendering process, sources of animal protein are placed in large tanks and cooked at temperatures (approximately 300 degrees F) high enough to kill most microorganisms but low enough to prevent the disintegration of the valuable fats and proteins.[110] The process yields commercially valuable products like tallow and concentrated animal protein. This "tanking" step, however, does not occur at temperatures sufficiently high to disable the, prions that cause mad cow disease.[111]

Rendered protein can be used to enhance the protein content of animal feeds for cattle, swine, and poultry.[112] Once mad cow prions contaminate animal feed, however, it is impossible to remove or destroy them without destroying the feed.[113] Therefore, the best way to prevent communication of mad cow disease is to ensure that mad cow prions do not infect cattle feed, and the best way to do that is to 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.[114] The World Health Organization recommended such a ban in 1996 and the United States imposed a partial ban in 1997.[115]

---

108 Kamb, *Cattle Feed Is Often a Sum of Animal Parts*, *supra*.

109 Van Smith, *What's Cookin?*, Baltimore City Paper, September 27, 1995, quoted in Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 61-62.

110 Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 70; Kamb, *Cattle Feed Is Often a Sum of Animal Parts*, *supra*.

111 Kamb, *Cattle Feed Is Often a Sum of Animal Parts*, *supra*.

112 Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 68. 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 with maximum efficiency enhance tissue growth and lactation. *Id*.

113 Harvard Center for Risk Analysis BSE Report, *supra*, at 36.

114 Rhodes, *Deadly Feasts*, *supra*, at 178.

115 Harvard Center for Risk Analysis BSE Report, *supra*, at 36, 41. *See infra* Section IV.B.1.

Although FDA has mentioned the possibility of imposing further limits on the use of animal protein in cattle feed in the future,[116] 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.[117] 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.[118]

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 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.[119] 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.[120] Since there is "no current disposal method for TSE-infected tissues shown to completely remove all infectivity,"[121] tissue from cattle buried on a ranch could make its way to the surface and be consumed by foraging cattle.[122]

C. Communication from Animals to Humans.

1. Communication Vehicles.

Most of the materials that have demonstrated BSE infectivity in cattle have traditionally been consumed by human beings.[123] 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.[124] Brains have also been used as a byproduct

---

116 *See infra* Section VIII.

117 Harvard Center for Risk Analysis BSE Report, *supra*, at 33.

118 Harvard Center for Risk Analysis BSE Report, *supra*, at 35.

119 Harvard Center for Risk Analysis BSE Report, *supra*, at 31. The HCRA report, however, concluded 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. *Id.*

120 Harvard Center for Risk Analysis BSE Report, *supra*, at 32.

121 Food and Drug Administration, Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 30936 (1997), at 30964 [hereinafter cited as FDA 1997 Feed Rule].

122 FDA has concluded, however, that "migration of prions from burial sites is expected to be minimal because prions "are unlikely to move with water through soil media, but are apt to be adsorbed to clay particles." FDA 1997 Feed Rule, *supra*, at 30964.

123 USDA SRM Interim Final Rule, *supra*, at 1865. Consumption of cattle eyes has been uncommon in the U.S. *Id.*

124 *Id.*

ingredient in foods.[125] Many meat products, like sausages, bologna and meat spreads, have also traditionally contained such risky tissues.[126]

The likelihood that risky materials from the nervous system, tonsils and small intestines of infected animals will wind up in human food accidentally is magnified by the drive toward greater efficiency in slaughterhouse production. Slaughterhouses have become huge assembly lines were animals are stunned, bled, beheaded, eviscerated, skinned, cleaned and split in half down the spine in one rapidly moving continuous operation.[127] Large meatpacking plants slaughter more than 4000 cattle per day, and line speeds operate at rates exceeding 300 cattle per hour.[128] 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 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,[129] pose a high risk of contaminating edible meat with brain and other CNS material. 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 after hand deboning at high pressure through very fine sieves that remove bone particles.[130] AMR systems employ hydraulic pressure to emulate the physical action of high-speed knives for the purpose of removing skeletal muscle tissue from bone.[131] 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 10 percent of the AMR system products in the field.[132] Even hand deboning techniques, when conducted at high speed and driven by efficiency concerns,

---

125 *Id*. Indeed some marketers have historically sold whole cattle heads to consumers for human consumption.

126 *See* Rhodes, *Deadly Feasts*, *supra*, at 175 (noting that cattle brains were incorporated into hamburger and meat pies).

127 *Frontline* Interview with Michael Pollan, undated, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews, at 8 [hereinafter cited as Pollan Interview].

128 *Modern Meat*, PBS *Frontline*, April 18, 2002, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/etc/script.html at 7 [hereinafter cited as *Frontline*, *Modern Meat*].

129 9 C. F. R. § 310.13(a)(2)(iv)(C)).

130 USDA SRM Interim Final Rule, *supra*, at 1866.

131 USDA AMR Interim Final Rule, *supra*, at 1876.

132 *Id*.

are not so accurate that a rushed employee can always avoid accidentally including spinal cord and other CNS material in meat destined for human consumption.[133]

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.[134]

2. 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. In 1996, for example, the U.K. banned the "sale of beef from cattle over the age of thirty months for human consumption."[135] The British government reasoned that "cattle over the age of 30 months could carry potentially substantial levels of infectivity in different tissues without having yet developed clinical signs of the disease."[136]

If accurate tests for BSE are available, 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. The EU, for example, has since 2000 required that all cattle more than 30 months old be tested for BSE, and meat from animals testing positive may not be used for human food.[137] Germany, Italy, and France test for BSE in all cattle older than 24 months prior to slaughter.[138] Since false negative is always possible, however, this solution still leaves direct 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. The European Union bans the

---

133 USDA SRM Interim Final Rule, *supra*, 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.").

134 *Frontline*, *Modern Meat*, *supra*, at 8.

135 Food Standards Agency, BSE and Beef, available at www.foodstandards.gov.uk/bse/beef/ [last visited on June 4, 2004]. *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 40.

136 Harvard Center for Risk Analysis BSE Report, *supra*, at 40.

137 http://europa.eu/int/comm/food/food/biosafety/bse/ [last visited on June 4, 2004]. *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 41.

138 TSE Forum, Frequently Asked Questions, available at http://www.tse-forum.de/tse_forum/englisch/offentlich/start_offentlich.htm (Germany); Xinhua News Agency, *Mad Cow Cases Increase to 62 in Italy*, Xinhua General News Service. World News, April 30, 2002 (available on Lexis Allnews database) (Italy); French Agriculture BSE webpage, available at http://www.agriculture.gouv.fr/esbinfo/esbinfo.htm (France).

sale of all Specified Risk Material (which includes nervous system tissues from animals greater than 12 months in age and all tonsils and distil ileum) for human consumption.[139] Canada has a similar ban in place for similar materials from animals greater than 30 months of age.[140] As described below, USDA promulgated a similar ban in January 2004.[141]

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, there are ways to minimize the risk of communication of TSEs through human consumption of beef and beef products. First, it is possible to cut contaminated tissue off of edible muscle tissue when it is spotted by alert employees on the line.[142] 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.[143]

IV Regulation of the Risk of Mad Cows in the United States Prior to January 2004.

When Congress created USDA in 1862, its primary aim was to ensure an adequate supply of food for American tables.[144] USDA did, however, have a relatively minor safety-related function -- to conduct ante- and post-mortem inspection of livestock.[145] 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 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.[146] The slaughterhouse

---

139 European Commission, BSE- Removal of Risk Materials, available at http://europa.eu/int/comm/food/food/biosafety/bse/risk_en.htm [last visited on June 4, 2004]. *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 41.

140 Health Canada, Federal Regulations Amended to Enhance BSE Controls by Preventing Specified Risk Material from Entering Human Food Supply, News Release, July 24, 2003, available at www.hc-sc.gc.ca/english/media/releases/2003/2003_59.htm [last visited on June 4, 2004].

141 *See infra* Section VII.B.

142 This is in fact what USDA regulations require. *See infra* Section VII.B.

143 *See* United States Department of Agriculture, Food Safety and Inspection Service, 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, dated February 14, 2002, at 3 [hereinafter cited as USDA Testing GMPs, 2/14/02].

144 Marion Nestle, *Safe Food: Bacteria, Biotechnology and Bioterrorism* (2003), at 63 [hereinafter cited as Nestle, *Safe Food*].

145 United States Department of Agriculture, Food Safety and Inspection Service, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, Proposed Rule, 60 Fed. Reg. 6774 (1995) [hereinafter cited as USDA HACCP Proposed Rule].

146 USDA HACCP Proposed Rule, *supra*, 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

meat inspection program that grew out of these requirements relied upon "organoleptic inspections," based on sight, touch, and smell, by USDA-employed veterinarians.[147] The primary concern was to reduce or eliminate "filth" in meat used for food.[148]

The Federal Food and Drug Act, also enacted in 1906, prohibited the marketing of misbranded or adulterated food other than meat subject to the FMIA.[149] Although the statute focused on chemical contamination as well as filth, it resembled the FMIA in its failure to address specific pathogens.[150] Unlike the FMIA, however, the statute did not require physical inspection of every source of human food. Rather, FDA had to rely upon random and programmed inspections and statistically determined sampling of food products.[151]

A. USDA Regulation.

The Federal Meat Inspection Act (FMIA)[152] 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.[153] 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."[154] The burden of proof, however, is

---

> 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."

21 U.S.C. 608.

147 USDA HACCP Proposed Rule, *supra*, at 6775.

148 National Academy of Sciences/National Research Council, Scientific Criteria to Ensure Safe Food (2003), at 14 [hereinafter cited as NAS Scientific Criteria to Ensure Safe Food Report].

149 *Id*. at 14-15.

150 *Id*. at 15.

151 Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 Seton Hall L. Rev. 61, 95-96 (2000).

152 21 U.S.C. § 601 et seq.

153 *Id*. § 610.

154 *Id*. § 601(m)(3). The statute defines an "adulterated carcass" to include:

> any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i)a pesticide chemical in or on a raw agricultural commodity; (ii)a food additive; or (iii)a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

on USDA to establish that any particular meat or poultry is in fact "unhealthful," "unfit for human food," or otherwise adulterated.[155] Meat products that bear or contain any poisonous or deleterious added substance which may render them injurious to health, and meat products that bear or contain inherent substances in sufficient quantity to ordinarily render them injurious to health are also "adulterated."[156] 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."[157]

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.[158] 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.[159] The inspectors must ensure that meat is not "adulterated" or "misbranded" within the meaning of the Federal Meat Inspection Act.[160] Meat may not be sold without USDA approval.[161]

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title. Provided, that an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulation of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter; ...

Id. § 601(m).

155 U.S. v. Lexington Mill & E Co., 232 U.S. 399, (1914); 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) ("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").

156 21 U.S.C. § 601(m)(1).

157 *Id*. § 601(m)(4).

158 National Research Council/National Institute of Medicine, Committee to Ensure Safe Food and Production to Consumption, Ensuring Safe Food: From Production to Consumption (1998), at 27 [hereinafter cited as NAS Safe Food Report]; United States Department of Agriculture, Food Safety and Inspection Service, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, Final Rule with Request for Comments, 61 Fed. Reg. 38806 (1996) [hereinafter cited as USDA HACCP Final Rule], at 38807.

159 NAS Safe Food Report, *supra*, at 27.

160 21 U.S.C.A. § 603(a); *see also* Jean M. Rawson, Meat and Poultry Inspection Issues, CRS Order Code IB 10082, at 3 (updated Jan. 18, 2002).

161 Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. at 6780.

The FMIA requires FSIS to inspect the carcasses, parts of carcasses, and meat food products to ensure that such articles are not adulterated.[162] If an inspector determines that carcasses, parts of carcasses, and meat food products are not adulterated, the inspector marks them as "Inspected and Passed."[163] Otherwise, they are deemed to be adulterated and may not be sold or distributed. The FMIA specifically authorizes the Secretary of Agriculture to "prescribe the rules and regulations of sanitation under which establishments shall be maintained" and to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed" if the sanitary conditions of the establishment are such that the meat or meat food products are rendered adulterated.[164]

USDA has historically taken the position that its function is not to ensure that meat is free of deadly pathogens. During the infamous Jack-in-the-Box disaster of January 1993, which killed four people and caused 55 extremely debilitating cases of hemolytic uremic syndrome, the head of FSIS noted accurately that USDA's regulations did not authorize FSIS to seize meat contaminated with the powerfully toxic bacterium E. coli O157:H7, because "the presence of bacteria in raw meat, . . . although undesirable, is unavoidable, and not cause for condemnation of the product."[165]

USDA's position was ratified in a 1974 lawsuit brought by the American Public Health Association to force the agency to require the industry to provide a label on packages of raw meat telling consumers how to cook the meat so as to render it safe. In *American Public Health Association v. Butz,*[166] the D.C. Circuit deferred to 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. Since Congress did not require meat to be free from pathogens, the court held that USDA was not required to force the industry to provide generic warnings on meat packaging labels.[167] 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."[168] 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.

When a 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

---

162 21 U.S.C. § 604, 606

163 *Id*. § 604, 606, 607

164 *Id*. § 608.

165 Nichols Fox, *Spoiled: The Dangerous Truth About a Food Chain Gone Haywire* (1997), at 321 [hereinafter cited as Fox, *Spoiled*], at 252 (quoting Russell Cross, Administrator, FSIS).

166 American Public Health Ass'n v. Butz, 511 F.2d 331 (DC Cir. 1974).

167 *Id*. at 332-35.

168 *Id*. at 334. The Fifth Circuit reaffirmed the *Butz* holding that Salmonella is not a per se adulterant in Supreme Beef Processors, Inc. v. USDA, 275 F.3d 432, 439 (quoting *Butz* at 334).

days.[169] 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.[170] The agency may only order a suspension, however, after a hearing before an independent Administrative Law Judge.[171]

The Animal and Plant Health Inspection Service (APHIS) is the agency within the USDA that is responsible for promoting agricultural health and protecting the Nation's agriculture from pests and disease.[172] To ensure detection of and swift response to pests and foreign animal diseases, such as BSE, APHIS develops and implements surveillance programs.[173] APHIS is currently leading an interagency BSE surveillance program that is described in more detail below.[174]

1. The HACCP Regulations.

As the meatpacking industry evolved into a concentrated conglomeration of huge slaughterhouses, it became increasingly clear that individual FSIS inspectors were losing the battle with increased line speeds driven by constant pressure for increased efficiency.[175] 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.[176] By the mid-1990s, FSIS had concluded organoleptic inspections were no longer adequate to ensure that meat was not adulterated and that "consumer education alone will not control pathogen-related foodborne illness," because "more people in our society are assuming responsibility for food handling and preparation in the home and elsewhere, without experience in food preparation and knowledge of safe food handling and storage methods."[177]

a) HACCP Plans.

On July 25, 1996, USDA promulgated regulations requiring slaughterhouses and certain other meat processing establishments to adopt the "Hazard Analysis at Critical Control

---

169 21 U.S.C. § 604, 672.

170 *Id*. § 604, 606, 607, 608, 671; 9 C.F.R. § 329, 329.9, 335.11.

171 9 C.F.R. § 305.3-305.6.

172 APHIS Website, http://www.aphis.usda.gov/lpa/about/welcome.html.

173 Bovine Spongiform Encephalopathy (BSE) Surveillance, May 20, 2004, available at http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html.

174 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, Animal Plant Health Inspection Service, Dr. Barbara Masters, Acting Administrator, Food Safety Inspection Service, May 21, 2004, available at http://www.usda.gov/Newsroom/0204.04.html. *See infra* Section VII.H.

175 Nestle, *Safe Food*, *supra*, at 67.

176 USDA HACCP Proposed Rule, *supra*, at 6780; NAS Safe Food Report. *supra*, at 27.

177 USDA HACCP Proposed Rule, *supra*, at 6783.

Points" (HACCP) approach to meat safety.[178] A radical departure from traditional organoleptic inspections, an approach that the agency now characterizes as "command and control,"[179] the HACCP rule is a "performance-based" standard that gives slaughterhouses greater autonomy while demanding greater responsibility for establishing process control measures capable of meeting FSIS performance standards.[180] HACCP is also "science-based" because it relies upon quantitative measurements, rather than qualitative judgments of individual inspectors.[181] The greatest virtue of HACCP, in the agency's view, is that it focuses on contamination prevention rather than after-the-fact detection.[182] An understanding of the HACCP process for meat is critical to an 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.

Under the HACCP approach, as envisioned by the FSIS regulations, slaughterhouses and meat processing establishments must first conduct a "hazard analysis" that identifies the hazards and analyzes the food safety risks at each stage of the food production process.[183] 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 "prevented, eliminated, or reduced to an acceptable level."[184] The third step is for the operator to define and establish "critical limits" for each of the CCPs.[185] 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.[186]

The next step is perhaps the most important from the standpoint of enforceability. The operator must establish monitoring requirements capable of measuring whether the

---

178 USDA HACCP Final Rule, *supra*. 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, *Safe Food*, *supra*, at 67.

179 USDA HACCP Final Rule, *supra*, at 38808.

180 USDA HACCP Final Rule, *supra*, at 38808 ("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 general discussion of the HACCP approach, *see* Jean M. Rawson, Meat and Poultry Inspection Issues, CRS Issue Brief for Congress, August 1, 2003, at CRS-1 [hereinafter cited as CRS Issue Brief 8/1/03]. *See also* Margaret O'K. Glavin, *HACCP: We've Only Just Begun*, 56 Food & Drug Journal 137, 138 (2001).

181 USDA HACCP Final Rule, *supra*, at 38811.

182 USDA HACCP Proposed Rule, *supra*, at 6784.

183 USDA HACCP Final Rule, *supra*, at 38815. A "hazard" is "any biological, chemical, or physical property that may cause a food to be adulterated or otherwise unsafe for human consumption." *Id.*

184 USDA HACCP Final Rule, *supra*, at 38815.

185 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." *Id.* at 38816.

186 *Id.*

parameters established in the critical limits are exceeded at any of the CCPs.[187] 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.[188] 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.[189]

HACCP plans must specify "corrective action" that the operator must undertake when monitoring identifies deviations from a critical limit at a CCP.[190] This requirement reflects USDA's understanding that "the existence of a HACCP plan does not guarantee that problems will not arise."[191] Operators must put recordkeeping procedures into place to document monitoring and corrective action and make those records available to FSIS inspectors.[192] Finally, establishments must systematically verify the effectiveness of their HACCP systems initially and over time.[193]

Although the HACCP plan is initially the responsibility of the individual establishment, the plan and all significant substantive revisions to the plan must be approved by FSIS.[194] Significantly, the substantive requirements of the HACCP plans themselves are not legally enforceable. Rather, the HACCP plan "is an industry process control system that provides opportunities to make inspection more effective."[195]

b) Sanitation Standard Operating Procedures.

The HACCP rule requires operators to establish sanitation standard operating procedures ("Sanitation SOPs") to complement the HACCP system.[196] Sanitation SOPs are a subset of a vaguely defined category of "prerequisite programs" that are currently playing a major role in the implementation of the January 2004 regulations. The purpose of sanitation SOPs is to ensure that "poor food handling practices, improper personal hygiene, and similar insanitary practices" do not "create an environment conducive to contamination of products."[197] Of particular relevance to the mad cow problem, the HACCP regulations envision that Sanitation SOPs will address "pre-operational sanitation procedures for cleaning facilities, equipment, and utensils."[198]

---

187 *Id*.

188 *Id*.

189 *See infra* Section XI.F.2.c.

190 USDA HACCP Final Rule, *supra*, at 38816.

191 *Id*.

192 *Id*. at 38817.

193 *Id*.

194 *Id*. at 38818 (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").

195 USDA HACCP Proposed Rule, *supra*, at 6815.

196 USDA HACCP Final Rule, *supra*, at 38829.

197 *Id*.

198 *Id*. at 38834.

The heart of Sanitation SOPs is an operator-generated "sanitation plan"[199] prescribing internal sanitation procedures, both pre-operational and during slaughtering and processing operations, for preventing direct contamination and adulteration of meat products.[200] The Sanitation SOPs must also specify the frequency with which the procedures must be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s)."[201] The responsible employee, however, may be the very employee who is carrying out the procedure. [202] Plants must keep daily records "documenting that sanitation and monitoring procedures listed in the Sanitation SOP's are performed."[203] In addition, SOPs must contain procedures "to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s)."[204]

The establishment is responsible for taking corrective action when either its employees or FSIS determines that the sanitation SOPs or their implementation "may have failed to prevent direct product contamination or adulteration."[205] The agency assured the industry that inspectors would not close down a plant for a single violation of its Sanitation SOPs. So long as the establishment took steps to correct the insanitary conditions resulting from the violation "in a timely manner" and made "proper disposition of any affected product," it would "be considered to be in compliance with the Sanitation SOP's regulations."[206]

Prior to promulgating the 1996 HACCP regulations, 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."[207] An extreme departure from the earlier "prescriptive" sanitation regulations,[208] the 1996 requirements for sanitation SOPs are flexible to a fault. Each establishment must "analyze its own operations and identify possible sources of direct contamination that must be addressed in

---

199 *Id*. at 38831.

200 *Id*. at 38830.

201 *Id*.

202 *Id*.

203 *Id*. at 38831.

204 *Id*. at 38830.

205 *Id*. at App A, B.

206 *Id*. at 38834.

207 *Id*. at 38832.

208 Two years after promulgating the final HACCP rule, FSIS amended its pre-existing sanitation rules to "convert many of the highly prescriptive sanitation requirements to performance standards." United States Department of Agriculture, Food Safety and Inspection Service, Sanitation Requirements for Official Meat and Poultry Establishments. Final Rule, 64 Fed. Reg. 56400 (October 20, 1999), at 56400 [hereinafter cited as 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.

its Sanitation SOP's"[209] and "determine for itself what procedures are necessary to prevent insanitary conditions that will cause direct product contamination or adulteration."[210] The regulations themselves are sorely lacking in detail as to what constitutes an adequate sanitation SOP. Indeed, the agency expected that for some establishments, the process of drafting sanitation SOPs would consist of little more than writing down their current practices.[211]

FSIS inspectors play almost no role at all in the writing and implementation of Sanitation SOPs for individual plants. In particular, the regulations do not give an FSIS inspector the authority to approve or disapprove a company's Sanitation SOPs.[212] Only "persistent and serious failures" will result in suspension or withdrawal of inspection with a consequent cessation of operations.

c) Performance Criteria and Standards.

To ensure that HACCP programs actually produced safer meat, FSIS prescribed "microbiological performance standards" for raw products that every HACCP program had to meet.[213] To measure of the overall performance of sanitation SOPs, FSIS required establishments to test for E. coli at a specified frequency and to attain performance "criteria" for E. coli contamination based on the prevalence of contamination of E. coli on carcasses produced nationwide.[214] A failure to meet the performance criteria would not by itself establish a violation of law, but it would be an indication that greater sanitation efforts were necessary and that appropriate corrective action might be required.[215]

The HACCP regulations used Salmonella as the target organism for the purpose of "objective" verification of the performance of HACCP plans in reducing pathogen levels at critical control points.[216] If Salmonella levels at all of the relevant critical control points were below the prescribed levels, the agency could safely assume compliance with the HACCP plan and, consequently, that the resulting meat was not adulterated. FSIS required a reduction of the prevalence of end-product Salmonella contamination to a level "below the current national baseline prevalence."[217] In the agency's view, this performance standard was "achievable using available technology."[218] Unlike the E. coli

---

209 USDA HACCP Final Rule, *supra*, at 38830.

210 *Id*. at 38833.

211 *Id*. at 38830.

212 *Id*. at 38832 ("FSIS will not approve Sanitation SOP's"); *id*. at 38834 ("FSIS inspectors will not be tasked with directing an establishment's sanitation procedures, nor with "approving" the establishment's Sanitation SOP's.").

213 *Id*. at 38836.

214 *Id*. at 38837-38.

215 *Id*. at 38838.

216 *Id*. at 38835. The agency chose Salmonella because (1) it was the most common cause of foodborne illness associated with meat and poultry products; (2) it was present in all major meat species; and (3) interventions targeted at reducing Salmonella could be "beneficial in reducing contamination by other enteric pathogens." *Id*.

217 *Id*. at 38838.

218 *Id*. at 38836.

criteria for the Sanitation SOPs, the requirement that Salmonella be below the national baseline average was intended to be a legally binding "standard" and the HACCP regulations required establishments to "meet the standard consistently over time as a condition of maintaining inspection."[219] On the other hand, Salmonella levels could not be used to "judge whether specific lots of product are adulterated under the law."[220]

In contrast to the minimal role assigned to the FSIS inspector under the Sanitation SOPs, FSIS inspectors were obliged to perform Salmonella testing for the purpose of determining compliance with the pathogen reduction performance standards.[221] A facility that failed the Salmonella test twice would have to "reassess its HACCP plan for the tested product, modifying the plan as necessary to achieve the Salmonella performance standard."[222] A third failure would result in a suspension of FSIS inspection services, which as a legal matter would mean that the facility would have to stop processing meat.[223] This "three-strike" rule was not, however, 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.[224] Consumer groups, on the other hand, argued that all HACCP-related documents should be available for public inspection.[225] The final rule allowed 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."[226] Since operators were not generally required by the regulations to submit copies of HACCP-related records to FSIS, copies of such records would not ordinarily be found in FSIS files where they would be available to the general public under the Freedom of Information Act (FOIA).[227]

The preamble to the final rule noted that HACCP and sanitation SOP records that did wind up in FSIS files would still be subject to the various FOIA exemptions. Since operators would spend time and money developing individualized HACCP plans and sanitation SOPs, the agency expected that most of them would contain commercially valuable confidential information and would therefore normally be protected from disclosure by the trade secrecy exemption to the FOIA. [228] Thus, the agency effectively assuaged industry concerns by assuring it that the public would know very little about the nature and effectiveness of individual HACCP plans.

---

219 *Id*. at 38838.

220 *Id*. at 38836.

221 *Id*. at 38848.

222 *Id*. at 38849.

223 *Id*.

224 *Id*. at 38821.

225 *Id*.

226 *Id*.

227 *Id*. at 38821, 38833.

228 *Id*.

e) Whistleblower Protections.

Whistleblower protections are legal requirements and procedures that are designed "to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers."[229] In the HACCP context, whistleblower protections would protect employees who report attempts by management to falsify HACCP reports. Without whistleblowers, the likelihood that FSIS will detect fraud in HACCP documentation is vanishingly 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.[230] 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.[231] It therefore declined to provide any protections.

f) The Supreme Beef Challenge.

Two years after USDA promulgated the HACCP regulations, Supreme Beef Processors, a small meat processing and grinding establishment, implemented its first HACCP pathogen control plan.[232] USDA's first validation test found 47 percent of the samples taken at the plant to be contaminated with Salmonella, far above the 7.5 percent national performance standard set out in the regulations.[233] A second round of validation testing showed improvement to 20.8 percent, but the level was still far below the performance standard. After a third validation test again fell short, FSIS issued a Notice of Intended Enforcement Action to Supreme Beef threatening to suspend inspections (and thereby force the company to cease processing beef) unless the company achieved the 7.5 percent performance standard by the end of the following month.

On the day that FSIS proposed to cease inspections, Supreme Beef sued the agency in a federal district court in northern Texas. The court held that the HACCP regulations were invalid as applied to Supreme Beef Processors.[234] The United States Court of Appeals for the Fifth Circuit later affirmed the district court's decision.[235]

The court of appeals noted first of all 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.'"[236] This was "because normal cooking practices for

---

229 *Id*. at 38822.

230 *Id*.

231 *Id*.

232 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001), at 435.

233 *Id*.

234 Supreme Beef Processors, Inc. v. USDA, 113 F. Supp.2d 1048, 1055 (N.D. Tex. 2000).

235 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001).

236 *Id*. at 439.

meat and poultry destroy the Salmonella organism, and therefore the presence of Salmonella in meat products does not render them "injurious to health."[237] Indeed, FSIS routinely labeled Salmonella-containing beef "inspected and passed."[238]

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."[239] 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."[240] 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."[241]

The court rejected the agency's argument that it could regulate Salmonella as a proxy for all microbiological contaminants in its HACCP "performance" standard because "the Salmonella performance standard, whether or not it acts as a proxy, regulates more than just the presence of pathogen controls."[242] Noting that Supreme Beef 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,[243] the court held that USDA was powerless to " regulate characteristics of the raw materials that exist before the meat product is 'prepared, packed or held.'"[244]

The court agreed with the district court that since neither the performance standard in general nor the Salmonella test in particular necessarily evaluated the conditions of a 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.[245]

In response to the *Supreme Beef* decision, USDA took the position that the court had 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.[246] FSIS has continued to require establishments to prepare HACCP plans and Sanitation SOPs and to ensure that corrective action is taken if critical levels are exceeded at critical control points.[247] On the other hand, it seems clear that after *Supreme Beef*, FSIS will have to justify very

---

237 *Id*.

238 *Id*.

239 21 U.S.C. § 601(m)(4).

240 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001), at 440.

241 *Id*.

242 *Id*. at 439.

243 *Id*. at 441.

244 *Id*.

245 *Id*. at 439.

246 CRS Issue Brief 8/1/03, *supra*, at CRS-6.

247 *Id*.

carefully 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 it became clear in the late 1980s that mad cow disease had become a serious animal health problem in Great Britain, USDA took several steps to protect the U.S. cattle population from that disease. These efforts generally fit into three categories: import restrictions, surveillance and education. Only the first action placed any regulatory constraints on the U.S. beef industry. FDA entered the picture in 1997 to promulgate regulatory restrictions on animal feeds aimed at preventing the spread of mad cow disease in the U.S. population should the disease find a niche in the U.S. cattle herd. In addition, USDA drafted and put into place a contingency plan specifying the steps that the various agencies in that Department would take should a BSE-positive animal be detected in the U.S. cattle population.

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

Since 1989, APHIS has imposed a ban on the importation of live ruminants and certain ruminant products from countries where BSE was known to exist.[248] In December 1991, the Department expanded the ban to prevent the importation of ruminant meat and edible products and most byproducts of ruminant origin from countries known to have BSE.[249] The ban was expanded further in 1997 to include live ruminants and most ruminant products for all of Europe.[250] This ban has remained in place ever since.

On May 20, 2003, Canada announced the discovery of a BSE-positive cow in Alberta.[251] USDA immediately placed Canada on a list of countries where BSE is known to exist and prohibited imports of all ruminants and ruminant products from Canada.[252] After Canada implemented additional risk mitigation measures and USDA experts conducted a scientific review, Secretary Veneman, on August 8, 2003, announced that the USDA would accept applications for import permits for certain low-risk products.[253] On August

---

248 Harvard Center for Risk Analysis BSE Report, *supra*, at 23; USDA BSE Overview, *supra*, at 5; FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 9.

249 USDA BSE Overview, *supra*, at 5.

250 *Id*. *See* 9 C.F.R. § 94.18 (2002) (restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy).

251 US Department of Agriculture, Animal and Plant Health Inspection Service, Importation of Processed Canadian Beef Products Regulatory Timeline 2004, available at http://aphisweb.aphis.usda.gov/lpa/issues/bse/bsechronjune10.pdf.

252 9 C.F.R. § 94.18(a)(1). *See* Statement by Ann M. Veneman Regarding Canada's Announcement of BSE Investigation, May 20, 2003, available at www.usda.gov/news/releases/2003/05/0166.htm.

253 USDA, Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted, August 8, 2003, available at www.usda.gov/news/releases/2003/08/0281.htm. The list included boneless bovine meat from cattle under 30 months, veal meat from calves 36 weeks or younger, fresh or frozen bovine liver, pet products and feed ingredients that contain processed animal protein and tallow of non-ruminant sources.

15, 2003, APHIS amended the August 8 list of low-risk products from Canada to include "trim," which is boneless beef trimmed from cattle under 30 months of age and veal from calves under 36 weeks.[254] USDA amended the August 15 low-risk Canadian products list on October 22, 2003 and again on April 19, 2004 to include edible bovine hearts, kidneys, tongues, and lips as well as bone-in beef for animals less than 30 months of age.[255] However, on April 26, 2004, a U.S. District Court issued a temporary restraining order prohibiting APHIS from issuing permits for products other than those on the August 15 list of low-risk Canadian products.[256]

b) USDA Surveillance Efforts Prior to December 2003.

The accuracy with which USDA and the general public can know the true incidence of BSE in the U.S. cattle population depends upon the range and intensity of the surveillance efforts that USDA undertakes to discover BSE. Because brain tissue is necessary for accurate testing, live animals cannot be tested for BSE.[257] Therefore 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.

FSIS inspectors have since the early-1990s been on the lookout for cattle exhibiting signs of CNS disorders.[258] At the same time, APHIS, an entirely separate agency within USDA, bears the primary responsibility for implementing the USDA BSE Surveillance Sampling Program.[259] FSIS inspectors would condemn non-ambulatory (downer) cattle and other animals exhibiting signs of CNS disorders and send samples from their brains

---

254 US Department of Agriculture, Animal and Plant Health Inspection Service, Importation of Processed Canadian Beef Products Regulatory Timeline, *supra*.

255 USDA, Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted, August 8, 2003, *supra*.

256 *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. 68 Fed. Reg. 62386 (2003). *See* USDA, USDA Issues Proposed Rule to Allow Live Animal Imports from Canada, 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 US. *Id*. USDA is currently reviewing the public comments it received regarding this proposed rule. US Department of Agriculture, Animal and Plant Health Inspection Service, Importation of Processed Canadian Beef Products Regulatory Timeline, *supra*.

257 Denise Grady, *9 Cows Linked to Mad Cow Inquiry Have Been Found*, New York Times, January 1, 2004.

258 *Potential transmission of Spongiform Encepholapathies to Humans: The Food and Drug Administration's [FDA] Ruminant to Ruminant Feed Ban and the Safety of Other Products: Hearing Before the House Comm. On Government Reform and Oversight*, 105th Cong. 48, 49 (1997) (statement of Dr. Linda A. Detwiler, Chair, TSE Working Group) [hereinafter cited as Detwiler Testimony].

259 See supra Section XI.F.2.g.1.

to APHIS laboratories for BSE analysis.[260] 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.[261] Private veterinarians were also encouraged to refer cases of possible CNS disorders to APHIS for BSE analysis.[262]

Since 1986, USDA has encouraged slaughterhouses to submit brain tissue voluntarily for testing in USDA laboratories.[263] Beginning in 1990, APHIS began an active BSE surveillance program aimed at sampling the brains of several hundred downer cattle per year for signs of BSE.[264] 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.[265] APHIS laboratories 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.[266] 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.[267] In FY 2003, APHIS expanded the testing program once again, and it later reported testing more than 20,000 cattle for BSE in that year alone.[268] Even 20,000 was less than 5 percent of the more than 400,000 downer cattle that appear annually in the U.S. cattle population,[269] and it was a tiny fraction of the 35 million cattle slaughtered annually in the United States[270]

c) Regulation of AMR and Mechanical Separation Technologies.

FSIS has traditionally regulated meat products produced by AMR systems under its authority to prevent misbranding of meat and meat products.[271] Under FSIS misbranding

---

260 U.S. General Accounting Office, Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts, GAO-02-13, January, 2002, at 20 [hereinafter cited as 2002 GAO Mad Cow Report].

261 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 11.

262 Detwiler Testimony, *supra*, at 49.

263 Harvard Center for Risk Analysis BSE Report, *supra*, at 45.

264 Detwiler Testimony, *supra*, at 49; Rhodes, *Deadly Feasts*, *supra*, at 223.

265 Harvard Center for Risk Analysis BSE Report, *supra*, at 45.

266 Harvard Center for Risk Analysis BSE Report, *supra*, at 45.

267 Donald G. McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, New York Times, December 26, 2003.

268 Marian Burros & Donald G. McNeil, Jr., *Inspections for Mad Cow Lag Those Done Abroad*, New York Times, December 24, 2003.

269 Bette Hileman, *Mad Cow Disease*, 82 Chemical & Engineering News 21 (2004) [hereinafter cited as Hileman, Mad Cow Disease].

270 Burros & McNeil Jr., *Inspections for Mad Cow Lag Those Done Abroad*, *supra*.

271 A meat or meat food product is misbranded under any of a number of circumstances, including if its labeling is false or misleading in any particular; 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

regulations promulgated in 1994, spinal cord is not a component of meat, and any product resulting from AMR processes is misbranded if it contains spinal cord material but is identified as "meat."[272] To clarify its position that product identified as "meat" was misbranded if it contained spinal cord material, FSIS in April 1998 issued a notice of proposed rulemaking that, among other things, adopted a "zero tolerance" for the presence of spinal cord material in meat products.[273] That rulemaking initiative was not finalized until the January 2004 mad cow rulemaking initiative.

Prior to January 2004, FSIS had not taken any regulatory action against AMR product identified as "meat" if it contained DRG and other CNS-type tissues.[274] A 2002 USDA survey of AMR establishments, however, found that meat product from 76 percent of them tested positive for spinal cord, DRG or both materials.[275] 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.[276] 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.[277]

USDA regulations for mechanically separated meat were even less effective at keeping potentially prion-contaminated tissues out of the resulting meat product. Unlike AMR systems in which bone and bone products are not purposefully incorporated in the final meat product, mechanical separation systems are designed to incorporate significant amounts of bone and bone components in the resulting meat food product to increase the amount of product that can be derived from a single animal.[278] USDA's regulations therefore permitted mechanically separated beef to include spinal cord and DRG in the final product, thus posing a serious risk of communicating TSE from infected animals to humans.[279]

d) Cattle Identification and Tracking Program.

The United States is currently without a comprehensive animal tracking system for expeditiously tracing livestock during disease outbreaks. While other countries have

---

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), (n)(2), (n)(3), and (n)(7)). *See* USDA AMR Interim Final Rule, *supra*, at 1875.

272 9 C.F.R. § 301.2. *See* 59 Fed. Reg. 62551 (1994).

273 63 Fed. Reg. 17959 (1998).

274 USDA AMR Interim Final Rule, *supra*, at 1876.

275 *Id*.; USDA SRM Interim Final Rule, *supra*, at 1866.

276 USDA AMR Interim Final Rule, *supra*, at 1876; USDA SRM Interim Final Rule, *supra*, at 1866.

277 USDA AMR Interim Final Rule, *supra*, at 1876; USDA SRM Interim Final Rule, *supra*, at 1866.

278 USDA SRM Interim Final Rule, *supra*, at 1866.

279 *Id*.

mandatory animal tracking systems,[280] the United States has lagged behind due largely to producer concerns over costs, legal liability and privacy.[281] Consequently, as the recent experience with the Washington state mad cow has highlighted, it is exceedingly difficult to determine the origins of a suspect cow when it 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 to avoid the stigma (and considerable economic risk) of being the owner of a ranch at which a BSE-positive animal was identified. 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.[282]

Since 2002, government and industry groups have been attempting to draft a nationwide Animal Identification Plan (AIP),[283] and after the discovery of the Mabton mad cow, USDA put that plan on a fast track for implementation.[284] 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.[285]

The current version of the plan would assign identification numbers to animal premises, individual animals and groups of animals.[286] 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.[287] The plan's goal is to ensure traceability within 48 hours through consistent identification of both premises and individual animals.[288] 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.[289] The program would be

---

280 Christopher Drew, Elizabeth Becker & Sandra Blakeslee, *Despite Mad-Cow Warnings, Industry Resisted Safeguards*, New York Times, December 28, 2003 (describing animal tracking programs in the European Union, Canada and Japan).

281 *See* Stephanie Simon, *USDA Plans to Beef Up Livestock ID System*, Los Angeles Times, January 11, 2004.

282 2002 GAO Mad Cow Report, *supra*, at 21.

283 U.S. Animal Identification Plan, version 4.1, National Identification Development Team, Dec. 2003, available at http://usaip.info/USAIP4.1.pdf, at 2 [hereinafter cited as Draft U.S. Animal Identification Plan].

284 Transcript of Remarks by Agriculture Secretary Ann M. Veneman Before the House Agriculture Committee, January 21, 2004, available at http://www.usda.gov/Newsroom/0031.04.html.

285 *See* U.S. Animal Identification Plan website, http://usaip.info/index.htm.

286 Draft U.S. Animal Identification Plan, *supra*, at 5.

287 Although the AIP does not commit to one method over the other overall, radio frequency is cited as the preferred method for cattle, *id*. at 28, and an electronic system would facilitate data transmittal and tracking. *See e.g.* Associated Press, *NDSU Researchers say Radio Tags Could Track Livestock*, The Bismark Tribune, Feb. 22, 2004, available at http://www.bismarcktribune.com/articles/2004/02/22/news/state/sta04.txt. Draft U.S. Animal Identification Plan, *supra*, at 13.

288 Draft U.S. Animal Identification Plan, *supra*, at 5-14.

289 *Id.* at 17-22.

phased in and oversight would be provided by a Board made up of industry and state and federal government officials.[290]

e) The Mad Cow Emergency Response Plan

Long before the discovery of the Mabton mad cow, APHIS and FSIS had cooperatively drafted a BSE Response Plan to be used when a BSE-positive animal was identified in the United States.[291] This response plan was activated in December 2003.[292] Under the plan, brain tissue from suspect animals identified by FSIS is sent to the APHIS laboratory in Ames, Iowa for histopathological evaluation, a process that in the past has taken 14-18 days.[293] If after the first 10- 13 days, BSE cannot be ruled out, the BSE Response Plan is initiated and the suspect samples are sent to the Central Veterinary Laboratory (CVL) in the United Kingdom for confirmation.[294] The preliminary BSE diagnosis also triggers the plan's notification component. At this point, the "BSE Response Team," which is responsible for gathering, evaluating, synthesizing, and disseminating all information during a BSE emergency, assembles in the "Situation Room" at the APHIS headquarters in Riverdale, Maryland.[295]

Upon a presumptive determination that the suspect animal was BSE-positive, APHIS field personnel establish a "routine state quarantine" of the herd that yielded the suspect animal.[296] They also attempt to trace both the suspect animal's progeny and its adult herd mates.[297] As progeny and herd mates are located, the quarantine is expanded to include them. The plan requires APHIS field personnel to continue theses efforts until a "complete trace out on the progeny and herd mates" is accomplished.[298] As the efforts to trace the origins of the Washington state mad cow made painfully clear, this goal is not always attainable.[299]

At the same time, FSIS personnel search for information concerning the disposition of the suspect animal's carcass and those of progeny and herd mates.[300] If the animal was not condemned, FSIS then traces all the food items and notifies the FDA.[301] If the food items

---

290 *Id.* at 25, 35.

291 United States Department of Agriculture, Bovine Spongiform Encephalopathy (BSE) Response Plan (October, 1998), available at http://www.aphis.usda.gov/oa/bse/bsesum.pdf [hereinafter cited as USDA BSE Response Plan]. *See also* FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 9.

292 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 9.

293 USDA BSE Response Plan, *supra*, at Response Plan Summary.

294 *Id*.

295 *Id*.

296 *Id*.

297 *Id*.

298 *Id*.

299 *See infra* Section VI.B.

300 USDA BSE Response Plan, *supra*, at Response Plan Summary.

301 *Id*. at 2.5-1. FDA also has a BSE contingency plan under which it determines feed history in an attempt to locate the source of potentially BSE contaminated feed and animals. FDA also attempts to trace any parts of the infected animal that were rendered. U.S. Food and Drug Administration, BSE Contingency Plan, February 15, 2001, available at http://www.fda.gov/oc/bse/contingency.html.

have been exported, the FSIS notifies the importing country.[302] For products distributed domestically, FSIS initiates a Class 1 voluntary recall affecting all meat, meat products and potentially affected products.[303] For animals that FSIS orders destroyed, USDA has authority to pay fair market value or up to one hundred percent of the expenses entailed in purchasing and disposing of animals and other materials required to be destroyed due to BSE, depending on the availability of funds.[304]

f) The FSIS Current Thinking Paper.

On January 17, 2002, USDA published for public comment a paper representing its "current thinking" on the approaches it should adopt toward a possible BSE outbreak in the United States[305] This paper anticipated the response that USDA would take exactly two years later. For example, the first option considered was a strict prohibition on "Specified Risk Material" in meat destined for human food.[306] The term "specified risk materials" would have included "brain and spinal cord from cattle aged 24 months and older and downer cattle regardless of age."[307] It would further have included all "intestine from all cattle regardless of age."[308] The Department was willing to consider, however, the possibility of lifting the prohibition for SRM from cattle that tested negative for BSE at a USDA-approved laboratory.[309] The current thinking paper also considered restrictions on AMR systems to ensure that SRM did not wind up in meat product from those systems.[310] The Current Thinking Paper put the industry on notice that if a case of mad cow was discovered in the United States, it would promulgate regulations along the lines outlined in the current thinking paper on an emergency basis.[311] As discussed below, FSIS did promulgate interim final regulations on an emergency basis, but they were not as stringent as those it considered in the current thinking paper.

B. FDA regulation.

The Food and Drug Administration (FDA), which is part of the Department of Health and Human Services, administers the food safety provisions of the Pure Food and Drug Act of 1906. In addition, FDA has responsibility for implementing the "feed additive" provisions of the 1958 Amendments to the Food, Drug and Cosmetic Act of 1938

---

302 USDA BSE Response Plan, *supra*, at 2.5-1.

303 *Id*. at 2.5-1. A Class 1 recall is initiated when there is a health hazard situation where there is a reasonable possibility that the use of the product will cause serious, adverse health consequences or death. *Id*. at 2.4-2.

304 9 C.F.R. § 53. *See* USDA BSE Response Plan, *supra*, at 2.1-27.

305 Bovine Spongiform Encephalopathy (BSE) Current Thinking Paper; Notice of Availability, 67 Fed. Reg. 2399-01 (January 17, 2002) [hereinafter cited as USDA Current Thinking Paper]

306 *Id*. at 11.

307 *Id*.

308 *Id*.

309 *Id*.

310 *Id*. at 11-12.

311 *Id*. at 12.

(FDCA).[312] The FDCA defines a "food additive" as "any 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."[313] To meet the "generally recognized as safe" (GRAS) exception, the proponent of a substance that would otherwise be a food additive must be 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."[314] Any food containing a food additive that has not been approved by FDA is adulterated and subject to seizure.[315] In 1997, FDA exercised those authorities and its general rulemaking authority[316] to promulgate its Ruminant Feed Regulations.[317]

1. The 1997 Ruminant Feed Regulations.

FDA considered banning the practice of feeding ruminant feed to ruminant animals in 1991, but it refrained from doing so after receiving assurances from the cattle industry that it would voluntarily stop feeding protein from sheep, cattle and other ruminants to cattle.[318] When FDA examined the actual practices of the rendering industry in 1993, however, it discovered that more than half of the renderers who were processing adult sheep were still selling protein from those sheep to manufacturers of cattle feed.[319]

On June 5, 1997, FDA promulgated regulations banning the use of protein derived from all mammalian tissues, with certain exceptions, in ruminant feed.[320] The all-important exceptions, however, included: blood and blood products; gelatin; plate waste; milk products; and any product whose only mammalian protein consisted entirely of pig or horse protein.[321] In addition, the rule did not apply to materials that were not proteins, such as tallow, fats, oils, grease, amino acids, and dicalcium phosphate.[322] Moreover,

---

312 NAS Safe Food Report, *supra*, at 22.

313 21 U.S.C. § 321(s)).

314 FDA 1997 Feed Rule, *supra*, at 30937.

315 21 U.S.C. § 402(a)(5).

316 *Id*. § 701(a).

317 21 C.F.R. § 589.2000. *See* Crawford Testimony, 1/27/04, *supra*.

318 Fox, *Spoiled*, *supra*, at 320.

319 *Id*.

320 FDA 1997 Feed Rule, *supra*. 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. 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.

321 21 C.F.R. § 589.2000(a)(1). *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 43; Rhodes, *Deadly Feasts*, *supra*, at 233.

322 FDA 1997 Feed Rule, *supra*, at 30938.

ruminant protein could still be used in feed for chickens, pigs and pets, and protein from those sources could still be rendered into cattle feed.[323]

To discourage "cross-feeding," the rule required renderers, protein blenders and feed manufacturers to place the cautionary statement "Do not feed to cattle or other ruminants" on feeds for nonruminant species that contained animal proteins.[324] In addition, those companies were required to maintain "records sufficient to track the materials throughout their receipt, processing, and distribution," and to make copies available for inspection and copying by FDA inspectors.[325] Renderers would, however, be exempt from the labeling and recordkeeping requirements if they used "exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by" FDA.[326] Finally, the regulations required establishments and individuals (including individual cattle producers and feedlots) that were responsible for feeding ruminant animals to maintain copies of purchase invoices and labeling for all feeds containing animal protein products that they received and to make the copies available for inspection and copying by FDA inspectors.[327] It appears from FDA's inspection spreadsheet that small entities have received at least some attention from FDA and state inspectors.[328]

FDA rejected the suggestions of several commenters that the agency eliminate the exemptions and "increase the scope of the regulations to include a partial or complete mammalian-to-ruminant prohibition or a mammalian-to-farm animal prohibition, or to apply a feed prohibition on all food-producing animals."[329] The agency explained that the "available data" suggested that the exempted materials either did not transmit the TSE agent or (in the case of plate waste) were at some point inspected by the FSIS, cooked, and subsequently rendered.[330] The agency was also confident that "current industry practices" provided "assurances" that some of the exempted products could be produced "without becoming commingled with potentially infective materials."[331] The agency did not explain how inspecting and cooking meat that winds up as plate waste would detect or neutralize any mad cow prions; nor did it explain how current industry practices, which were not necessarily designed with mad cow disease in mind, would insure that mad cow prions would not be commingled with uninfected materials.

FDA further rejected the suggestion that it should a least ban feeding chicken litter from chickens that had been fed protein derived from ruminants to ruminants.[332] The agency

---

323 Rhodes, *Deadly Feasts*, *supra*, at 233.

324 21 C.F.R. § 589.2000(c)(1)(i); FDA 1997 Feed Rule, *supra*, at 30937.

325 21 C.F.R. § 589.2000(c)(1)(ii); FDA 1997 Feed Rule, *supra*, at 30937.

326 21 C.F.R. § 589.2000(c)(2).

327 *Id*. § 589.2000(f).

328 FDA/BSE Ruminant Feed Inspections Firm Inventory Report, available at http://www.accessdata3.fda.gov/BSEInspect/ [visited on May 22, 2004].

329 FDA 1997 Feed Rule, *supra*, at 30939.

330 *Id*.

331 *Id*.

332 *Id*.

had no reason for rejecting this suggestion, which was based upon a plausible scenario, but simply noted that it was "unaware of any research on this issue that would indicate that the agency should take regulatory action on poultry litter at this time."[333] Apparently ignorance was a sufficient excuse to avoid precautionary regulation.[334]

The agency also rejected a related suggestion that it ban the use of tissue from downer cattle in the feed for *any* animals, including pigs and chickens, on the theory that mad cow prions could be transmitted from the food consumed by pigs and chickens into food for cattle during the process of rendering tissues from the former animals into feed for the latter. The agency's terse response was that it did not have any information suggesting that using tissue from downer cattle in feed for animals that could in turn be rendered into cattle feed presented "a risk of TSE infection to ruminants."[335] It may be that cost considerations played a quiet role in this decision. In a regulatory impact analysis accompanying the rule, FDA concluded that the option that it selected was the most "cost-effective" of the seven options that it considered.[336]

Finally, FDA belittled concerns expressed about the enforceability of the new rule. To the objection that effective enforcement would probably be hampered by the fact that FDA was unaware of the names and locations of all companies engaged in the rendering business, the agency responded that it could compile a comprehensive list of renderers through publicly available sources such as trade publications.[337] To another concern that it would be difficult for FDA inspectors, who are not present at all times a feed manufacturing establishments, to ensure cattle protein intended for nonruminants did not wind up in cattle feed, the agency predicted, without citing any evidence in the record, that "the great majority of affected establishments" would not use cattle protein even in nonruminant feed.[338] FDA's subsequent enforcement efforts proved both of these assessments to be overly optimistic.

2. Enforcement of the 1997 Feed Restrictions.

The FDA Feed Rule applies to almost 5000 large and small feed manufacturers and distributors and to large feedlots, a substantial enough number of establishments to stretch even an ample enforcement budget.[339] 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

---

333 *Id*. at 30940.

334 In January, 2004, FDA announced that it would ban the use of chicken litter as a source of cattle feed, but it has not yet proposed the regulations necessary to implement that promise. FDA Statement 1/26/04, *supra.*

335 FDA 1997 Feed Rule, *supra*, at 30945.

336 *Id*. at 30974. FDA considered seven alternatives, including a prohibition on all mammalian-derived protein in ruminant feed, with no exceptions, that was more stringent than the chosen alternative. *Id*. at 30968.

337 *Id*. at 30942.

338 *Id*. at 30941.

339 2002 GAO Mad Cow Report, *supra*, at 47.

operations.[340] The sheer scope of FDA's enforcement obligations should have been enough to discourage its highly optimistic predictions about the likelihood that the feed and cattle industries would avoid mixing ruminant protein with feed for ruminants.

Unlike FSIS, which has an inspector at every slaughterhouse and meat production facility, FDA uses a sampling strategy "in which fewer inspectors per year pay periodic visits to settings where food is produced, processed, or stored to verify compliance with its requirements."[341] In fact, FDA has entered into cooperative arrangements with state agencies under which state inspectors conduct about 80 percent of all animal feed inspections.[342]

Not surprisingly, the 1997 Feed Rule got off to a spotty start. In a July 2001 update on its BSE enforcement activities, FDA reported that of the 2,653 firms handling prohibited materials at the most recent inspection, 431 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 recordkeeping requirements.[343] Moreover, when re-inspected to determine if violations had been corrected, eight percent of the violators remained out of compliance.[344]

A report prepared in January 2002 by the United States General Accounting Office (GAO) noted that at least 4800 unlicensed feed mills were required to comply with the restrictions in the 1997 Animal Feed Rule, but FDA was still not confident four years after the feed restrictions went into effect that it had identified all of them.[345] Although 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.[346] GAO found "several instances in which firms were out of compliance in repeated inspections, yet FDA had not even issued a warning letter."[347] It also found "instances in which firms were out of compliance but had not been inspected for a year or more -- and in some cases for more than 2 years."[348] GAO concluded that FDA's feed restrictions were not being adequately

---

340 FDA has promulgated a "Small Entities Compliance Guide" for feeders of ruminant animals with and without on-farm mixing operations. U.S. Food and Drug Administration, Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Mixing Operations (February 1998) [hereinafter cited as FDA Small Entities On-Farm Compliance Guide]; U.S. Food and Drug Administration, Small Entities Compliance Guide for Feeders of Ruminant Animals without On-Farm Mixing Operations (February 1998) [hereinafter cited as FDA Small Entities Off-Farm Compliance Guide].

341 NAS Safe Food Report, *supra*, at 22.

342 2002 GAO Mad Cow Report, *supra*, at 22.

343 U.S. Food and Drug Administration, CVM Update: Ruminant Feed (BSE) Enforcement Activities (July 6, 2001), at 3 [hereinafter cited as FDA Feed Rule Activity Report 7/6/01].

344 FDA Feed Rule Activity Report 7/6/01, *supra*, at 3.

345 2002 GAO Mad Cow Report, *supra*, at 47.

346 *Id*. at 23. *See also* FDA Feed Rule Activity Report 7/6/01, *supra*, 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).

347 2002 GAO Mad Cow Report, *supra*, at 23.

348 *Id*.

implemented and enforced and as a consequence, "consumers may unknowingly eat foods that contain central nervous system tissue from a diseased animal."[349]

FDA has historically suffered from a chronic lack of resources for enforcement of its feed additive requirements. The 2003 NAS Ensuring Safe Food report noted that "FDA's shrunken inspection force is seriously over-extended, and FDA appears to have insufficient resources to meet its statutory obligations."[350] This situation changed rather dramatically after the September 11 terrorist attacks. In FY 2002 and 2003, Congress appropriated more than $195 million for food safety programs, and FDA used these additional resources to hire an additional 655 new food personnel.[351] Of these additions, 433 have been assigned to duties relating to imports enforcement.[352] Although it is not clear how many of the remaining 222 new slots have been devoted to animal feed inspections, FDA announced in January 2004 that it would be increasing its inspections of feed mills and renderers in 2004. From a base funding level of $3.8 million in 2001 for all of its BSE-related programs, FDA received 2004 funding of $21.5 million.[353] FDA says that it plans to undertake 2800 inspections of renderers, protein blenders and feed mills in 2004 and will work with state agencies to fund an additional 3100 contract inspections.[354]

3. Dietary Supplements.

The manufacturers of dietary supplements frequently use material from cattle brains and nervous system to make popular pills called "glandulars."[355] So long as the brains and other nervous system material comes from cattle aged 30 months or older, it may still be used in such dietary supplements, despite the fact that those tissues are among the most infective tissues from animals that are BSE positive. Thus, it is perfectly lawful for a Florida company to market capsules containing "bovine Brain Concentrate" which has been "processed at low temperature to insure rawness."[356]

V The Harvard Center for Risk Analysis Study.

---

349 *Id*. at 10-11. 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.

350 NAS Safe Food Report, *supra*, at 87.

351 U.S. Food and Drug Administration, Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation's Food Supply (July 23, 2003), available at http:www.cfscan.fda.gov/~dms/fssrep.html, at 3 [hereinafter cited as FDA 2003 Progress Report].

352 *Id*. at 4-5.

353 Crawford Testimony, 1/27/04, *supra*.

354 *Id*.

355 Stephanie Simon, *Mad Cow Case Casts Light on Beef Uses*, Los Angeles Times, January 4, 2004.

356 Donald G. McNeil Jr., *Mad Cow Disease Raises Safety Issues Beyond the Kitchen*, New York Times, January 29, 2004.

In 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA), a center associated with the Harvard School of Public Health, to "evaluate the robustness of U.S. measures" to prevent the spread of BSE to animals and humans "if it were to arise in this country."[357] Over the next three years HCRA developed and applied a "quantitative simulation model" to characterize how the introduction of BSE would affect animal health over time and to predict the extent to which it "could result in human exposure to contaminated food products."[358] The results of the HCRA simulation were published in November 2001 and updated in October 2003.[359] Further revisions are underway.[360]

A. The Gedanken Experiment.

The HCRA risk analysis was not a typical risk assessment in which data from epidemiological or animal studies are extrapolated to human populations to estimate the incidence of disease at human exposure levels. Instead, it was an exercise in scenario-building that used computer simulations to carry assumptions about hypothetical possibilities through to logical conclusions. Therefore, the conclusions that HCRA drew from this exercise were based upon assumptions, rather than on empirical analysis.

The base case assumptions that HCRA employed were designed to reflect contemporary conditions in the U.S, including the regulatory requirements that were in place in 2001.[361] Thus, the 1989 USDA import restrictions and the 1997 FDA Feed Rule were the primary regulatory programs included in those assumptions.[362] Since no BSE-positive animal had, at the time the study was written, been identified in the United States, the base case assumed that ten BSE infected animals were imported into the United States despite the USDA import restrictions.[363] The authors believed that the USDA import rule made the importation of such a high number of infected cattle highly unlikely.[364] The authors also believed that the FDA Feed Rule "greatly reduces the chance that BSE will spread from a sick animal back to other cattle through feed."[365] Because USDA had at that point engaged in very little BSE surveillance and because the infirmities in FDA's enforcement of the Feed Rule had not yet been disclosed, neither of these beliefs had any solid empirical basis.

Plugging these base case assumptions into the HCRA model yielded a prediction that no more than three new cases of BSE would result from the introduction of 10 BSE-positive

---

357 Harvard Center for Risk Analysis BSE Report, *supra*, at vii.

358 *Id*. at 1.

359 Harvard Center for Risk Analysis BSE Report, *supra*.

360 Department of Agriculture and Department of Health and Human Services, Federal Measures to Mitigate BSE Risks: Considerations for Further Actions, ___ Fed. Reg. ___ (2004) [hereinafter cited as USDA/HHS BSE ANPR] (reporting that USDA contracted with HCRA to "revise and update" its model "to reflect recent events that have occurred in the United States.").

361 Harvard Center for Risk Analysis BSE Report, *supra*, at 86.

362 *Id*. at viii.

363 *Id*. at 86.

364 *Id*.

365 *Id*. at viii.

animals, and there was a 75-95 percent likelihood that no new cases would result.[366] Even in the extreme (95th percentile) case, only 11 new cases would result.[367] These conclusions flowed primarily from the assumption that the 1997 Feed Rule would prevent protein from the improperly imported cattle to be rendered into feed for ruminants. The fact that any cases at all resulted was attributable to the model's assumption that the feed rule would not be perfectly observed. The disease would have a short duration as the Feed Rule continued to work its magic, and the model predicted that there was "virtually no chance" that any infected animals would be present 20 years after the importation of the infected animals.[368]

The authors cautioned that the computer projections were "not amenable to formal validation because there are no controlled experiments in which the introduction and consequences of BSE introduction to a country have been monitored and measured."[369] The authors did, however, attempt to use the small outbreak of BSE in Switzerland following importation of infected cattle from the United Kingdom as a test of the model's plausibility.[370]

The HCRA modeling exercise did not purport to be a human health risk assessment for two reasons. First, since the authors did not attempt to quantify the probability that BSE would be introduced into the United States, all of the risk estimates in the report were "conditional on hypothetical scenarios."[371] Second, although the report did attempt to quantify potential human exposure to BSE-contaminated food products, it did not "estimate how many people will contract variant Creutzfeldt-Jakob Disease" because "the available information is inadequate."[372]

B. General Weaknesses of the HCRA Study.

The HCRA projections were very well-received by USDA and the various industry trade associations. The "Harvard study" is still conspicuously cited by the industry, USDA and FDA in response to arguments that more stringent protections are necessary to protect the public health from an outbreak of vCJD. Yet there is no way to know whether the HCRA's predictions are accurate for the simple reason that the model that it employed was "not amenable to formal validation."[373] Given the confidence with which the report and subsequent descriptions of that report by HCRA personnel portray its conclusions, the absence of empirical verification is disturbing.

---

366 *Id*. at 87.
367 *Id*.
368 *Id*.
369 *Id*. at ix.
370 *Id*. at 91-94.
371 *Id*. at 2.
372 *Id*.
373 *Id*. at ix.

More disturbing still is the admitted "lack of data on other factors that could have a greater effect on risk."[374] A technical review of the HCRA study noted that the original outbreak of mad cow disease in Great Britain was the result of "an unforeseen event – a change in the rendering process that resulted in a prolonged period of exposure to many animals."[375] The confident statements that "the U.S. is highly resistant to any introduction of BSE or a similar disease" and that it was "extremely unlikely to become established in the U.S." may therefore be based upon a similar blissful ignorance of changes in U.S. cattle production and meat preparation practices.[376] The Japanese government concluded that Japan was free of BSE based upon a study premised upon similar assumptions, but greatly enhanced surveillance designed to gather real data on the incidence of BSE soon revealed many cases of mad cow disease in that country.[377]

The primary factor driving the HCRA model's predictions was FDA's 1997 Feed Rule. Because the only vehicle for spreading the disease from animal to animal was assumed to be feed made from protein derived from BSE-positive ruminants, the restrictions on feeding protein from ruminants to ruminants, even considering the wide ranging exceptions for blood, plate waste and feed for pigs and poultry, ensured that the impact of any BSE outbreak would be limited and would rapidly diminish to zero. The report simply assumed that none of the materials allowed in cattle feed by the 1997 FDA Feed Rule posed a risk of transmitting BSE.[378] FDA's recent announcement that it may expand the universe of banned materials in cattle feed indicates that the agency has now recognized at least some of the previously allowed materials may pose a risk of transmitting BSE.[379] The report also admitted that "the effectiveness of the feed ban is somewhat uncertain because compliance rates are not precisely known."[380] Indeed, the study did not even consider the distribution system for cattle feed in an effort to evaluate the likelihood of misfeeding.[381] If the study did not consider the feed distribution system, its assumptions concerning mislabeling and misfeeding rates must have been based almost entirely on pure speculation.

The report's sunny conclusions also seem at odds with the actual experience in the U.K. For example, the report did not attempt to explain why restrictions almost identical to the 1997 FDA Feed Rule put in place in England in 1988 failed to restrict the spread of mad cow disease in that country. The British government was forced to expand the restrictions considerably beyond the restrictions currently in place under the current FDA

---

374 Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Final Report, Prepared for USDA by RTI, Research Triangle Park, N.C., Oct. 2002, available at http://www.fsis.usda.gov/oa/topics/BSE_Peer_Review.pdf, at 2-2 [hereinafter cited as RTI HCRA Risk Assessment Review].

375 *Id*.

376 Harvard Center for Risk Analysis BSE Report, *supra*, at vii.

377 Michael Kilian, *Mad Cow Risk Low in U.S., Report Says*, New York Times, December 1, 2001, at 12 (quoting University of Oregon Scientist Thomas Pringle).

378 Harvard Center for Risk Analysis BSE Report, *supra*, at 33-35.

379 *See infra* Section VIII.

380 Harvard Center for Risk Analysis BSE Report, *supra*, at 97.

381 *See* RTI HCRA Risk Assessment Review, *supra*, at 2-5.

Feed Rule to ban the feeding of any animal protein to farm animals.[382] Because a much larger proportion of the British cattle population was BSE-positive at the time its original feed restrictions went into effect, the British experience may be distinguishable. Nevertheless, it should raise a warning flag when USDA and others confidently cite the HCRA modeling exercise for the proposition that "it can't happen here." The chief veterinarian of Switzerland, the one country whose experience HCRA did cite in attempting to validate its model, sharply disagreed with the HCRA assessment. He observed that "Harvard says if you wait long enough, (BSE) will die out," but his experience was that "if you don't implement strong measures, it will go on and on."[383]

The HCRA risk assessment did not consider the possibility that BSE would be intentionally introduced into the United States.[384] In this day of concern for terrorist attacks on the United States this could be considered a major gap in the analysis. Another good reason to question the accuracy of the HCRA's risk assessment is its rosy conclusion that imports of cattle from Canada "are extremely unlikely to pose a risk of introducing BSE into the U.S.," an assessment that was later belied by the well-accepted fact that the Washington mad cow came from a Canadian herd.[385]

Although the HCRA risk assessment attempted to estimate human exposure to BSE-contaminated food products, it did not attempt to "estimate how many people will contract variant Creutzfeldt-Jacob Disease."[386] Its aim was to model the likelihood of an outbreak of mad cow disease in the U.S. *cattle* population in a hypothetical scenario in which BSE-positive cattle were imported into the United States and FDA's 1997 feed restrictions were in place but not perfectly enforced. It was not a study of the likelihood of an outbreak of vCJD in *human beings* in the United States

C. Uncertainty in the HCRA Model.

Most of the hundreds of pages and most of the more than 100,000 simulations in the HCRA report and its numerous appendices are devoted to an analysis of potential uncertainties in the model estimates. However, the report adequately addresses only one simple form of uncertainty about the model's results. The harder questions go unanswered, and internal evidence suggests that the report could have seriously understated the risks of a BSE outbreak in the United States.

There are at least three major varieties of error and uncertainty that could have affected the predictions of the HCRA BSE model.

---

382 Sandi Doughton, *Should U.S. follow U.K. on Mad Cow?*, Seattle Times, February 5, 2004 (quoting Roy Smith, of the U.K. Department for Environment, Food and Rural Affairs).

383 Les Blumenthal, *Mad Cow "Truths" Doubted*, Sacramento Bee, February 16, 2004.

384 RTI HCRA Risk Assessment Review, *supra*, at 2-6.

385 Harvard Center for Risk Analysis BSE Report, *supra*, at 23.

386 *Id*. at 2.

- First, the model could have made erroneous statements about the relationships involved. That is, it could have failed accurately to describe the pathways through which BSE could spread. In short, it could have employed the wrong equations.
- Second, even if the relationships and equations were appropriate, the numerical parameters used in the model could have been wrong. For example, the probabilities of contamination, spread of infection, and so on, could have been under- or over-stated.
- Finally, even if the model relationships and parameters were chosen as accurately as possible, the model still only predicted probabilities of key events. Its forecast for any specific year (or sequence of years) still remained uncertain.

Analogizing to a game employing dice, the first category involves uncertainty about whether the rules of the game have been described correctly; the second is uncertainty about the weighting of the dice; and the third category concerns what will happen the next time the dice are rolled.

The HCRA report's elaborate analysis deals well with the third category of uncertainty. Given a set of relationships and equations, and a list of specific values for all the numerical parameters (assumptions about the rules of the game, and about how the dice are weighted), it is possible to roll the dice repeatedly and tabulate the results. Indeed, this is what a Monte Carlo analysis consists of. In the BSE model, the same relationships and equations are used throughout; scenarios are defined by different sets of values for key parameters. For each scenario, the HCRA analysts ran 5,000 simulations. The model results, consisting of summaries of patterns of the 5,000 outcomes for each scenario, make it possible to discuss the probability of a particular outcome under any one scenario. For example, an outcome that appears in only 250 of the 5,000 simulations has a 5% chance of occurring in that scenario. Thus, within each scenario, the modeling exercise provides useful information about the uncertainties that result from rolling the dice.

The report's treatment of the first two types of uncertainty is much less satisfying. Regarding the relationships assumed in the model, the narrative is extremely detailed, but almost entirely verbal rather than mathematical. Many individual portions of that narrative sound reasonable, but it is not clear that the structure as a whole is appropriate. The equations that represent these relationships are not provided anywhere in the report or appendices, a deficiency that the peer reviewers of the original HCRA report objected to.[387] The computer software developed to implement the model was, according to the peer reviewers, poorly documented and impossible to evaluate in a reasonable length of time.[388] The HCRA response to the peer reviewers was defensive and does not appear to be responsive on this point.[389]

---

[387] Research Triangle Institute (RTI), Review of the Potential for Bovine Spongiform Encephalopathy in the United States, Conducted by the Harvard Center for Risk Analysis, Harvard School of Public Health & Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, Final Report, October 31, 2002, at 7-1 to 7-2 and elsewhere throughout [hereafter cited as RTI Review].

[388] RTI Review, *supra*, at 11-1 to 11-5. The response says that documenting the code and making it accessible to anyone else was beyond the scope of work of the study; Joshua T. Cohen and George M. Gray, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Response to

Hence with respect to the first type of uncertainty, the reader must take it on faith that a reasonable overall model structure has been developed, represented through appropriate equations, and correctly represented in the software implementation of the model. The equations are nowhere to be found, the software is comprehensible only to its creators, and despite the description of the report as peer-reviewed, the authors have essentially stonewalled the reviewers on these points.

These problems, however, are dwarfed by the failures in the second category of uncertainty, involving the estimates of parameters and the choice of scenarios that are analyzed. How, exactly, has nature weighted the dice that are rolled to determine the spread of BSE? Has the HCRA model considered all the relevant possibilities? Here the report argues at length that it has addressed all credible uncertainties and shown that a major BSE outbreak is unlikely. But that happy assessment is quite unconvincing.

1. Choosing Parameters

The HCRA model is staggeringly detailed, involving 49 different numerical parameters.[390] The authors identify 17 of these parameters that they consider important enough for more detailed analysis, divided into three groups: 3 parameters involve cattle population dynamics, 8 describe aspects of the slaughter process, and 6 refer to feed production and feeding practices.[391] Some of the 17 parameters are actually lists of values, as seen in examples discussed below. For each of the 17 key parameters, the report's authors estimate three values: the base case which they consider most likely to describe reality; a best case (the value least likely to promote the spread of BSE), and a worst case (the value most likely to spread BSE). The report explains, however, that:

> [W]e determined that evaluation of the best case values was not necessary because use of base case assumptions . . . [leads to model predictions] that the prevalence of BSE decreases over time and eventually reaches zero with near certainty . . . . Using more optimistic assumptions for a parameter would only result in a prediction that the spread of BSE is even more limited than the base case suggests.[392]

Thus the analysis reduces to a comparison of base case versus worst case values for the 17 key parameters.

The HCRA analysis of worst case values raises two separate questions. First, do the report's "worst case" figures accurately describe the worst plausible values for the

---

Review Comments submitted by Research Triangle Institute, October 2003, at 22-23 [hereafter cited as HCRA Response to RTI Review].

389 HCRA Response to RTI Review, *supra*, at 16-17.

390 The parameter definitions are presented in the Harvard Center for Risk Analysis BSE Report, *supra*, at Appendix 1, at 4-8.

391 The list is presented for the first time in the Harvard Center for Risk Analysis BSE Report, *supra*, at, Table 3-10, at 80-82.

392 Harvard Center for Risk Analysis BSE Report, *supra*, at 69.

parameters? Second, how much synergy occurs between the worst case values for different parameters?

2. Is the HCRA Worst Case Bad Enough?

On the first question, the terminology itself conveys the report's intended message: the "worst case" values are as bad as things can get. Yet, as with the missing equations, the reader largely has to trust the analysts on this point. As the report explains, the worst case values reflect the authors' judgments, not the worst logical possibilities:

> The worst case bounding assumptions for each parameter reflect the judgment of this report's authors given the available scientific literature. Although these assumed values are not intended to represent absolute bounds on a parameter's value, we have selected them with the intention of identifying levels beyond which a parameter's true value is very unlikely to fall.[393]

The report and its appendices, however, contain very little documentation of the basis for the authors' judgments about worst cases. For example, one of the 17 key parameters is the proportion of various cattle tissues recovered for human consumption; it is not a single number, but a list of proportions for 14 different tissues. The report states that when moving from base case to worst case, the proportion recovered for human consumption increases from .05 to .30 for blood, from .5 to .6 for hearts, from .25 to .35 for kidneys, from .01 to .02 for brains, and from .001 to .002 for eyes; the proportions of lungs, dorsal root ganglia, and trigeminal ganglia for human consumption are unchanged at zero in both cases.[394] These could be excellent professional judgments, but the report does not explain why. In the appendices, the list of base case values for this parameter is explained with a single, short paragraph citing four published sources.[395] In contrast, the worst case values are only listed, not explained or referenced in any way; they simply appear in the report without comment, citation, or calculation to back them up.[396] Perhaps more disturbingly, the appendix presenting the worst case values is in general much shorter and less detailed than the one presenting the base case values.[397]

In this example, it is of course logically possible for humans to consume more than 30% of the blood, 60% of the hearts, 35% of the kidneys, etc., from cattle. To validate the model, an independent evaluation would be needed, not only for this case but for all 17 parameters, of whether the worst case is as bad as things can get. The judgment of the peer reviewers of the original HCRA study is not reassuring on this point: while praising the study for its use of existing data when available, the reviewers noted that appropriate

---

393 *Id*. at 69.

394 *Id*. Table 3-8, at 77.

395 *Id*. Appendix 1, section 2.8.1, at 15; compare to corresponding values in Appendix 1, section 3.8.1, at 46.

396 *Id*. Appendix 2, section 2.2.5, at 6-7; this section presents no information beyond that contained in the main text, Table 3-8 (supra, note 8).

397 *Id*. Appendix 1, presenting and justifying the base case values, is 86 pages long. Appendix 2, presenting the worst case values and all other non-base case values used in the report, is 30 pages long.

data did not always exist, and noted their "general observation . . . that, in instances where subjective interpretations had to be given, an optimistic choice was regularly made . . . ."[398]

3. Synergy among Worst Case Parameters

The HCRA report almost completely ignores the uncertainty resulting from the interaction between worst case values. In multi-variable worst-case analysis of the kind undertaken in report, undesirable synergies may occur. If two or more parameters simultaneously take on worst case values, the results could be much worse (i.e., more prone to the spread of BSE) than the sum of the individual parameter effects. Although largely glossed over in the text, the problem can be seen in some of the of the HCRA model results,

Much of the analysis in the HCRA report consists of introducing worst case values, one at a time, for individual parameters, and displaying the results. The base case is compared to 17 such "single-worst-case" scenarios, each of which has a worst case value for one parameter and base case values for the other 16 parameters. This analysis concludes that for 14 of the single-worst-case scenarios, there is at least a 95% probability that BSE, once introduced into the US, will die out fairly quickly on its own. The results are often described in terms of a calculated quantity called R_0, which is the lifetime total number of new cases of BSE caused, on average, by one existing case. If $R_0 < 1$, the disease dies out naturally; if $R_0 > 1$, the disease tends to spread. The report concludes that:

> with the exception of three parameters (3.2.3.1 – Render reduction factor, 3.2.3.5 – Render mislabeling, and 3.2.3.6 – Misfeeding), use of worst case assumptions in place of base case assumptions [for one parameter at a time] produces R_0 values that remain below unity with at least 95% probability. Even for these last three parameters, use of worst case values results in R_0 values exceeding unity with less than 25% probability.[399]

The probabilities mentioned above refer to the Monte Carlo analysis performed for each scenario. In 14 of the single-worst-case scenarios, R_0 was less than 1 in 95% or more of the 5,000 simulations. In the other three single-worst-case scenarios, R_0 was less than 1 in at least 75%, but fewer than 95%, of the simulations. These three parameters, with their base case and worst case values, are shown in Table 1. (All three are in the feed production and feeding procedures group of parameters.) If any one of these three parameters assumes its worst case value, one cannot say with 95% confidence – the conventional scientific standard of statistical significance – that BSE, once started, will naturally die out.

---

398 RTI Review, *supra*, at 3-17 to 3-18.

399 Harvard Center for Risk Analysis BSE Report, *supra*, at 101.

Table 1: Individual parameter worst cases most likely to cause the spread of BSE

Parameter	*Base case*	*Worst case*
Render reduction factor: proportion of rendering using		
Batch reduction	5%	5%
Continuous/fat added (99% reduction in infectivity)	45%	20%
Continuous/no fat added (90% reduction in infectivity)	45%	70%
Vacuum reduction	5%	5%
Probability of prohibited feed being mislabeled as non-prohibited	5%	33%
Probability of correctly labeled prohibited feed being fed to cattle	1.6%	15%

Source: HCRA BSE Report Table 3-9, at 79; infectivity explained in Appendix 1, at 21-22.

An even greater problem arises from synergy between worst-case values for multiple parameters. The peer reviewers of the original HCRA report criticized its failure to consider synergistic effects;[400] in response, the revised report added six scenarios assuming worst case values for the three groups of parameters.[401] Three scenarios assume worst case values for all the parameters in a single group – cattle demographics, the slaughter process, and feed procedures – and three more assume worst case values for each pair of groups. In some of these scenarios there is more than a 25% probability that a few infected cattle would lead to large numbers of resulting cases of infection.

Among the simulations of the six multiple-worst-case scenarios, only one shows BSE dying out with a 95% probability, and only three show BSE dying out with a 75% probability. In other words, in three scenarios there is a 25% or greater chance that BSE, once introduced, will continue to spread. One of those scenarios implies at least a 25% chance of a raging epidemic, with infected cattle numbering in the millions.

Each scenario assumes the appearance of ten infected animals in the United States and then calculates, among other results, the total number of resulting cases of infection over the next twenty years.[402] The typical infection cycle, from infection of one animal to the resulting infection of another, is just under 5 years in length. So if $R_0 = 1$ (the threshold for a self-perpetuating disease, as discussed above) then each of the original 10 infected cases should result in four more over the 20-year simulation period, for a total of 50.[403] Table 2 presents selected results, for the base case, the three single-worst-case scenarios

400 RTI Review, *supra*, at 9-1 to 9-4.

401 HCRA Response to RTI Review, *supra*, at 21-22.

402 Harvard Center for Risk Analysis BSE Report, *supra*, at 68.

403 That is, the 20-year totals combine the original 10 and the resulting 40 cases. *See id*. at 101.

with the greatest potential for BSE, and all the multiple-worst-case scenarios. Results shown in boldface are the ones implying R0 > 1 means that BSE, once introduced, does not spontaneously die out.

Table 2: Number of Infected Cattle (20-year Total)

Scenario	*Percentile*		
	50	***75***	***95***
Base case	10	11	26
Single-worst-case scenarios:			
Render reduction factor	10	11	**83**
Feed mislabeling	11	14	**160**
Misfeeding of correctly labeled food	11	26	**430**
Multiple-worst-case scenarios:			
All demographic parameters	10	11	**58**
All slaughter process parameters	11	12	43
All feed procedures parameters	12	**170**	**1,600**
Demographic and slaughter parameters	11	12	**110**
Demographic and feed parameters	23	**1,300,000**	**4,500,000**
Feed and slaughter parameters	16	**1,400**	**6,200**

Numbers are the total number of cases of infection resulting over 20 years following the introduction of 10 infected cattle. Percentiles refer to positions in the distribution of simulation results from the Monte Carlo analysis of each scenario. Numbers in boldface are results implying that BSE, once introduced, does not spontaneously die out.

Source: HCRA BSE Report, Appendix 3D, Table 1, at 29, 38, 47

Table 2 shows that no scenario reaches or even approaches 50 infected cattle at the 50th percentile; that is, the median simulation in the Monte Carlo analysis for each scenario showed BSE dying out, with $R_0 < 1$. Thus, there is at least a 50% chance that BSE will quickly die out on its own in any scenario. However, at the 75th percentile, all the scenarios involving the feed procedures parameter group, alone or in combination with other groups, have well over 50 infected cases. So there is at least a 25% chance that BSE will not die out in these scenarios. At the 95th percentile, all but one of the scenarios shown here, other than the base case, have totals of more than 50 infected cases, implying $R_0 > 1$; there is at least a 5% chance of a serious outbreak in all these scenarios.

In short, there is at least a 25% chance that BSE will not die out in 3 of the report's 24 scenarios, and at least a 5% chance in 8 scenarios. Moreover, in one scenario, with worst

case values for all the demographic and feed parameters, there is at least a 25% chance that there are more than a million projected cases of BSE within 20 years of the introduction of ten infected cattle into the US.

Dismissing the epidemic

These findings would appear to be cause for concern, motivating extensive additional analysis into the parameter combinations that lead to such disturbing outcomes. In explaining its intended approach to sensitivity analyses, the HCRA report acknowledges as much:

> We used sensitivity analysis to identify the most important sources of uncertainty . . . The purpose of the sensitivity analysis is to identify assumptions that should be regarded as candidates for further refinement.[404]

However, the authors apparently concluded that further refinement was not necessary in the case of the assumptions that implied more than one million infected cattle. The multiple-worst-case scenarios, introduced in revisions in response to peer reviewers, barely register in the discussion of the model in the revised report. They are introduced in the briefest possible manner in the initial description of scenarios,[405] and the description of results mentions the huge numbers of infections that are possible in multiple-worst-case scenarios with no suggestion of alarm or even curiosity.[406] The final summary of the meaning of the analysis discusses each of the three single-worst-case scenarios that are cause for greatest concern, but does not say a word about any of the multiple-worst-case scenarios.[407] The same is true for the executive summary.[408]

It appears, in other words, that the HCRA analysts never took their multiple-worst-case scenarios seriously. The three single-worst-case scenarios which loom large in their conclusions imply, at the 95th percentile, 83 to 460 cases of mad cow disease (see Table 2 above). In contrast, two of the multiple-worst case scenarios imply thousands of cases, and another one implies millions; yet these scenarios are invisible in the conclusions.

This would be an appropriate method of analysis only if the analysts were absolutely certain that the base case estimates were correct for at least 16 of the 17 parameters, and the remaining uncertainty merely concerned which single worst case might be occurring. The report does not, however, attempt to defend this quaint and credulous approach to uncertainty.

What happens if one admits the possibility of more than one worst case occurring? What happens is that the number of options to be analyzed immediately becomes overwhelming. With 17 parameters, each independently assuming either its base case or

---

404 *Id*. at 68.

405 *Id*.

406 *Id*. at 102-103.

407 *Id*. at 113.

408 *Id*. at ix – xi.

worst case value, there are 2^{17}, or 131,072, possible scenarios. The HCRA report has analyzed 24 of them. The qualitative behavior of a few hundred other scenarios might be deduced from the information in the report.[409] Still, roughly 130,000 more scenarios remain unexplored. Focusing on scenarios that include just two worst case values and 15 base case values, there are 136 possibilities; with three worst case values there are 680. The report analyzes none of the double-worst-case scenarios, and only one of the triple-worst-case ones, involving the three demographic parameters.

To reduce the numbers, the search might initially focus on the worst cases for the nine parameters in the demographic and feed groups, the ones that jointly produced the million-infection simulations. The simultaneous occurrence of nine worst-case values might seem unlikely, but what are the consequences of just a few of these nine taking on their worst-case values? There are 36 scenarios involving just two worst case values among these nine, and 84 involving three. A rigorous analysis of the implications of the HCRA model would require exploration of quite a few additional multiple-worst-case scenarios, or a detailed discussion of the likelihood of multiple worst case values, or both.

Such possibilities are never even mentioned in the report. The "candidates for further refinement" found by the HCRA report were apparently known in advance to be restricted to single-worst-case scenarios. Nothing that arose in the analysis removed those reassuring blinders from the analysts' eyes. Even a scenario with a 25% probability of more than a million cases of BSE was just not interesting enough to change a predefined research design – or to modify a comforting, predetermined conclusion.

D. Conclusion.

The source of the HCRA report is also relevant to the confidence that the public can place in its predictions. The HCRA is funded primarily by companies and trade associations that have an interest in belittling the health and environmental risks posed by their products and activities, and it has a long history of producing analytically soft, but reassuring assessments of such hazards.[410] The Director of HCRA during the time that the mad cow report was being written once told a group of political strategists assembled by the Heritage Foundation that "environmental regulation should be depicted as an incredible intervention in the operation of society."[411] Although USDA funds paid for all of the HCRA mad cow risk assessment, some scientists have questioned USDA's

---

409 For example, there are 255 distinct scenarios with worst case values for all the demographic and feed parameters, and in addition worst case values for 1 to 8 of the slaughter parameters. These presumably all have results at least as bad as the worst case for the demographic and feed parameters alone, the case that leads to more than a million infected cattle at the 75th percentile (*see* Table 2 above).

410 Blumenthal, *Mad Cow "Truths" Doubted*, *supra*; Public Citizen, John Graham and Corporate America's Back Door to the White House (March, 2001), at 26-29 [hereinafter cited as Public Citizen Graham Report] (table comparing conclusions of HCRA reports with the positions of the companies that provide funding to HCRA).

411 Public Citizen Graham Report, *supra*, at 4.

selection of HCRA, which has also received funding from the meat and beef industries, to conduct the study.[412]

Despite the many clear weaknesses and analytical shortcomings in the HCRA risk assessment, the following description of the federal government's reaction to the discovery of an actual case of mad cow disease in the United States shows that USDA and FDA have relied upon the "Harvard study" time and again to reassure the public that mad cow disease does not pose a serious risk to public health in the United States and to justify less stringent controls on the practices that pose the greatest risk of stimulating and perpetuating a mad cow outbreak in this country. Those that invoke the "Harvard study" in the public arena seldom mention that HCRA does not speak for Harvard University and that Harvard University does not endorse its assessments.[413]

VI Immediate Governmental Actions in the Wake of the Discovery of the Washington State Mad Cow.

The discovery of the Mabton mad cow automatically triggered USDA's BSE Response Plan, and the Department pursued the steps set out in the plan throughout the Christmas holidays.[414] First, 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.[415] Second, USDA immediately began to investigate the origin of the mad cow and its herd mates.[416] 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.[417] In sum, the Department implemented its BSE Emergency Response Plan carefully and effectively.

All of this activity, however, came at a bad time for the Bush Administration, because it added to the uncertainty of an already unstable economic environment at the outset of an election year.[418] It was also awkward, because it clearly called for greater regulatory restrictions to protect consumers and the agricultural economy from an industry that had been a "financial and political ally" in the exceedingly close 2000 election.[419] According to the Center for Responsive Politics, Republican candidates received 79 percent of the

---

412 Michael Kilian, *Mad Cow Risk Low in U.S., Report Says*, *supra*, at 12.

413 *See* Testimony of Ann M. Veneman, Secretary, Department of Agriculture before the Senate Committee on Agriculture, January 21, 2004 (Secretary Veneman testifies that "USDA requested Harvard University to conduct an independent risk assessment . . . .").

414 Mark Sherman, *British Lab Confirms that Mad Cow Disease Is in US*, Boston Globe, December 26, 2003.

415 *Id*.

416 Matthew L. Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, *supra*.

417 *Id*.

418 Mike Allen, *Mad Cow Case Clouds Bush's Political Outlook*, Washington Post, December 28, 2003, at A9.

419 *Id*.

livestock industry's $4.7 million in contributions for the 2000 elections and 84 percent of the $1.1 million the industry contributed to the 2004 campaign.[420]

To calm public fears, muffle expected criticism from Democratic presidential candidates, and reduce the opposition of importers to U.S beef, the Administration had to appear to take forceful action to prevent an outbreak of mad cow disease. At the same time it needed to do as little as possible to damage or otherwise alienate a critically important political constituency. It navigated this difficult terrain adroitly by: (1) taking to the airwaves with frequent and repeated assurances that the public health was not at risk; (2) promulgating a group of stringent-appearing, but mostly toothless regulations to prevent risky materials from getting into human food; (3) promising, but not delivering much more costly regulations that could cause economic pain to the beef industry; (4) pressuring importers to drop any import restrictions; and (5) doing as little as possible to find another mad cow.

A. The Voluntary Recall.

The first action taken to address the threat to the U.S. economy and the public health from the Washington state Holstein was to urge companies that might have produced or received meat from the animal to participate in a voluntary recall of any potentially contaminated meat. Although it is impossible to tell how effective this effort was in protecting consumers, it ultimately resulted in the recall of slightly more than 10,000 pounds of potentially contaminated meat. The recall was initially limited to potentially contaminated beef from the suspect cow and 19 others that were processed at the same time.[421] Within days it expanded to five major grocery chains in California, Nevada, Oregon, Washington, Alaska, Hawaii, Idaho and Montana that had been selling beef purchased from an Oregon meat distributor that processed meat that may have come from the infected cow.[422] 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.[423] One supermarket chain was later the target of a lawsuit alleging negligence in failing to tell consumers about the recall.[424]

B. The Search for the Washington Holstein's Origins.

Officials quickly learned that the BSE-positive cow came from the Sunny Dene Ranch, a dairy farm in Mabton, Washington, and had lived there for 4-5 years before being sent to slaughter at the Vern's Moses Lake Meats slaughterhouse in Moses Lake, Washington.[425]

---

420 *Id*.

421 Matthew L. Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, *supra*.

422 Steve Mitchell, *Mad Cow Meat Sent to 42 Additional Locales*, United Press International, April 29, 2003; Willman & Shiver, *Diseased Cow Traced to Canada, U.S. Says*, *supra*.

423 Vedantam & Harden, *Probe of Infected Cow Spreads, So Does Worry*, *supra*.

424 Connie Thompson, *Lawsuit Against QFC Allowed To Continue*, June 17, 2004, available at http://www.komotv.com/stories/31775.htm.

425 Vedantam, *Mad Cow Case Found In U.S. for First Time*, *supra*.

USDA officials then began to navigate the "spiderweb of possibilities" that flowed backward from that herd to the herd into which the Holstein was born.[426] Fortunately, within less than a week they were able to place to infected animal within a group of 81 cows imported into the United States from Alberta, Canada.[427] Perhaps more importantly, investigators determined that the cow was probably old enough to have consumed cattle feed prior to feed bans that were implemented in the United States and Canada in 1997.[428] A subsequent investigation by Canadian authorities isolated two Canadian feed mills as the probable source of feed for both the Mabton mad cow and the single Canadian mad cow detected in May 2003.[429] Officials speculated that both cows received feed from one of the two mills prior to the implementation of Canada's feed restrictions.[430] The Director of HCRA allowed that the mad cow discovery "doesn't tell us everything is right, but it's not a direct indication that our feed ban is failing."[431]

Finding the herd of origin was only the beginning. 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. In late December 2003, USDA's chief veterinarian initially expressed confidence that "we will be able to determine the whereabouts of most if not all these animals in the next several days."[432] The outcome did not match the Department's confident prediction.

On February 9, 2004, USDA announced that it had ended its investigation.[433] The Department reported that it had located 29 of the 81 animals in the birth herd of the Washington state mad cow.[434] Of the 25 cows most likely to have eaten the same feed as mad cow, USDA had located only 11.[435] The search for the 81 took USDA investigators to 189 farms and ranches where they identified and slaughtered 225 "animals of interest,"

---

426 Vedantam & Harden, *Wash. Animal May Have Been Import*, *supra* (quoting Ron DeHaven, Chief Veterinarian, USDA).

427 United States Department of Agriculture, Technical Briefing and Webcast with U.S. Government Officials on BSE Case, Release No. 0451.03, December 30, 2003 (remarks of Ron DeHaven). DNA testing later confirmed that the cow came from Canada. Shankar Vedantam & Deneen L. Brown, *DNA Tests Trace Infected Holstein to Canada*, Washington Post, January 7, 2004, at A8.

428 Nicholas K. Geranios, *Canadians Irked by U.S. Blame for Mad Cow*, *supra*; Shankar Vedantam, *Mad Cow Case May Predate Feed Ban*, Washington Post, December 30, 2003, at A1.

429 *Feed in Mad Cow Cases Traced to Two Mills*, Washington Post, March 20, 2004, at A8.

430 *Feed in Mad Cow Investigation Is Traced to 2 Mills in Canada*, New York Times, March 20, 2004.

431 Rob Stein, *Holstein's Origin Will Be Clue to U.S. Safeguards' Success*, Washington Post, December 30, 2003, at A12.

432 Shankar Vedantam & Blaine Harden, *Sick Cow Probably Imported*, Washington Post, December 28, 2003, at A1.

433 *U.S. Ends Its Hunt for More Cases of Mad Cow Disease*, Los Angeles Times, February 10, 2004.

434 *Id*.

435 *Id*.

none of which were afflicted with the disease.[436] A spokesperson for the Department said that despite the disappointing results, it was "time to move on."[437]

C. Culling Suspect Herds.

In early January, USDA decided to "depopulate" a herd of 450 calves that included one of the offspring of the Washington mad cow because it could not determine which one was the suspect offspring.[438] Although USDA was confident that there was "no public health concern," the slaughter was ordered out of "an abundance of caution."[439] Days later, 130 more cattle that may have eaten the same feed as the BSE-positive animal were slaughtered and tested for BSE.[440]

D. The Effect on the Domestic Markets for American Beef.

In mid-January, after news coverage of the Washington mad cow had subsided, the National Cattlemen's Beef Association (a beef producer trade group) launched a $5.5 million advertising campaign aimed at putting the public's mind at ease about the risks of contracting vCJD from U.S. beef.[441] Just in time for the Super Bowl,[442] the campaign was financed out of a controversial, and quite possibly unconstitutional,[443] beef "check-off" program in which producers are assessed a mandatory fee when their cattle are slaughtered to finance industry promotional efforts.[444]

The Mabton mad cow's very limited initial impact on markets for U.S. beef, discussed above,[445] diminished as time went on and U.S. consumers became increasingly confident in the safety of the U.S. beef supply.[446] In fact, demand rose 10.4 percent in the first quarter of 2004 compared to the previous year as consumers continued to adhere to popular low carbohydrate diets.[447] Some large meatpackers received a windfall of sorts as prices for cattle dropped because of continuing refusal of major importing countries to

---

436 *Id*.

437 Shankar Vedantam, *U.S. Ends Investigation of Mad Cow Case*, Washington Post, February 10, 2004.

438 Marc Kaufman, *450 Calves in Washington State to Be Killed This Week*, Washington Post, January 6, 2004, at A2.

439 *Id*.

440 Richard Cowan, *U.S. to Kill 130 More Animals in Mad Cow Probe*, Reuters, January 9, 2004.

441 Steve Raabe, *Groups Launch Ads To Counter Mad-Cow Publicity*, Denver Post, January 20, 2004

442 Joe Ruff, *Beef Industry Unveils Post-Mad Cow Ad*, Associated Press, Jan. 26, 2004.

443 *See* Livestock Marketing Ass'n v. U.S. Dept. of Agriculture, 335 F.3d 711 (8th Cir. 2003), cert. petition filed, 72 USLW 3539 (Feb. 13, 2004) (finding beef check-off program unconstitutional).

444 Steve Raabe, *Groups Launch Ads To Counter Mad-Cow Publicity*, *supra*.

445 *See supra* Section I.

446 Thompson, *Mad Cow Scare Didn't Turn U.S. Against Beef*, *supra* (beef prices remained high into May, 2004 in part because of popular low carbohydrate diets); Ira Dreyfuss, *Mad Cow, Bird Flu Affect Meat Production*, Associated Press, March 10, 2004 (reporting that although the number of cattle slaughtered decreased, prices for beef declined only slightly from the previous year's highs).

447 Thompson, *Mad Cow Scare Didn't Turn U.S. Against Beef*, *supra*.

lift their bans on U.S. beef but consumer retail prices remained unaffected.[448] The primary economic loss was suffered by specialty meat producers like Creekstone Farms that sold a large proportion of their output in export markets and dairy farms and other owners of cattle greater than 30 months of age.[449]

E. Pressuring Trading Partners.

The Administration moved rapidly to undo the economic damage caused by the import restrictions imposed by Japan, Mexico and other countries.[450] On February 23, 2004, Secretary Veneman publicly criticized Mexico for being slow in re-opening its borders to U.S. beef and beef products.[451] Not long thereafter, Mexico agreed to open its borders to U.S. imports of boneless cuts from animals less than 30 months old and veal from animals less than 9 months old.[452] Later Indonesia also agreed to accept U.S. beef imports.[453] The effort was hampered in the case of Japan by the fact that the United States was not prepared to lift the ban on the import of Japanese beef that it had imposed when the first case of mad cow disease was discovered there in 2001.[454] As of mid-July 2004, Japan had not eased its restrictions on U.S. beef imports.

VII 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.[455] From the vacationing President's Crawford, Texas ranch, a "senior administration official" promised that President Bush would endorse additional protections for consumers of beef.[456] Two days later, on December 30, 2003, USDA Secretary Veneman announced that USDA would be implementing "additional safeguards to bolster the U.S. protection systems" against BSE

---

448 Alwyn Scott, *For Some in Beef Industry, Mad-Cow Disease "Almost a Windfall"*, Seattle Times, February 29, 2004.

449 *Id*.

450 Jonathan Weisman & Margaret Webb Pressler, *Importers Won't Take Shipments Of U.S. Beef*, Washington Post, January 8, 2004, at E1; *U.S. Mad-Cow Rules Not Enough, Japan Says*, Globe News, Jan. 5, 2004.

451 *U.S. Frustrated with Mexico on Mad Cow*, Reuters, February 24, 2004.

452 Roxana Hegeman, *Swift, Excel First to Resume Beef Exports to Mexico*, Associated Press, March 10, 2004. A month later, Mexico opened its borders to a broader array of beef products, including trimmings, livers, tongues, lips, hearts and kidneys. *Mexico Further Relaxes Its Ban on U.S. Beef*, Los Angeles Times, April 14, 2004.

453 *RI Lifts Ban On U.S. Meat Imports*, Earth Wire, June 01, 2004. Unfortunately, the Indonesia export market was a very small market for the United States, having imported only about 4 percent of its beef from here. Phyllis Jacobs Griekspoor, *Indonesia Rescinds Its Ban on U.S. Beef*, Wichita Eagle, June 3, 2004.

454 *Japan Wants U.S. To Lift Beef Ban*, United Press International, February 14, 2004.

455 Mike Allen, *Candidates Criticize Bush on Beef Safety*, Washington Post, December 29, 2003, at A3.

456 *Id*.

and "further protect public health."[457] In addition, Secretary Veneman promised that USDA would "begin immediate implementation of a verifiable system of national animal identification."[458]

The Food Safety and Inspection Service (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 the testing reports (the "Product Holding Guideline").[459] In addition, the agency sent to the *Federal Register* interim final rules for specified risk material, AMR processes, and the air-injection stunning of cattle. The rules for specified risk material (the "SRM Rule") included a requirement that all downer cattle be "condemned"[460] and a ban on the use of mechanically separated meat.[461] The promised "immediate implementation of a verifiable national animal identification program," however, was only on the drawing board where it had been sitting for a year-and-a-half, and it would not be ready for at least another year-and-a-half.[462]

Soon after issuing the rules, USDA sent a letter to countries from which the United States imports beef informing them of their obligation to adopt the recently promulgated USDA regulations for any beef that they planned to import into the United States[463] Soon thereafter, Secretary Veneman reported to a senator that all of the countries had adopted the same or equivalent regulations and were 100 percent compliant,[464] an extraordinary accomplishment given the difficulties in achieving compliance with the those regulations in the United States.[465]

A. The Product Holding Guideline.

In connection with the January 2004 rulemaking, USDA issued a Notice to inspectors making it clear that they should no longer "[p]ass and apply the mark of inspection to the carcasses and parts of cattle that are selected for testing by APHIS for BSE testing until the test results are received and the results are reported negative for BSE."[466] This "Product Holding Rule" adopts the very sensible precautionary position that meat from carcasses of cattle selected for BSE testing should be held in storage until the BSE tests

---

457 Veneman Announces Additional Protection Measures To Guard Against BSE, *supra*.

458 *Id*.

459 USDA, FSIS, Bovine Spongiform Surveillance Program, 69 Fed. Reg. 1892 (2004).

460 9 C.F.R. § 309.3.

461 *Id*. § 319.5.

462 *See* Denise Grady, *Way to Track U.S. Cattle Isn't Ready for Quick Use*, New York Times, January 3, 2004; *See infra* Section IV.A.2.d.

463 Charles Abbott, *U.S. Expects Beef Nations To Adopt Its Mad Cow Rules*, Reuters, January 21, 2004.

464 *All Beef Exporters to U.S. Adopt Mad Cow Rule-USDA*, Reuters, January 27, 2004.

465 *See infra* Section XIII.C.

466 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 11. *See* USDA, Food Safety and Inspection Service, Bovine Spongiform Encephalopathy Surveillance Program, Notice, 69 Fed. Reg. 1892 (2004).

are completed.[467] This will help prevent future recall fiascoes like the one attempted in connection with the Washington state mad cow.

B. The Specified Risk Material Interim Final Rule

USDA's new regulations governing "specified risk material" (the SRM Rule) were intended to be a "fourth firewall" aimed particularly at preventing human beings from contracting vCJD from BSE-infected cattle.[468] The regulations prohibited the use in human food of SRM from cattle. The term SRM was defined to include brain, skull, eyes, trigeminal ganglia, spinal cord of cattle more than 30 months old[469] and the tonsils and distal ileum (part of the small intestine) of all cattle.[470] FSIS estimated that 84 percent of the 4,033 federal and state inspected establishments, or 3,388 establishments, regularly dealt with SRM.[471]

The SRM regulations required establishments that slaughter cattle and those that process meat from cattle to "develop, implement, and maintain written procedures for the removal, segregation, and disposition" of SRMs.[472] Covered establishments had to incorporate such procedures into their formal HACCP plans or, if appropriate, into less formal Sanitation SOPs or "prerequisite programs."[473] When either the establishment or FSIS determined that the establishment's procedures or the implementation of those procedures "failed to ensure" that SRMs were removed from edible materials and disposed of properly, the establishment had to take "appropriate corrective action."[474] Finally, the rules required establishments to maintain daily records sufficient to document the implementation and monitoring of the required SRM removal procedures and any corrective action.[475]

1. Definition of SRM.

---

467 USDA, Food Safety and Inspection Service, Bovine Spongiform Encephalopathy Surveillance Program, Notice, *supra*.

468 FDA Statement 1/26/04, *supra* ("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.").

469 The regulations provide 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." 9 C.F.R. § 310.22(e).

470 *Id*. § 310.22(b). The SRM regulations provide that: "Specified risk material are inedible and shall not be used for human food." *Id*.

471 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 5.

472 9 C.F.R. § 310.22(d)(1).

473 *Id*.

474 *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).

475 *Id*. § 310.22(d)(4).

The prohibition on the use of any SRM in human food was intended 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."[476] As a prudent measure, FDA decided to designate "all materials from cattle that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue."[477] In laboratory studies involving a small number of animals, "the highest levels of infectivity" were "detected in the brain and spinal cord at the end stages of disease."[478] Thus, some "bone-in" beef products (e.g., T-bone steaks) from animals greater than 30 months old would contain spinal cord, DRG or both and would therefore contain SRM in addition to bone marrow.[479] Because head meat, cheek meat, and tongue were not technically part of the skull, those materials were not designated as SRM, even though they could easily become contaminated with SRM from within the skull during the slaughter and preparation of meat.[480] USDA also recognized that in one test, bone marrow had demonstrated infectivity 38 months after exposure, but it concluded that the findings of that study were "not conclusive."[481]

The 30-month age cut-off for CNS material reflected FSIS'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 30 months of age.[482] 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."[483]

Of particular concern to the agency were reports from Japan of BSE detected in cattle under 24 months of age as part of that country's program of testing all cattle destined for human consumption.[484] To USDA, however, the "immediate implications" of these findings were "not readily apparent at this time."[485] 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 Department expected that the younger infected cattle in Europe had received very high doses of the BSE agent early

476 USDA SRM Interim Final Rule, *supra*, at 1869.
477 *Id*. at 1868.
478 *Id*. at 1864.
479 *Id*. at 1865.
480 *Id*. at 1868.
481 *Id*. at 1864.
482 *Id*.
483 *Id*.
484 *Id*.
485 *Id*.

in their lives.[486] In support of its narrower definition of SRM, FSIS noted that its definition of SRM was identical to the Canadian definition.[487]

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.[488] 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.[489] 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.[490]

2. Procedures for Removal, Segregation and Disposition.

The SRM rule also addressed 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.[491] 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.

3. Effect of BSE Testing on Use of SRM.

FSIS considered exempting materials from cattle that tested negative for BSE from the SRM requirements, an option suggested in its 2002 Current Thinking paper, but decided against it because of the absence of any sensitive and reliable live animal test for BSE and the limitations on post-mortem BSE testing of animal tissue. The preamble to the regulations noted that since "post-mortem diagnostic tests can only indicate that cattle have the disease two to three months before the onset of clinical disease or after the onset of clinical disease," it would not ensure that all contaminated material was removed from the human food supply.[492] The Department did, however, hold open the possibility that appropriate tests could become available in the future.[493]

---

486 *Id*.

487 *Id*. at 1868.

488 *Id*. at 1870.

489 *Id*. at 1869.

490 *Id*. at 1869-70.

491 *Id*. at 1869.

492 *Id*. at 1871.

493 *Id*.

C. The Advanced Meat Recovery Rule

As discussed above, AMR systems have consistently produced beef product that has tested positive for spinal cord and DRG.[494] FSIS had in fact formally proposed in April 1998 to adopt a "zero tolerance" for the presence of spinal cord in AMR product.[495] Even though the 2001 HCRA risk assessment identified AMR technology as "the most important means by which low risk tissue can become contaminated" with mad cow prions,[496] the proposal languished in the Department for nearly five years until the discovery of the Mabton mad cow.

The AMR interim final rule promulgated on January 12, 2004 amplified the prohibition of SRM in edible meat by prohibiting the use the word "meat" to describe the output of any AMR process that contained "any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG)" without regard to the age of the animal from which the meat was derived.[497] It furthermore applied the same restriction to skulls and vertebral column bones from cattle 30 months of age or older.[498] As with the SRM rule, the restriction did not apply to bone marrow.[499]

Like the SRM rule, the AMR rule required the 30 or so establishments operating AMR systems to come up with procedures to ensure that their production processes complied with the zero-tolerance restrictions.[500] For cattle-processing establishments, the program had to be included in a HACCP plan, Sanitation SOP, or other prerequisite program.[501] All plans had to describe the establishment's "on-going verification activities," including "the testing of the product exiting the AMR system" for prohibited materials."[502] As with the SRM rule, establishments had to keep accurate records and make them available to USDA inspectors.[503] Any product not meeting the requirements of the rule could not be labeled "meat," and any violative material labeled "meat" would be subject to seizure.[504]

The technical rationale for the BSE-related aspects of the AMR rule was essentially the same as the rationale for the SRM rule. Like the SRM rule, the AMR rule vested a great deal of discretion in the establishments themselves to implement the zero tolerance requirement for prohibited CNS materials in AMR product. Establishments were "expected to determine how and when they will test product for" prohibited materials,

---

494 USDA AMR Interim Final Rule, *supra*, at 1876. *See supra* Section III.C.1.

495 63 Fed. Reg. 17959 (1998).

496 Harvard Center for Risk Analysis BSE Report, *supra*, at 98.

497 9 C.F.R. § 301.2.

498 *Id*. § 301.24(a).

499 USDA AMR Interim Final Rule, *supra*, at 1883.

500 9 C.F.R. § 301.24(b). *See* FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 6 (30 establishments produce AMR products derived from beef vertebrae).

501 9 C.F.R. § 301.24(b)(2).

502 *Id*.

503 *Id*. § 301.24(b)(3) - (4).

504 *Id*. § 301.24(c).

and they were encouraged to use any testing methodology that would be "effective."[505] FSIS "expect[ed] that the establishment will ensure that each production lot is in compliance with the provisions of" the regulation.[506] As with the SRM Rule, consumers were left to the good graces of the regulated establishments to come up with effective plans and adequate testing procedures.

D. The Ban on Mechanically Separated Meat Technologies.

Because 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.[507] 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.[508]

E. Limited "Condemnation" of Downer Cattle.

In addition to addressing SRMs directly, the SRM regulations required that all "seriously crippled" and non-ambulatory disabled livestock be identified as "suspect."[509] Furthermore, all non-ambulatory disabled cattle had to be condemned and properly disposed of in accordance with USDA's condemnation regulations.[510] Disabled cattle that were not non-ambulatory could still be slaughtered for human consumption.[511]

USDA 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."[512] The Department noted that under its existing regulations, all downer cattle and seriously crippled livestock presented for slaughter were already "automatically suspected of being affected with a disease or condition that may require condemnation of the animal" and were branded "U.S. Suspects."[513]

FSIS understood that a complete prohibition on the use of non-ambulatory cattle for human food was likely to be overly broad because it involved no inquiry into the reason

---

505 USDA AMR Interim Final Rule, *supra*, at 1882.

506 *Id*.

507 USDA SRM Interim Final Rule, *supra*, at 1862, 1865.

508 FSIS BSE Interim Rules Preliminary Analysis, supra, at 52, n. 43 (noting that "very few, if any, establishments were intentionally producing MS(beef) before the SRM rules became effective").

509 9 C.F.R. § 309.2. The term "seriously crippled" is not defined in the regulations.

510 *Id*. § 309.2, 309.3. 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.

511 USDA SRM Interim Final Rule, *supra*, at 1870.

512 *Id*. at 1863, 1870.

513 *Id*. at 1870.

for an animal's non-ambulatory status. The prohibition applied, for example to a cow that became non-ambulatory because of an acute injury on the way to the slaughterhouse and even to a cow that broke its leg getting off the truck at the slaughterhouse, neither of which would indicate the presence of BSE.[514] Nevertheless, FSIS believed that complete prohibition on the use downer cattle for human consumption 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.[515] 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."[516] 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."[517] The protein resulting from the tanking process may be used for any other lawful purpose.

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. As a practical matter, the January 2004 USDA regulations governing downer cattle only prevent the use of meat from those cows in human food.[518]

F. The Air Injection Stunning Rule.

The Humane Methods of Slaughter Act (HMSA) requires slaughterhouses to use humane methods in slaughtering livestock.[519] Under that statute, USDA had approved "air-injection captive bolt stunning,"[520] 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."[521] 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.[522] Moreover, malfunctioning captive bolt stunners can transfer much higher amounts of such tissue into

514 *Id*. at 1870.

515 9 C.F.R. § 309.13.

516 *Id*. § 314.1, 314.3.

517 *Id*. § 314.1(a)(1)

518 *See* Denise Grady, *9 Cows Linked to Mad Cow Inquiry Have Been Found*, *supra* (quoting chief USDA veterinarian Ron DeHaven) (expressing USDA's position that companies may still render downer cattle into feed for poultry and swine and other products such as tallow and oils).

519 7 U.S.C. § 1901-1906.

520 9 C.F.R. § 310.13(a)(2)(iv)(C)).

521 USDA Stunning Device Interim Final Rule, *supra*, at 1887.

522 *Id*.

edible meat.[523] Although USDA was "not aware of any cattle slaughter establishments in the United States that use air-injection stunning,"[524] it concluded that the practice posed "a risk of exposing humans to materials that could contain the BSE agent."[525] It therefore prohibited the use of such stunning devices in cattle.[526] Like the ban on mechanically separated meat, however, this action had no impact on the relevant industries because they had already abandoned that stunning technique.

G. Costs and Benefits of the Regulations.

A Preliminary Regulatory Impact Analysis of USDA's January 2004 regulations concluded that they would impose annual costs of $110.3 to $149.1 million on the beef industry.[527] Although this was not an insubstantial impact, the analysis also concluded that the "aggregate beef price impacts" of the regulations were "not expected to be significant."[528] The benefits of the regulations were more difficult to estimate. Noting that U.S. exports of beef, veal and variety meats were valued at $3.8 billion in 2003, a one-paragraph analysis concluded that "[f]ailure to assure consumer confidence in beef products could easily reduce cash receipts to the cattle sector by $5 to $10 billion annually."[529]

The preliminary analysis did not attempt to "evaluate the quantitative likelihood that humans will develop variant Creutzfeld Jakob Disease (vCJD) if exposed to the BSE agent."[530] It did, however, attempt a very rough estimate of the degree to which the regulations would reduce human exposure to the BSE agent in food. That analysis was considerably hampered by the fact that FSIS had no idea how many cattle in the United States were infected with BSE. Employing the HCRA-developed benefit assessment model, the preliminary analysis estimated that no matter what the initial incidence of BSE in the U.S. cattle population, the measures adopted in the SRM and AMR regulations would reduce the total infectivity of infected cattle by 80 percent.[531]

H. Expanded Governmental Testing, but Zero Nongovernmental Testing.

After the discovery of the Mabton mad cow, the beef industry announced that it would not be opposed to more thorough USDA testing of cattle for BSE,[532] and USDA yielded

---

523 *Id*. at 1888.

524 USDA SRM Interim Final Rule, *supra*, at 1867; USDA Stunning Device Interim Final Rule, *supra*, at 1889.

525 USDA SRM Interim Final Rule, *supra*, at 1867.

526 9 C.F.R. § 313.15(b)(2)(ii).

527 FSIS BSE Interim Rules Preliminary Analysis, *supra*, at 2.

528 *Id*. at 3.

529 *Id*. at 58.

530 *Id*. at 57.

531 *Id*. at 57-58.

532 McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*.

to public pressure for greater testing by gently expanding its testing program from 20,000 tests per year to 40,000.[533] APHIS continued to limit the program to downer cattle or adult cattle displaying signs of CNS disorders, and the program continued to be wholly voluntary.[534] A subsequent report from an International Advisory Panel,[535] a recommendation from an FDA advisory committee,[536] and continued public pressure from consumer groups[537] forced APHIS to initiate 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 1.5 year period beginning on June 1, 2004.[538] In addition, the program would for the first time include approximately 20,000 healthy looking animals of more than 30 months in age.[539] Early predictions were 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.[540] The program got underway on schedule on June 1, 2004, but USDA continued to struggle with a number of implementation issues.[541]

The Department's announcement did not say whether the expanded program would continue to depend upon voluntary submissions of animals for testing by slaughterhouses, but a spokesperson later confirmed that the program remained entirely voluntary.[542] It would not be random, but would instead concentrate on the 40 slaughterhouses that have historically slaughtered 86 percent of all slaughtered cattle at federally inspected plants.[543]

---

533 Sandi Doughton, *Groups Urge Expanded Mad-Cow Protections*, Seattle Times, January 16, 2004. 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 percent 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. Donald G. McNeil Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, New York Times, February 9, 2004.

534 Rhodes, *Deadly Feasts*, *supra*, at 223; USDA BSE Overview, *supra*, at 4.

535 *See infra* Section X.

536 Alicia Ault, *Federal Panel Recommends More Testing for Mad Cow*, New York Times, February 14, 2004.

537 Matthew Daly, *Consumer Groups Want More Cattle Testing*, Associated Press, Jan. 16, 2004 (pressure from consumer groups for greater testing).

538 USDA, Veneman Announces Expanded BSE Surveillance Program, Press Release No. 0105.04, March 15, 2004. *See also* Hileman, Mad Cow Disease, *supra*, at 22.

539 Marc Kaufman, *Testing for Mad Cow Disease To Expand*, Washington Post, March 16, 2004, at A1; Veneman Announces Expanded BSE Surveillance Program, *supra*; Hileman, *Mad Cow Disease*, *supra*, at 22.

540 Kaufman, *Testing for Mad Cow Disease To Expand*, *supra* (268,000 estimate); Steve Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, United Press International, March 16, 2004 (200,000 estimate).

541 Richard Cowan, *USDA Still Working on Details for Mad Cow Testing*, Reuters, June 4, 2004; Ira Dreyfuss, *Government Begins Expanded Mad Cow Tests*, Seattle Post-Intelligencer, June 1, 2004.

542 *Critics Say Voluntary Mad Cow Testing Doesn't Equal Surveillance*, Associated Press, March 18, 2004.

543 Transcript of Technical Briefing, May 21,2004, available at www.usda.gov/Newsroom/0204.04.html.

APHIS would make some attempt to assure geographical diversity.[544] 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.[545]

To meet this greatly increased testing load, USDA decided to allow a number of state laboratories to use the BSE testing kits that had previously been the exclusive domain of USDA's Ames, Iowa laboratory. Furthermore, it announced that it was "working to approve rapid tests for use in the testing program,"[546] and it certified the first two rapid testing kits within days of the announcement.[547] At the end of May 2004 USDA announced that it had certified twelve geographically diverse state laboratories to conduct rapid BSE tests to assist in the expanded surveillance program.[548] Inconclusive or positive screening test results are to be forwarded to APHIS's National Veterinary Services Laboratory in Ames, Iowa, for confirmatory testing.[549]

Consumer groups were still not convinced that testing 200,000 out of 35 million cows would ensure that mad cow disease did not go undetected in the U.S. cattle population.[550] One consumer group disputed USDA's conclusion that the expanded testing program would be capable of detecting a BSE incidence of 1 in 10 million and concluded that the program, which was still limited largely to downer cattle, "seems to be designed to give the public and would-be importers of American cattle false assurance."[551] He noted that hundreds of non-suspect cattle had tested positive for BSE in Europe.[552] Another consumer group complained that the limitation of the testing of non-downer cattle to older cattle ignored the fact that BSE had been detected in cattle as young as 20 months old.[553] It further argued that the enhanced surveillance should not be limited to a one-

---

544 The goal of the high-risk sampling program was "to test as many adult cattle in the targeted high risk population as possible in a 12-18 month period while ensuring that there is statistically appropriate geographical representation of the adult cattle population in the U.S." USDA, Overview of Bovine Spongiform Encephalopathy (BSE) Surveillance Plan, March 15, 2004, available at www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf.

545 Transcript of Technical Briefing, May 21,2004, *supra*.

546 Veneman Announces Expanded BSE Surveillance Program, *supra*.

547 Edward D. Murphy, *Idexx Joins Fight Against "Mad Cow"*, Portland Press Herald, March 19, 2004; Bette Hileman, *USDA Licenses Rapid Assay For Mad Cow Disease*, Chemical & Engineering News, March 24, 2004; *USDA Certifies Bio-Rad Test for Mad Cow Disease*, Reuters, March 18, 2004.

548 USDA Certifies Five New Laboratories for BSE Sample Analysis, USDA Press Release, May 11, 2004; USDA Certifies Seven Laboratories for BSE Sample Analysis, USDA Press Release, March 29, 2004.

549 USDA, Bovine Spongiform Encephalopathy (BSE) Surveillance, May 20, 2004, available at http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html.

550 Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, *supra* (quoting Michael Hanse, Consumers Union).

551 *Id*. (quoting Dr. Peter Laurie, Public Citizen).

552 *Id*. (quoting Dr. Peter Laurie, Public Citizen).

553 Consumers Union, USDA Announcement of More Mad Cow Testing Still Inadequate to Protect Public Health, Press Release, March 16, 2004.

time program.[554] The National Cattlemen's Beef Association, by contrast, supported the expanded testing program, so long as it proved to be "workable."[555]

At the same time that 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, 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.[556] Creekstone immediately petitioned 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.[557] It predicted that testing would cost the company about $20 per animal, but it was confident that it could pass that additional cost on to its high-end customers.[558] Creekstone even invested $500,000 in a state-of-the-art mad cow testing laboratory.[559] The American Meat Institute's reaction to this effort by a small company to regain its lost export markets was strongly negative. Noting that BSE testing had always been done by the federal government, it saw no need to take such an "unprecedented" step.[560]

USDA rejected Creekstone's petition in early April 2004,[561] and it even threatened to file a criminal action against Creekstone if it conducted any testing at all.[562] Under the Virus-Serum-Toxin Act,[563] establishments that manufacture and import veterinary biological products, like the BSE test kits that Creekstone wanted to use, must be licensed by USDA.[564] No person may sell a 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.[565] USDA long ago issued

---

554 *Id*.

555 Sandi Doughton, *U.S. to Expand Mad-Cow Testing*, Seattle Times, March 16, 2004 (quoting James Reagan, vice president of the National Cattlemen's Beef Association).

556 Libby Quaid, *Lawmakers Pushes USDA on Mad Cow Testing*, June 23, 2004, available at http://www.kansas.com/mld/kansas/news/state/8995581.htm; Sandra Blakeslee, *One Producer of U.S. Beef Wants to Test All Its Cattle*, New York Times, February 27, 2004; Roxana Hegeman, *Kansas Meatpacker Plans to Test All Cattle for Mad Cow*, Associated Press, February 27, 2004.

557 Blakeslee, *One Producer of U.S. Beef Wants to Test All Its Cattle*, *supra*. In May, 2004, another small establishment, Gateway Beef, filed a similar petition. Stephanie Simon, *U.S., Some Ranchers Clash Over Mad Cow Tests*, Los Angeles Times, May 24, 2004.

558 Hegeman, *Kansas Meatpacker Plans to Test All Cattle for Mad Cow*, *supra*.

559 Marc Kaufman, *Company's Mad Cow Tests Blocked*, Washington Post, April 16, 2004 at A1.

560 Hegeman, *Kansas Meatpacker Plans to Test All Cattle for Mad Cow*, *supra*.

561 Kaufman, *Company's Mad Cow Tests Blocked*, *supra*; Donald G. McNeil Jr., *U.S. Won't Let Company Test All Its Cattle for Mad Cow*, New York Times, April 10, 2004; Libby Quaid, *USDA Rejects Meatpacker's Mad Cow Plan*, Seattle Post-Intelligencer, April 9, 2004.

562 Hileman, *Mad Cow Disease*, *supra*, at 24.

563 21 U.S.C. § 151-158.

564 *Id*. § 154-155. 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. Pub. L. No. 99-198, § 1768, 99 Stat. 1654 (codified at 21 U.S.C. § 151, 154-154a, 157, 159).

565 21 U.S.C. § 151.

regulations banning the shipment within the United States of individual veterinary biological products unless the manufacturer has satisfied USDA requirements for purity, safety, potency, and efficacy.[566] As discussed above, USDA had in mid-March 2004 approved two rapid BSE testing kits and expanded the number of state-run laboratories that may lawfully test for BSE.[567] The head of APHIS explained its refusal to allow Creekstone to use those kits for the purpose of testing 100 percent of its cattle on the ground that USDA was determined to "stick to the science" in testing for mad cow disease.[568] As discussed below, Creekstone and many others have been sharply critical of this determination.[569]

VIII The January 26, 2004 FDA Announcement.

On January 26, 2004, Health and Human Services Secretary Tommy G. Thompson announced that 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. First, Secretary Thompson announced that FDA intended to ban from human food and dietary supplements a wide range of bovine-derived material to match USDA's recently promulgated restrictions on downer cattle and SRMs in meat. Second, 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 to non-ruminant feed.[570] Finally, FDA promised to increase inspections of feed mills and renderers to ensure compliance with the revised feed rule.[571] While not conceding that the 1997 Feed Rule had failed to protect the public health, Secretary Thompson maintained that "we must never be satisfied with the status quo where the health and safety of our animals and our population is at stake."[572] As with every other action the Administration proposed to address the mad cow problem, the new regulations would be "science-based."[573]

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

Although FDA had in 2002 published an Advance Notice of Proposed Rulemaking[574] and was presumably prepared to promulgate the promised "interim final" regulations immediately, a curious silence followed Secretary Thompson's dramatic announcement, a

---

566 9 C.F.R. § 113 (1987).

567 *See supra* Section VII.H.

568 Kaufman, *Company's Mad Cow Tests Blocked*, *supra*.

569 *See infra* Section XI.D.2.

570 FDA Statement 1/26/04, *supra*.

571 *Id*.

572 *Id*.

573 *Id*.

574 Food and Drug Administration, Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, Advance Notice of Proposed Rulemaking, 67 Fed. Reg. 67572 (2002).

silence that lasted for more than five months as FDA apparently deliberated over what the emergency rule would require. On July 8, 2004 FDA announced that it was fulfilling one of the promises that Secretary Thompson made in January and reneging on another.[575] It was sending to the *Federal Register* not two interim final rules as promised, but only a single interim final rule limited to the promised ban on including SRMs and meat from downer cattle in any food, cosmetics or dietary supplements.[576] FDA also proposed an additional rule containing recordkeeping requirements to aid the agency in enforcing that ban.[577]

Instead of the promised elimination of the mammalian blood, chicken litter and plate waste exemptions from the 1997 Feed Rule, FDA and USDA issued a joint Advance Notice of Proposed Rulemaking (ANPR) that did not take or even propose any particular action but offered some additional "considerations for further action."[578] In addition to a description of the HCRA Report, the USDA International Panel Report, and the previous BSE-related actions undertaken by both agencies, the ANPR requested public comment on whether USDA's long awaited national cattle identification program should be voluntary or mandatory and on whether FDA should amend the 1997 Feed Rule to remove SRMs from all animal feed, whether FDA should require dedicated equipment for handling and storing feed to prevent cross-contamination, whether FDA should prohibit the use of all mammalian and poultry protein in ruminant feed, and whether FDA should prohibit the use of materials from dead and downer cattle in all animal feed.[579]

X Advisory Committee Reports.

On January 6, 2004, Secretary Veneman announced that she had appointed an international team of experts, headed by Dr. Ulrich Kihm, the former chief veterinary officer of Switzerland, to review USDA's programs related to mad cow disease, including the recently promulgated interim final regulations and to make recommendations for improvement.[580] The expert panel (the "USDA International Panel") was a subcommittee of the Secretary's existing Foreign Animal and Poultry Disease Advisory Committee. On February 2, 2004, the panel issued its report (the "USDA International Panel Report").[581]

---

575 Letter to Colleague from Melinda K. Plaisier, dated July 9, 2004, available at http://www.fda.gov./oc/bsc/ltr-InterimReg.html.

576 Food and Drug Administration, Use of Materials Derived from Cattle in Human Food and Cosmetics, Interim Final Rule, ___ Fed. Reg. ___ (2004) [hereinafter cited as FDA Food and Cosmetics Rule].

577 Food and Drug Administration, Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle, Proposed Rule, ___ Fed. Reg. ___ (2004). FDA estimated that total first year costs would be about $1 million with recurring costs of around $187,000 per year. FDA Food and Cosmetics Rule, *supra*, at Tables 2, 3.

578 USDA/HHS BSE ANPR, *supra*.

579 USDA/HHS BSE ANPR, *supra*.

580 Emad Mekay, *Industry Slowing Action on Mad Cow Disease - Activists*, lnter Press Service, January 6, 2004.

581 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

The USDA International Panel Report had some good news and some bad news for USDA. The good news was that the Department had done a good job in reacting to the discovery of the Mabton mad cow. The panel was generally supportive of the steps that USDA had taken to investigate the Washington mad cow incident and indeed suggested that the culling of existing herds may have been a bit too extensive.[582] It also agreed with the Secretary's decision to end the investigation even though only about half of the birth herd had been accounted for.[583] The panel believed that the Department's limited resources could better be spent on a greatly expanded surveillance program.[584]

The bad news was that there were probably more mad cows in the United States, and existing regulatory protections, even as supplemented by USDA's recent interim final rules, were insufficient to protect the agricultural economy and the public health. The panel warned that "the significance of this BSE case cannot be dismissed by considering it 'an imported case.'"[585] According to the panel, it was "probable that other infected animals have been imported from Canada and possibly also from Europe."[586] This meant that "infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the USA have also been indigenously infected."[587] The panel's chairman predicted that if USDA began a thorough testing program, the United States "could have a case a month" of mad cow disease.[588] The panel urged USDA to expand its definition of materials banned from human food, eliminate AMR techniques, greatly increase the number of cattle tested for BSE, test all downer cattle for BSE, and adopt rapid BSE screening tests. It urged FDA to extend the existing feeding restrictions to ban the use of risky material from cattle in all animal feed and to ban the use of all rendered animal protein from cattle feed.[589] Thus, while the panel generally applauded USDA investigative efforts, it found much to be desired in the regulatory efforts of both USDA and FDA, and it urged them to take immediate steps to improve regulatory protections.

The beef industry attacked the USDA International Panel report as "misguided" and "nonscientific," and it suggested that the panel was too greatly influenced by the European experience.[590] The United States situation was very different because "the long-standing firewalls in place in our country have been effective."[591] A spokesperson

---

Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States (February 2, 2004) [hereinafter cited as International Panel Report].

582 *Id*. at 2.

583 *Id*. at 3.

584 *Id*.

585 *Id*. at 4.

586 *Id*. at 3.

587 *Id*.

588 Donald G. McNeil, Jr. & Denise Grady, *Ban Urged on All Animal Protein for Cattle*, New York Times, February 5, 2004; Marc Kaufman, *More U.S. Cattle Likely To Have Mad Cow Disease*, Washington Post, February 5, 2004, at A2.

589 International Panel Report, *supra*, at 4-9.

590 Kaufman, *More U.S. Cattle Likely To Have Mad Cow Disease*, *supra*.

591 *Id*.

for HCRA was likewise confident in the safety of U.S. meat, pointing out that "[o]ne a month wouldn't even bring us up to the state of Japan right now."[592] Consumer groups, on the other hand, read the report as "an implicit admission that the critics have been correct and B.S.E. has been here all along."[593]

FDA's initial reaction to the panel's report was a by now quite predictable reference to the HCRA risk assessment. The Director of FDA's Center for Veterinary Medicine observed that the panel's report had come to conclusions very different from those of the HCRA risk assessment.[594] Refusing to budge from her position that mad cow disease did not present "a significant issue in this country,"[595] Secretary Veneman referred the USDA International Panel report to an existing 17-member advisory committee for still more advice. The new panel was composed of academics, veterinarians, and representatives of the beef and feed industry, but it did not include any representatives of any consumer or environmental groups.[596] The chairman of the new panel, who was also the head of the West Virginia Department of Agriculture, expressed surprise at some of the USDA International Panel's recommendations and noted that it had "far-reaching consequences that could develop a far worse situation for us."[597] This second advisory committee recommended that USDA expand its testing program to include animals that died on ranches, but it declined to endorse the USDA International Panel's call for testing all downer animals. The second committee also questioned the USDA International Panel's prediction that more cases of mad cow would be identified in the United States if USDA looked harder.[598] Still another advisory committee appointed by FDA also recommended that the testing program be expanded.[599]

XI 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 another, ground along with meat from many different states in still another state, and sold

---

592 Randy Fabi & Christopher Doering, *Harvard, Expert Panel at Odds Over U.S. Mad Cow Risk*, Reuters, February 4, 2004

593 McNeil, Jr. & Grady, *Ban Urged on All Animal Protein for Cattle*, *supra* (quoting Michael Hansen, Consumers Union).

594 Denise Grady, *Mad Cow Quandary: Making Animal Feed*, New York Times, February 6, 2004.

595 *Mad Cow Risk Is Downplayed*, Los Angeles Times, February 6, 2004.

596 Randy Fabi, *USDA Panel To Offer Mad Cow Advice By Mid-Feb*, Reuters, February 6, 2004.

597 *Id*.

598 Sandi Doughton, *Panel Calls for Changes In Testing, Tracking Cows*, Seattle Times, February 24, 2004.

599 Alicia Ault, *Federal Panel Recommends More Testing for Mad Cow*, New York Times, February 14, 2004.

and cooked in yet another state, this incentive is not especially powerful.[600] 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."[601]

Similar obstacles to imposing accountability for negligent conduct reduce the incentive provided after-the-fact by the common law of torts.[602] 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 has mandated that USDA and FDA take proactive action to protect the public health.[603] 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 -- USDA's import controls, FDA's feed restrictions, and USDA's BSE surveillance program. In the wake of the discovery of the Mabton mad cow, the Bush Administration offered strong assurances that the protections already in place were adequate to the task of protecting the public health, but it promised to do even more. To put the public's mind at ease, USDA in January 2004 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. And FDA promised to enhance the feed restriction firewall by eliminating some of the original exemptions.

The American public has apparently taken comfort in the Administration's assurances that these firewalls will prevent mad cow disease from becoming a serious public health problem in the United States. The Mabton mad cow may pose a significant economic issue for the beef industry and the State Department because of the apparent unwillingness of our trading partners to accept U.S. beef, but so far it has not resulted reduced demand for beef and beef products in the United States. Relying heavily upon the HCRA modeling exercise, government officials have actively encouraged this benign

---

600 *See* Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 Willamette L. Rev. 411 (1997), at 443 [hereinafter cited as Lassiter, *Hoof to Hamburger*].

601 NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 16.

602 *Id*. (noting that "personal injury litigation provides only a weak incentive for food companies to improve their food safety efforts, because there is 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 consequences").

603 See supra Section IV.A.2.

public assessment.[604] Apologists in industry-supported think tanks blame all of the attention that mad cow disease has thus far received on "attempts by activists and special interest groups of all kinds to scare consumers into making irrational choices.[605]

As the USDA International Panel Report suggests, however, the reality of the current regulatory regime, even as supplemented by USDA's January 2004 activities, 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 do not enter the food supply before completion of the testing, it undertook very little in the way of genuine substantive reform to a regulatory regime that is badly broken. 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. Sound Advance Planning and a Precautionary Product Holding Guideline.

USDA deserves credit for engaging in a thoughtful planning exercise prior to the outbreak of mad cow disease in the United States. Although the Department could have searched more diligently for a less industry-dominated outside consultant than the HCRA to prepare a mad cow risk assessment, it did go to considerable effort and expense to examine those risks carefully. With the publication of its "Current Thinking" paper in January 2002, the Department had already engaged in much of the research and analysis necessary to support more stringent regulation of BSE risks. Finally, the Department had in place a rapid response plan setting out in detail how it would respond to the discovery of mad cow disease in the United States[606] The Administration's actual response to the discovery in Washington state closely adhered to the highly technical BSE Response Plan and was reasonably successful in bringing about a recall of potentially contaminated meat and in investigating the source of the infected animal.

The Administration deserves credit for issuing the Product Holding Notice to FSIS and state inspectors. If adequately enforced, the Notice will prevent meat from mad cows that are detected during future ante-mortem inspections from entering the human food supply. It will not, of course, prevent tissue from mad cows that are not identified during ante mortem inspection from becoming incorporated into human food. The only question raised by the notice is why its sensible requirement had not been in place all along.

The Administration's efforts soon veered away from the precautionary action suggested in its planning documents, however, and focused instead on an intense public relations

---

604 Testimony of Ann M. Veneman, Secretary, Department of Agriculture before the Senate Committee on Agriculture, January 21, 2004.

605 Gregory Conko, Creating Cow Concerns Should Make Mad Consumers, Competitive Enterprise Institute Press Release, February 27. 2004.

606 *See supra* Section IV.A.2.e.

campaign designed to put the public's mind at ease and thereby ensure the continued economic well-being of the beef industry.

B. The Import Restriction Firewall.

The first "firewall" in place to protect the public against an outbreak of mad cow disease is the restrictions that USDA imposed in 1989 on the importation of ruminants and certain ruminant products from countries where BSE is known to exist.[607] The restrictions were initially applicable to the U.K. and European countries in which the first BSE outbreaks had occurred, but USDA continued to ban imports from other countries, such as Japan and, most recently, Canada, as mad cows were detected in those countries.[608] The importation of the Mabton cow from Alberta, Canada did not technically breach the importation firewall, because it occurred prior to the May 2003 discovery of a mad cow in Canada.

The importation firewall was, however, significantly jeopardized on April 19, 2004 when USDA quietly informed import brokers that it would immediately lift the ban on imports of all edible beef products from Canadian cattle under 30 months of age, including processed meat that contained bones and offal.[609] Both Canadian beef producers and U.S. beef producers with facilities in Canada had been lobbying the Department to ease the import restrictions.[610] Apparently unconcerned with the reaction of U.S. consumers, a USDA official told the media that the modification of the import restrictions was intended to "test the U.S. industry's reaction."[611] At least one segment of the industry reacted very strongly. Within a week after the issuance of the April 19 policy memorandum, the Ranchers Cattlemen Action Legal Fund (R-CALF), an organization of cattle ranchers, persuaded a court to issue a preliminary injunction against the rescission of the import ban.[612] The court found it "troubling" that 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.[613] This reaction was more than enough to cause USDA to back off and rescind its previously unannounced policy directive.[614] A

---

607 FDA Statement 1/26/04, *supra* (describing the three "firewalls"); USDA BSE Overview, *supra*, at 4. *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 22.

608 *See supra* Section IV.A.2.a.

609 Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted, August 8, 2003, available at www.usda.gov/news/releases/2003/08/0281.htm. *See also* Dawn Walton, *U.S. Lifts Ban on Canadian Beef*, Montreal Globe and Mail Home News, April 19, 2004, at A7. USDA had previously lifted the ban for boneless meat products that, in the Department's opinion, had a very low risk of containing TSEs. Becky Bohrer, *USDA Blocked on Canada Beef Imports*, Los Angeles Times, April 26, 2004.

610 Marc Kaufman and Cindy Skrzycki, *USDA Rescinds Policy Allowing Sale of Canadian Beef*, Washington Post, May 6, 2004, at A2.

611 Walton, *U.S. Lifts Ban on Canadian Beef*, *supra*.

612 Bohrer, *USDA Blocked on Canada Beef Imports*, *supra*.

613 Kaufman & Skrzycki, *USDA Rescinds Policy Allowing Sale of Canadian Beef*, *supra*.

614 *Id*.

USDA spokesperson admitted that "we probably could have been more clear in our administrative steps."[615]

Things only got worse for USDA when R-CALF discovered that APHIS had covertly allowed U.S. meatpackers to import 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.[616] 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 30 months old and agreeing to remove SRM material before processing the meat.[617] The Department refused to disclose which meat processors had received the special exemptions.[618] In a response to a request by three senators, USDA's Inspector General is conducting an investigation into the incident.[619]

While the public (including U.S. cattle producers) thought that the import "firewall" was protecting it from mad cow risks, the Department charged with responsibility for providing that protection was quietly allowing millions of pounds of beef pass through the firewall. Having admitted that it had allowed several U.S. meat processors to circumvent the ban on imports of most Canadian beef products though a clandestine permit process, USDA proceeded to cover up the names of the companies that had been importing the meat. After a severe grilling by congresspersons from both parties, USDA acknowledged that "the process and our failure to announce some of these actions was flawed," but it maintained that only 7.3 million pounds of the illicit meat had been imported into the United States[620] The White House rejected demands for Secretary Veneman's resignation, and President Bush praised her for doing "an outstanding job."[621] U.S. consumers might legitimately have questioned whether its government was looking out for their interests or those of unidentified meat processors.

C. The Feed Restriction Firewall.

Probably the most critical of the original three "firewalls" is the FDA Ruminant Feed Rule.[622] That regulation was fiercely resisted by the rendering industry at the time it was

---

615 *Id*.

616 Marc Kaufman, *USDA Allowed Canadian Beef In Despite Ban*, Washington Post, May 20, 2004, at A1.

617 Kaufman, *USDA Allowed Canadian Beef In Despite Ban*, *supra*.

618 *Id*.

619 Marc Kaufman, *USDA Expands Mad Cow Inquiry*, Washington Post, July 3, 2004, at A2; *Daschle Calls for Investigation Into Canadian Beef Ban*, Associated Press, June 24, 2004.

620 Marc Kaufman, *USDA Says It Erred on Beef*, Washington Post, May 22, 2004, at A3.

621 *Veneman Unaware of Banned Beef Shipments, USDA Says*, Bloomberg.com, May 21, 2004.

622 According to the Director of the HCRA, the feed ban is "the main thing that prevents the spread." Guy Gugliotta & Christopher Lee, *Mad Cow Alerts Began Years Ago*, Washington Post, December 27, 2003, at A06. USDA's chief veterinarian called 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." United States

promulgated. The National Renderers Association's chief veterinarian complained that "[t]he science just isn't clear enough. There are lots of theories, but there hasn't been any specific proof on how the disease is transmitted."[623] This by now quite familiar demand for "specific" and irrefutable proof to support protective governmental action is the opposite of the precautionary approach to food safety that the European Union has adopted in the wake of its mad cow disease outbreak. The industry's resistance resulted in weak feed restrictions that were riddled with critical exemptions and an anemic enforcement effort that achieved only a modest degree of compliance.

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.[624] Under the rule cattle protein may be fed to pigs and chickens, which can in turn be rendered into cattle feed.[625] 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.[626] Even the HCRA Risk Assessment cautioned that "BSE infectivity could pass through chicken and become available in cattle feed supplemented with chicken litter."[627] Nobel Laureate Stanley Prusiner has called the exemption for feeding calves cattle blood to replace the protein lost when they are prematurely weaned from dairy cattle "a really stupid idea."[628] USDA's International Advisory Panel 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."[629]

In sharp contrast, the European Union (EU) prohibits the use of any processed animal protein in feed intended for ruminants *and all farm animals which are kept, fattened, and bred for production of food*.[630] The EU rule also has a much narrower list of

---

Department of Agriculture, Technical Briefing and Webcast with U.S. Government Officials on BSE Case, , December 30, 2003, *supra*.

623 Rhodes, *Deadly Feasts*, *supra*, at 232 (quoting Don Franco).

624 21 C.F.R. § 589.2000(a)(1). *See also* Harvard Center for Risk Analysis BSE Report, *supra*, at 43; Rhodes, *Deadly Feasts*, *supra*, at 233.

625 Christopher Drew, Elizabeth Becker & Sandra Blakeslee, *Despite Mad-Cow Warnings, Industry Resisted Safeguards*, New York Times, December 28, 2003.

626 *See supra* Section IV.B.1. *See also* Stephanie Simon, *Mad Cow Case Casts Light on Beef Uses*, Los Angeles Times, January 4, 2004; Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, *supra* (quoting former USDA official Linda Detwiler).

627 Harvard Center for Risk Analysis BSE Report, *supra*, at 32.

628 Eric Schlosser, *The Cow Jumped Over the U.S.D.A.*, New York Times, January 2, 2004 (Pruisner quote); Simon, *Mad Cow Case Casts Light on Beef Uses*, *supra*; Drew, Becker & Blakeslee, *Despite Mad-Cow Warnings, Industry Resisted Safeguards*, *supra*.

629 International Panel Report, *supra*, at 8.

630 European Commission, Commission Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001, available at http://europa.eu/int/comm/food/food/biosafety/bse/ban_en.htm and www.defra.gov.uk/animalh/bse/animal-health/feedban-legislation.html#euro [last visited June 3, 2004]. Processed animal proteins include the following: meat and bone meal, meat meal, bone meal, blood meal,

exceptions.[631] An EU Council Directive further bans the use of plate waste as feed for pigs and poultry.[632] In addition, the EU has a cannibalism ban that prohibits any intra-species recycling except for fish and fur animals.[633] FDA concluded that the European experience was not especially relevant to the United States and cited the HCRA study for the proposition that the risk factors for BSE were much lower in the United States.[634]

On January 26, then-FDA Commissioner Mark McClellan announced: "Today we are bolstering our BSE firewalls to protect the public."[635] To accomplish this, "FDA will publish two interim final rules that will take effect immediately upon publication."[636] FDA would first ban from human food "a wide range of bovine-derived material so that the same safeguards that protect Americans from exposure to the agent of BSE through meat products regulated by USDA also apply to food products that FDA regulates."[637] FDA would also "prohibit certain currently allowed feeding and manufacturing practices involving feed for cattle and other ruminant animals."

The next day, *USA Today* dutifully reported that FDA "took some of its biggest steps yet to protect the American public against mad cow disease."[638] 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.[639] Three days later, the *New York Times* reported that "[o]n Monday, the Food and Drug Administration banned the use of dead or disabled cows in the products it regulates, as well as the use of brains, spinal cord, eyes and other high-risk parts from cows older than 30 months."[640] Editorials praised the agency for its

---

dried plasma and other blood products, hydrolysed protein, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatin and any other similar products including mixtures, feeding stuffs, feed additives, and premixtures containing these products. *Id*.

631 *Id*. The EU exceptions include 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. *Id*.

632 Regulation (EC) No. 1774/2002, available at http://europa.eu/int/comm/food/food/biosafety/bse/byproducts_en.htm; Council Directive on Swine Fever, available at http://europa.eu.int/comm/food/animal/diseases/controlmeasures/csf_en.htm [last visited June 3, 2004].

633 Regulation (EC) No 1774/2002, available at http://europa.eu/int/comm/food/food/biosafety/bse/byproducts [last visited June 3, 2004].

634 2002 GAO Mad Cow Report, *supra*, at 44.

635 FDA Statement 1/26/04, *supra*.

636 *Id*.

637 *Id*.

638 Elizabeth Weise, *FDA Toughens Its Mad Cow Safeguards*, USA Today, January 27, 2004.

639 *See* Denise Grady & Donald G. McNeil, Jr., *Rules Issued on Animal Feed and Use of Disabled Cattle*, New York Times, January 27, 2004 (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"); Shankar Vedantam, *Ban on Meat From "Downers" Grows*, Washington Post, January 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, January 27, 2004 (reporting that "FDA strengthened those feed rules yesterday").

640 Donald G. McNeil, Jr., *Mad Cow Disease Raises Safety Issues Beyond the Kitchen*, New York Times, January 29, 2004.

forceful action.[641] In reality, FDA did not take any regulatory action at all until July 9, 2004, and the very limited action that it did take did not fulfill its January promises.

Construed most charitably, the Administration's unqualified assertion that it was taking bold action to protect the public health at a time of high consumer uncertainty about the safety of U.S. beef represented the kind of empty political hyperbole that a cynical public has come to expect of its public officials. Given that the agency was manifestly not prepared to act on the Commissioner's promise, however, his statements could less charitably be characterized as deceptive. Despite its powerful rhetoric, FDA's leadership apparently did not believe that the risk of BSE to human health warranted quick responsive action.

The only final action that FDA took on July 9, 2004 was to issue an interim final rule banning SRMs, meat from downer cattle and mechanically separated meat product from food, cosmetics and dietary supplements.[642] This very limited action was a "no brainer" because USDA had in January made a very effective case for removing those risky materials from the meat supply. It was not likely to have a significant impact on the affected industries. Brains and other central nervous system materials were only banned if they came from cattle greater than 30 months old, and only a tiny portion of slaughtered cattle are that old. FDA estimated that the rule would have little impact at all on the food and dietary supplements industry and only a very modest impact on the cosmetics industry.[643] The primary economic impact would come from a regulation that FDA included in an accompanying notice of proposed rulemaking that would, when finalized, impose limited recordkeeping requirements on manufacturers, processors and importers of the banned materials.[644]

Instead of promulgating an interim final rule eliminating the exemptions for mammalian blood, poultry litter, and plate waste as outlined in its 2002 Advance Notice of Proposed Rulemaking and promised in January, FDA issued a second Advance Notice of Proposed Rulemaking soliciting information in response to about two dozen questions that the agency believed were raised by the USDA International Panel Report.[645] A decision to issue an Advance Notice of Proposed Rulemaking is in reality a decision not to decide. Rather than "bolstering our BSE firewalls to protect the public" by beefing up its animal feed rules, as Secretary Thompson promised, FDA elected to put off to another day, long after the upcoming November 2004 elections, additional animal feed-related protections.

---

641 *See Litter In The Feed*, St. Petersburg Times, February 11, 2004.

642 FDA Food and Cosmetics Rule, *supra*.

643 The impact on the cosmetics industry would stem from the costs entailed in switching from inedible tallow to alternative ingredients, which FDA estimated would range from $0 to $18 million. *Id*. at Table 1.

644 FDA, Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle, *supra*. FDA estimated that total first year costs would be about $1 million with recurring costs of around $187,000 per year. FDA Food and Cosmetics Rule, *supra*, at Tables 2, 3.

645 USDA/HHS BSE ANPR, *supra*.

The delay appears calculated to ensure as little disruption in the animal feed industry as possible. By putting off the promised additional restrictions on the use of mammalian protein in ruminant food,[646] FDA has preserved the rendering market for downer cattle, most of which must now be condemned under USDA's SRM Rule.[647] 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 also appears that the poultry industry has played a role in 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. That industry strongly opposed the idea of banning chicken litter from cattle feed, and it apparently convinced FDA that fertilizer markets could not easily adsorb millions of pounds of poultry litter.[648]

2. Poor Enforcement of Feed Restrictions.

As discussed previously, FDA has a very spotty record of enforcing its feed restrictions.[649] This 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.[650] Although there are indications that FDA's enforcement record has improved, 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

There is evidence that compliance with the Feed Rule is improving from the dismal performance documented by the General Accounting Office.[651] The April 2004 update on FDA and state enforcement activities under the 1997 Feed Rule reported that at the most recent inspection, only 11 firms out 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.[652] 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.[653]

---

646 *See supra* Section VIII.

647 *See infra* Section XI.E.

648 Chris McGann, *Hot Debate Over Chicken Dung In Cattle Feed*, Seattle Post-Intelligencer, April 22, 2004.

649 *See supra* Section IV.B.2.

650 Sandi Doughton, *Should U.S. follow U.K. on Mad Cow?*, *supra* (quoting Roy Smith, of the U.K. Department for Environment, Food and Rural Affairs).

651 *See supra* Section IV.B.2.

652 U.S. Food and Drug Administration, CVM Update: April 2004 Update on Ruminant Feed (BSE) Enforcement Activities (April 22, 2004), at 1, 4 [hereinafter cited as FDA Feed Rule Enforcement Update, 4/22/04].

653 *Id*. at 1,4.

Soon after the Mabton mad cow was discovered, FDA told the press that the feed manufacturing industry had achieved a 99 percent compliance rate.[654] 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.[655] This was to some extent unavoidable, because there are no FDA-approved chemical tests that can distinguish banned ruminant proteins from allowable swine proteins.[656] An agency official admitted that "the records could be perfect, but you could potentially have prohibited material in the feed."[657] FDA's claim of 99 percent compliance with its feed restrictions is also inconsistent with a March 2004 survey of FDA's records of inspections of California feed companies showing that about 40 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.[658] More troubling still, almost 20 percent of the facilities designated by FDA as "high priority" had not been inspected during that same period.[659]

State agencies, under contract with FDA, play a major role in the enforcement of the 1997 Feed Rule, conducting more than 70 percent of all inspections under that rule.[660] 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."[661] FDA has recently received a hefty increase in funding for enforcing its Ruminant Feed Rule, and it has promised to undertake 2800 inspections of renderers, protein blenders and feed mills in 2004 and to work with state agencies to fund an additional 3100 contract inspections.[662] Whether these additional resources will improve FDA's enforcement record remains to be seen.

D. The Surveillance Firewall.

USDA has since the discovery of mad cow disease in England been in a perpetual state of denial about the potential for an outbreak of BSE in the United States. In both Democratic and Republican administrations, USDA has consistently belittled the risk to

---

654 Vanessa Ho, *FDA Blasted over Past Enforcement of Feed Ban*, Seattle Post-Intelligencer, December 27, 2003; Guy Gugliotta & Dan Morgan, *Inspection Practices Examined*, Washington Post, December 25, 2003, at A16 (quoting FDA Deputy Commissioner Lester M. Crawford).

655 Ben Feller, *Mad Cow Case Renews Feed Testing Debate*, Associated Press, December 29, 2003.

656 Doughton, *Should U.S. follow U.K. on Mad Cow?*, *supra*. 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, February 24, 2004. *See also Test May Provide Safeguard Against Mad Cow*, *ABC News*, KERO-TV 23, March 10, 2004.

657 Feller, *Mad Cow Case Renews Feed Testing Debate*, *supra*.

658 Jon Ortiz, *Feed Checks Falling Short*, Sacramento Bee, March 28, 2004.

659 *Id*.

660 FDA Feed Rule Enforcement Update, 4/22/04, *supra*, at 1 (state agencies perform around 70 percent of all inspections under the 1997 Feed Rule); 2002 GAO Mad Cow Report, *supra*, at 22 (state agencies conduct more than 80 percent of all inspections under the 1997 Feed Rule).

661 2002 GAO Mad Cow Report, *supra*, at 49.

662 Crawford Testimony, 1/27/04, *supra*.

the U.S. herd of BSE infection, in later years justifying its confident assurances on the HCRA's mathematical modeling exercise.[663] Until December 2003, USDA stressed at every opportunity the "fact" that "[n]o cases of BSE have been confirmed in the U.S.A. with 13 years of active surveillance."[664] Indeed, as of the end of mid-July 2004, the USDA website still conveyed that comforting, if wholly inaccurate message.[665] As detailed below, the "13 years of active surveillance" have in fact been 13 years of careful efforts to avoid finding mad cow disease while appearing to be looking for it.

1. Insufficient USDA Surveillance.

Although FSIS is the agency within USDA with responsibility for promulgating and implementing the BSE regulations, an entirely separate agency, APHIS, is responsible for conducting the BSE surveillance program. As discussed in more detail below, this split in responsibilities has a great potential for miscommunication and disputation that can only hinder effective overall implementation of USDA's mad cow program.

APHIS has been looking for mad cow disease for a number of years, but it has not been looking nearly hard enough. Indeed, it frequently appears that APHIS has adopted a "see-no-evil" approach under which it struggles *not* to find BSE in the U.S. cattle population. On March 15, 2004, USDA yielded to strong public pressure generated by the discovery of the Mabton mad cow and announced a one-time greatly expanded surveillance plan to define the incidence of BSE in the United States.[666] These recent efforts represent a considerable improvement, at least on paper, but APHIS still has a long way to go before it can know the true extent of mad cow disease in the United States.

USDA has historically taken the position that its testing program is merely an animal health surveillance program designed to detect a one-in-a-million incidence of mad cow in the target population of downer cattle, and it is not a food safety program designed to protect the public health.[667] Consequently, in the nine years prior to 2003, APHIS had tested only about 30,000 downer animals for BSE.[668] This was in the opinion of many experts a laughably small number of cows to be testing if the Department was serious about determining the incidence of mad cow disease in the United States. Public pressure and strong advice from scientists outside of USDA forced the Department to initiate a one-time testing program of as many animals as possible, estimated to be about 200,000 to 268,000, over a 1.5 year period.[669] Although the new program is supposed to include

---

663 Harvard Center for Risk Analysis BSE Report, *supra*.

664 USDA BSE Overview, *supra*, at 2.

665 *Id*.

666 USDA, FSIS Bovine Spongiform Encephalopathy (BSE) Surveillance Plan, March 15, 2004, *supra*.

667 McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*.

668 *See supra* Section IV.A.2.b.

669 Veneman Announces Expanded BSE Surveillance Program, March 15, 2004, *supra; See also* Hileman, *Mad Cow Disease*, *supra*, at 22.

approximately 20,000 healthy looking animals of more than 30 months in age,[670] it will continue to depend upon the voluntary participation of the slaughterhouses.

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, although it is not limited completely to downer cattle and cattle exhibiting signs of CNS disorders, it will include only 20,000 normal animals, and those will be limited to older animals of greater than 30 months in age. Second, the cattle that are selected will be drawn from a population that is not representative of the entire universe of cattle being raised in the United States. 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. Fourth, there are several disturbing indications that APHIS has adopted a "see-no-evil" approach to administering its surveillance program in the past, and little indication that the agency plans to abandon that approach in the future. Finally, although the desirability of a universal testing program for all cattle or all cattle above a prescribed age is a very controversial topic, USDA has adamantly rejected any sort of universal testing approach, despite its adoption in several other countries that have experienced mad cow outbreaks.

a) Overemphasis on Downer Cattle.

APHIS has in the past designed the BSE surveillance program to focus exclusively upon testing downer cattle and cattle displaying signs of CNS disorders.[671] The recent revisions did not change the agency's overall approach to testing cattle for mad cow disease, despite the well-known fact that not all cattle suffering from BSE are old or exhibit clinical signs of BSE infection.[672] The expanded testing program announced on March 15, 2004 will test an additional 20,000 apparently healthy cattle in the category of older cattle, but that remains an exceedingly small sample. A doctor for a prominent public interest group has concluded that the expanded program "seems to be designed to give the public and would-be importers of American cattle false assurance."[673]

b) Incomplete Universe of Cattle.

As discussed above,[674] USDA concluded that complete prohibition on the use downer cattle for human consumption would provide a greater level of protection than relying exclusively upon BSE tests.[675] This sensible decision, however, complicated the

---

670 Veneman Announces Expanded BSE Surveillance Program, USDA March 15, 2004, *supra*; Hileman, *Mad Cow Disease*, *supra*, at 22.

671 McNeil, Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, *supra*; Detwiler Testimony, *supra*.

672 McNeil, Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, *supra* (noting that "some experts question the assumption that only downers are at risk, since many healthy-looking animals in Europe have tested positive").

673 Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, *supra* (quoting Dr. Peter Laurie, Public Citizen).

674 *See supra* Section VII.E.

675 USDA SRM Interim Final Rule, *supra*, at 1870.

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 and those suffering from neurological disease.[676] 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.[677] USDA lacks authority to test animals until they are physically unloaded from trucks at slaughterhouses or rendering establishments. Thus, if a producer decides to dispose of downer cattle other than by rendering, such cattle are highly unlikely to be tested for mad cow disease under the APHIS surveillance program. A producer can even avoid testing of ambulatory cattle that show signs of neurological disease at the slaughterhouse by keeping them on the truck. Indeed, anecdotal evidence exists of producers loading wobbly cattle back onto trucks before USDA inspectors could spot them.[678] Although the Department plans to use some of the $70 million re-allocated to the BSE surveillance program to providing financial incentives to owners of downer animals to present those animals for testing,[679] there will still be a strong incentive on their part to avoid testing.

c) Unscientific Selection Criteria.

The surveillance program has never been a scientifically designed random sampling program. Instead, it has historically been an almost completely voluntary hit or miss program aimed at only a very small sample of a small class of especially suspect cattle.[680] For example, a search of USDA records undertaken after the discovery of the Mabton mad cow revealed that APHIS had not tested any cattle at commercial slaughterhouses in Washington state during the first seven months of 2003 and that it had not undertaken a single BSE test in any of the six federally registered facilities in that state for the previous two years.[681] The same search disclosed that during the previous two years, BSE tests had been conducted at fewer than 100 of the 700 known slaughterhouses, that no tests had been conducted at some of the nation's largest slaughterhouses, and that only 11 percent of the tests were conducted on cattle from the states producing 70 percent of the nation's slaughtered cattle.[682] This study dramatically demonstrated that APHIS's extremely limited BSE surveillance program has historically been conducted in an entirely unsystematic way that was by no means random.[683] Noting a pattern of disproportionate testing at smaller plants, a former USDA inspector observed that "[i]t's almost like the

---

676 Doughton, *U.S. to Expand Mad-Cow Testing*, *supra*; Grady, *9 Cows Linked to Mad Cow Inquiry Have Been Found*, *supra* (quoting chief USDA veterinarian Ron DeHaven).

677 *Critics Say Voluntary Mad Cow Testing Doesn't Equal Surveillance*, *supra*.

678 Mitchell, *USDA refused to release mad cow records*, *supra*.

679 Doughton, *U.S. to Expand Mad-Cow Testing*, *supra*.

680 Shannon Dininny, *Mad Cow Surveillance System Criticized*, Boston Globe, March 15, 2004; McNeil, Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, *supra*.

681 Steve Mitchell, *No mad cow tests in Wash.*, United Press International, January 15, 2004.

682 *Id*.

683 McNeil, Jr., *Doubling Tests for Mad Cow Doesn't Quiet Program Critics*, *supra* ("Critics say the current testing program is unscientific because so many plants are not included.).

USDA wants to protect the big plants from a finding because the implications would be too scary."[684]

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.[685] In June 2003, APHIS offered to pay Vern's $10.00 apiece for samples from the brains of up to 1000 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 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.[686] Vern's employees took a total of 258 samples from October through December 2003.

Other sources reveal that after expanding the program to 20,000 animals in 2002, USDA had such difficulty persuading companies to participate in the voluntary program in the Northwest that it failed to meet its numerical goals for that region.[687] 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 1,608 animals from 3,064 in December 2003.[688]

Under the expanded BSE surveillance program that USDA announced on March 15, 2004, USDA will attempt to test as many downer cattle as it can locate during the twelve to eighteen months that the program is in existence. The Department said that it would attempt to make the tests geographically representative, but it did not say that it would attempt to obtain a statistically valid sample. Since the program still remains voluntary, it is hard to see how it could be conducted randomly. Senator Tom Harkin challenged Secretary Veneman to demonstrate that the expanded one-time BSE surveillance program was in fact statistically valid. He observed that "[t]he plan seems to be dictated primarily

---

684 Mitchell, *No mad cow tests in Wash.*, *supra*.

685 Affidavit of Thomas A. Ellestad, February 9, 2004, at 3 [hereinafter cited as Ellestad Affidavit].

686 Testimony from FSIS inspectors suggests that APHIS commonly allows the slaughterhouses to choose the animals to be tested. Sandi Doughton, *Groups Urge Expanded Mad-Cow Protections*, *supra* (quoting USDA inspector Paul Carney).

687 Sandi Doughton, *Number Of Mad-Cow Tests In NW Didn't Reach Federal Agency's Goal*, Seattle Times, February 24, 2004. FSIS inspectors can also sample the brains of suspect cattle and send the those samples to APHIS laboratories for testing, but only if APHIS agrees to accept them. *See infra* Section XI.D.1.d. However, these samples are also 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.

688 Dininny, *Mad Cow Surveillance System Criticized*, *supra*.

by how many cattle USDA wants to test, rather than by the number that would have to be tested, using statistical methods, to reach accurate and reliable conclusions."[689]

The expanded program will test 20,000 apparently healthy cattle of greater than 30 months of age, but these animals will be selected from the 40 slaughterhouses that process most of the older dairy cattle.[690] The Department would not reveal the names of the companies because it feared that it would make the companies less cooperative.[691] Although 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.[692] And 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. aged cattle population. It is also not at all clear why USDA has limited the expanded testing program for 20,000 non-suspect cattle to older cattle. As discussed above, BSE has been detected in cattle much younger than 30 months of age, and the exclusive focus on older cattle will rule out such younger cattle.[693] 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.[694]

d) Disturbing Indications of a "See No Evil" Policy.

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.[695] This reaction to the first positive BSE sample in the history of the program could hardly be characterized as "science-based." 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. Instead, APHIS ensured that any outbreak would go undetected by discontinuing the testing program at the Vern's facility.

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

---

689 Jerry Hagstrom, *Senator Challenges USDA Mad Cow Testing Plan*, National Journal's Congress Daily, May 11, 2004.

690 Doughton, *U.S. to Expand Mad-Cow Testing*, *supra*.

691 Steve Mitchell, *No Mad Cow Tests at Texas Firm in 2004*, United Press International, May 14, 2004 (quoting Ron DeHaven, Chief Veterinarian, USDA).

692 Doughton, *U.S. to Expand Mad-Cow Testing*, *supra*.

693 Consumers Union, Press Release, USDA Announcement of More Mad Cow Testing Still Inadequate to Protect Public Health, March 16, 2004.

694 Senator Harkin notes 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. Hagstrom, *Senator Challenges USDA Mad Cow Testing Plan*, *supra*.

695 Ellestad Affidavit, *supra*, at 3-11.

for slaughter.[696] A mystified consumer advocate speculated that "You would think that given the area where the animals [in the mad cow's birth herd] were located after they came from Canada, there'd be every reason to focus attention on auctions and slaughterhouses in that part of Washington."[697] USDA's refusal to test was especially curious at a time when only 13 of the 81 animals in the birth herd had been accounted for.[698]

In the wake of the discovery of the Mabton mad cow, several FSIS inspectors expressed considerable frustration over the performance of the APHIS laboratory at Ames, Iowa, claiming that it was quite secretive and had a history of producing ambiguous and conflicting results.[699] The tension between the two agencies had grown so high that one FSIS veterinarian reported that APHIS employees seldom bothered to pick up brains from suspect cattle that were under 30 months of age.[700] Another FSIS veterinarian reported that many of his colleagues did not seriously attempt to sample brains from suspect animals any more because they believed there was little chance that the APHIS laboratory would report a positive result if it found one.[701]

A recently reported APHIS response to a BSE testing request from a Texas FSIS inspector provides even stronger evidence that APHIS is pursuing a "see no evil" policy with respect to the incidence of mad cow disease in this country. 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.[702] 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.[703] The cow was then rendered into feed for pigs without ever being tested for BSE.[704] This constituted a clear, but unexplained breach of USDA protocol for testing animals with signs of CNS disorder.[705] The 12-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.[706] Since the animal's brain was not preserved for testing, the question whether the cow was in fact BSE-positive will never be answered.[707]

---

696 Ray Rivera, *Hunt for infected cows leaves out "slaughter auctions"*, Seattle Times, January 15, 2004.

697 *Id*.

698 *Id*.

699 Steve Mitchell, *USDA Vets Question Agency's Mad Cow Lab*, United Press International, February 9, 2004.

700 Steve Mitchell, *USDA Vet: Texas Mad Cow Breach Not Unique*, United Press International, May 4, 2004.

701 Mitchell, *USDA Vets Question Agency's Mad Cow Lab*, *supra*.

702 Richard Cowan, *USDA: Mad Cow Testing Procedure Violated in Texas*, Reuters, May 3, 2004.

703 Donald G. McNeil Jr., *Calls for Federal Inquiry Over Untested Cow*, New York Times, May 6, 2004; Steve Mitchell, *Only 3 Mad Cow Tests Done At Texas Firm*, United Press International, May 4, 2004.

704 Hileman, *Mad Cow Disease*, *supra*, at 24.

705 Mitchell, *Only 3 Mad Cow Tests Done At Texas Firm*, *supra*.

706 Richard Cowan, *FDA Links Condemned Texas Cow, Pre-Ban Type Feed*, Reuters, May 6, 2004.

707 Suzanne Gamboa, *Federal Officials OK Texas Cow Material For Swine Feed*, Seattle Post-Intelligencer, May 4, 2004; Mitchell, *USDA Vet: Texas Mad Cow Breach Not Unique*, *supra*. The media

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."[708] On the very next day, however, USDA's Dallas district office issued a gag order forbidding all Texas employees to discuss the San Angelo cow with the press and instructing them to refer all inquiries to the USDA Congressional Public Affairs office.[709]

e) USDA's Adamant Opposition to Universal Testing.

Despite its reluctant and gradual movement toward more comprehensive BSE testing, USDA remains adamantly opposed to universal testing, even of the subcategory of animals more than 30 months old.[710] In response to Japan's insistence that USDA follow Japan's practice of testing all cattle, Secretary Veneman testified to the House Agriculture Committee that "testing of all animals is not based on sound science."[711] Secretary Veneman's invocation of "sound science" in this context, however, is puzzling. Dr. Stanley Prusiner, who won the Nobel Prize for his work in identifying the mad cow prion, remains convinced that eventually every cow should be tested.[712] At a cost of a few pennies per pound of beef, Pruisner concludes that the added security that universal testing would provide is easily worth the cost.[713]

USDA trade advisor David Hegwood probably came closer to disclosing the real reason for the Department's refusal to order universal testing 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."[714] The question

---

later discovered that although the San Angelo plant was the eighteenth largest slaughterhouse in the U.S., only three 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, *Only 3 Mad Cow Tests Done At Texas Firm*, *supra*. USDA explained that BSE tests had not been performed at the plant in recent months because the plant no longer accepted downer cattle. Mitchell, *No Mad Cow Tests at Texas Firm in 2004*, *supra*.

[708] Memorandum to VSMT, Regional Directors/AVICs, Veterinary Services from John R. Clifford and William Smith re: Policy statement regarding BSE sampling of condemned cattle at slaughter plants -- for immediate implementation, dated May 5, 2004.

[709] Steve Mitchell, *USDA Orders Silence On Mad Cow in Texas*, United Press International, May 11, 2004.

[710] McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra* (quoting Dr. Ron DeHaven).

[711] *USDA Veneman Sees No Need for Blanket Mad Cow Tests*, Reuters, January 21, 2004.

[712] Charles Abbott, *Test All Cattle To Be Safe From Mad Cow-Nobelist*, Reuters, January 28, 2004 ("Only the Japanese solution of testing every slaughtered cow or bull will eliminate prions from the food supply and restore consumer confidence"); Blakeslee, *Expert Warned That Mad Cow Was Imminent*, *supra*. This advise may have reflected the fact that Dr. Pruisner had patented through his university an inexpensive test for mad cow disease in cattle tissue. *Id.*

[713] Hileman, *Mad Cow Disease*, *supra*, at 22.

[714] Abbott, *Test All Cattle To Be Safe From Mad Cow-Nobelist*, *supra*.

whether an additional test is "scientifically *necessary*" is not the same as whether it is *desirable* from a scientific perspective. Science is generally hungry for data because every additional valid data point can enhance understanding. The question of 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 otherwise go to 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.

The USDA's chief veterinarian explained that universal testing would be "like a doctor testing every patient who comes through the door for prostate cancer."[715] This is not a "scientific" objection to universal testing, but it is a reasonable economic efficiency-based objection. The analogy, however, seems inappropriate. While prostate cancer is, like mad cow disease, a devastating affliction, a single case of prostate cancer in a human being cannot be spread to hundreds or even thousands of other human beings. A single case of mad cow disease can result in the spread of infectious prions to hundreds or thousands of consumers of meat derived from that cow.

In any event, it would appear that 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. 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.

f) Testing requirements in Other Countries.

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 to release for human consumption.[716] The European Union in 2000 mandated testing of all cattle over 30 months old for BSE.[717] The EU also requires

---

715 McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra* (quoting Dr. Ron DeHaven).

716 *See* Blakeslee, *Mad Cow Disease in the United States: Expert Warned that Mad Cow was Imminent*, *supra*, and Yoshio Yamakawa, *et al.*, *Atypical Proteinase K-Resistant Prion Protein (PrPres) Observed in an Apparently Healthy 23-Month-Old Holstein Steer*, Japanese Journal of Infectious Disease, No. 56, 2003.

717 Community Legislation on BSE, Chronological List, available at http://europa.eu.int/comm/food/fs/bse/bse15_en.pdf. *See generally* Frequently Asked Questions about BSE-Tests, available at http://europa.eu.int/comm/food/food/biosafety/bse/m04_113_en.pdf.

testing of all downer cattle of greater than 24 months old.[718] Germany, Italy and France all test for BSE in all cattle older than 24 months prior to slaughter.[719] This amounts to about one in every four animals slaughtered.[720] Thus, France tests more cows in one week than the United States tested in the decade prior to 2004.[721]

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.[722] 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 30 months old 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.[723] This represents a real, if highly disturbing, contribution to the scientific understanding of TSEs.

g) Conclusion.

The fundamental underlying problem with 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."[724] The APHIS testing program may be reasonably effective as a surveillance program to determine the incidence of mad cow disease in the 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, merely expanding the number of animals tested for a brief interval will not yield an adequate testing program.

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

As described above, USDA flatly rejected a petition by Creekstone Farms to conduct universal testing of its cattle at a $500,000 on-site testing laboratory and threatened the

---

718 Frequently Asked Questions about BSE-Tests, available at http://europa.eu.int/comm/food/food/biosafety/bse/m04_113_en.pdf; *See generally* Questions and Answers on BSE, available at http://europa.eu/int/comm/food/food/biosafety/bse/mo3_3_en.pdf [last visited June 4, 2004].

719 TSE Forum, Frequently Asked Questions, available at http://www.tse-forum.de/tse_forum/englisch/offentlich/start_offentlich.htm (Germany); Xinhua News Agency, *Mad Cow Cases Increase to 62 in Italy*, Xinhua General News Service. World News, April 30, 2002 (available on Lexis Allnews database) (Italy); French Agriculture BSE webpage, available at http://www.agriculture.gouv.fr/esbinfo/esbinfo.htm (France).

720 Sandra Blakeslee, *Jumble of Tests May Slow Mad Cow Solution*, New York Times, January 4, 2004.

721 *Id*.

722 Donald G. McNeil Jr., *Research in Italy Turns Up a New Form of Mad Cow Disease*, New York Times, February 17, 2004.

723 *Id*.; *New Form Of Mad Cow Disease Found*, New Scientist, February 17, 2004.

724 Diedtra Henderson, *USDA's Selective Screens Aren't Enough, Say Some Firms, Scientists*, Denver Post, May 31, 2004.

company with criminal prosecution if it went ahead with its universal testing program.[725] Despite the fact that it has recently licensed five new "rapid test" kits for testing tissue for BSE,[726] USDA justifies its adamant refusal to allow companies voluntarily to engage in universal testing of their cattle on the ground that universal testing is not "sound science."[727]

The Department's obstinate opposition to an effort to gather more information about a little understood phenomenon is, however, incomprehensible from a scientific perspective. As Professor David Westaway, a molecular biologist and prion specialist at the Centre for Research in Neurodegenerative Diseases at the University of Toronto, explains, "tests are better than no testing" because testing is necessary "to get the prevalence."[728] By no means a consumer activist, Dr. Westaway expects that it is "unlikely we have an enormous epidemic -- but we don't know what's out there," and testing will tell us that.[729] As discussed above, universal testing in Italy has contributed to the scientific understanding of the relationship of BSE to CJD as well as to an understanding of the prevalence of BSE.[730]

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 USDA to be so confident in its assessment that it is unwilling to abide 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 if the word got out to U.S. trading partners, the current import restrictions could be extended and new restrictions imposed.[731] The companies advocating universal testing, however, are willing to allow USDA or some other agency to confirm the tests to ensure against false positives.[732] 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 USDA.[733] This objection seems specious for several reasons. First, until

---

725 Hileman, *Mad Cow Disease*, *supra*, at 24; Kaufman, *Company's Mad Cow Tests Blocked*, *supra*. *See supra* Section VII.H.

726 Hileman, *Mad Cow Disease*, *supra*, at 23.

727 *Id*. at 25 (quoting USDA spokesperson Jim Rogers). *See also* Kaufman, *Company's Mad Cow Tests Blocked*, *supra* (head of APHIS says that the agency will "stick to the science").

728 Nikiforuk, *North Americans Haven't Tested Rigorously Enough For Mad-Cow Disease*, *supra*.

729 *Id*.

730 *See supra* Section XI.D.1.f.

731 Simon, *U.S., Some Ranchers Clash Over Mad Cow Tests*, *supra* (quoting USDA spokesperson Jim Rogers).

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

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

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, 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.

In the final analysis, it seems clear that the real reason that USDA is willing to threaten companies that voluntarily test for mad cow disease with criminal prosecution has much more to do with the economic well-being of the five huge companies that control 84 percent of the meatpacking market than with the efficiency with which USDA or consumers allocate their resources.[734] The larger companies, which primarily serve domestic markets, did not see any drop in demand for their products after the discovery of the Mabton mad cow and could therefore keep prices steady while at the same time paying less to producers for cattle in markets depressed by reduced exports.[735] 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 give rise to U.S. consumer expectations that domestic meat has been tested, and this would create consumer pressure on larger companies to engage in universal testing.[736] 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."[737] The dominant companies in any industry are, of course, always concerned about innovative competitors, 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.[738] 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.[739]

One way to prevent "upstart" companies like Creekstone Farms from intruding into a comfortable market is to pressure USDA to prevent them from exercising their acumen and competitive instincts by testing every animal for BSE.

---

734 Hileman, *Mad Cow Disease*, *supra*, at 23 (quoting John Stewart, CEO of Creekstone Farms).

735 Scott, *For Some in Beef Industry, Mad-Cow Disease "Almost a Windfall"*, *supra*.

736 Hileman, *Mad Cow Disease*, *supra*, at 25.

737 Donald G. McNeil, Jr., *Niche Meatpacker Is Cut Off From Its Best Markets*, New York Times, April 18, 2004.

738 *Id*.

739 Boyle Interview, *supra*, at 4.

Ultimately, USDA's obstinacy may harm all U.S. cattle interests other than the big five slaughterhouses. If USDA allows universal testing, the specialty beef producers who are willing to test for BSE will stay in business, and increased export markets will increase prices for domestic cattle. It is also possible that private companies will conduct testing more efficiently than USDA. The CEO of Creekstone Farms suggests that "[t]he American people should be outraged that the government is going to spend $72 million to test 220,000 animals -- about $300 per animal -- when we are going to do it for $20 per animal" and pass the cost on to Japanese consumers.[740] As Creekstone Farms lays off employees and careens toward bankruptcy as a result of USDA's inexplicable determination to protect the big five meat producers, Australian beef producers are rapidly establishing themselves, perhaps inextricably, in Japanese meat markets.[741]

E. The Downer Cattle Firewall.

In the recent past, more that 150,000 downer cattle per year have been consumed by human beings without being tested for BSE.[742] The new SRM Rule, however, requires that all non-ambulatory cattle that are presented to a slaughterhouse be condemned. Assuming that this prohibition on the use of non-ambulatory cattle in human food is adequately enforced (perhaps an optimistic assumption given the pressures on FSIS inspectors), it represents a reasonable and long overdue precautionary requirement that will help protect human health. It was, however, the obvious thing to do. Several states had already banned the sale for human consumption of meat from downer cattle, many of the large restaurant chains (e.g. McDonalds and Wendy's) had eliminated meat from downer cattle from their product lines, and USDA itself had in 2001 decided not to use meat from downer cows in its school lunch program.[743]

The fact that it took an actual outbreak of mad cow disease to motivate the Department to institute the ban speaks volumes about the power of the beef industry to dictate regulatory policy in both the Executive Branch and Congress. The industry vigorously opposed legislation banning downer cattle in human food for more than a decade.[744] USDA had only recently denied a 1998 petition from an animal rights group, Farm Sanctuary, to condemn downer cattle, and a court of appeals had just agreed, over the government's opposition, to hear the group's challenge to that action.[745] Congress had considered and both houses had approved a ban on downer cattle in the two years prior to 2004, but the

---

740 Hileman, *Mad Cow Disease*, *supra*, at 25.

741 *Beef Exports to Japan on the Rise*, ABC Online, 10 June 2004 (reporting that Australia is now supplying 90 percent of Japan's imported beef); McNeil, Jr., *Niche Meatpacker Is Cut Off From Its Best Markets*, *supra*.

742 Michael Moss, Richard A. Oppel Jr. & Simon Romero, *Mad Cow Forces Beef Industry to Change Course*, New York Times, January 5, 2004.

743 Johanna Neuman & Edwin Chen, *Hunt on to Trace Diseased Animal*, Los Angeles Times, December 27, 2003 (restaurant bans); Judy Pasternak, *Disease Heightens Beef Debate*, Los Angeles Times, December 26, 2003 (state bans, USDA ban).

744 Eric Pianin & Guy Gugliotta, *Banning Sale of 'Downer' Meat Represents a Change in Policy*, Washington Post, December 31, 2003, at A6.

745 Pasternak, *Disease Heightens Beef Debate*, *supra*.

industry vigorously opposed the legislation on the ground that it was not sufficiently "risk-based." Industry lobbyists persuaded the leadership of the House Agriculture Committee to block both pieces of legislation in Conference Committee.[746] Ironically, a 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.[747]

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, it is clear as a scientific matter that mad cow disease is not limited to nonambulatory cattle or even to cattle displaying signs of CNS disorders. Tests in Japan and Italy, for example, have found healthy appearing animals to be BSE-positive.[748]

Second, it is not always easy to identify a downer animal. There is in fact an ongoing debate over whether the Washington Holstein was a downer cow.[749] 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.[750] The USDA inspector at the plant apparently approved the animal for slaughter because it showed no signs of disease or injury.[751] USDA's Chief Veterinary Officer has conceded that it is possible for a nonambulatory animal to "recover ambulation" prior to slaughter.[752] Interpretational questions will inevitably arise at the margins in determining the "downer" status of suspect animals. 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.[753] Pointing out that many downer cattle are merely lame,[754] the industry is pressing for a clearer definition of

---

746 Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, *supra*.

747 Pasternak, *Disease Heightens Beef Debate*, *supra*.

748 McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*.

749 Steve Mitchell, *USDA Vet Says Mad Cow Was a Downer*, United Press International, March 17, 2004.

750 Sarah Linn, *Man Who Says He Killed Mad Cow Challenges USDA*, Seattle Post-Intelligencer, February 3, 2004; Matthew Weaver, *People Close to Mad Cow Question USDA's Downer Position*, Columbia Basin Herald, January 27, 2004; Shankar Vedantam, *U.S. Recalls Meat Linked To Wash. Slaughterhouse*, Washington Post Staff, December 25, 2003, at A1.

751 Vedantam, *U.S. Recalls Meat Linked To Wash. Slaughterhouse*, *supra*.

752 Vedantam, *U.S. Recalls Meat Linked To Wash. Slaughterhouse*, *supra*. As a result of differences in the testimony of Vern's employees and the official USDA report on the BSE-positive cow, USDA's Inspector General has launched a criminal investigation to determine whether official documents had been forged. Phuong Cat Le, *U.S. Opens Criminal Investigation Into Mad Cow Case*, Seattle Post-Intelligencer, March 4, 2004; Donald G. McNeil Jr., *Official Tells of Investigation Into Mad Cow Discrepancies*, New York Times, March 4, 2004.

753 Elizabeth Weise, *Cattle Slaughter Rules Yield Few Easy Answers*, USA Today, February 9, 2004.

754 McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*; Pasternak, *Disease Heightens Beef Debate*, *supra*.

"downer" that would exclude animals that suffer from physical ailments, such as broken limbs, that clearly have no relationship to mad cow disease.[755]

Third, a strict ban, without more, does not solve the problem of what to do with the downer cattle once they are condemned.[756] The ban may have the perverse effect of encouraging producers to slaughter downer cattle themselves and sell or give away the meat locally. Failing that, they may simply dispose of them on the premises. It is generally lawful to dispose of dead cattle by burying them so long as sufficient cover is provided.[757] Sadly, in rural areas where state enforcement budgets are low another option is to leave downed cows by the side of an isolated stretch of road.[758]

Fourth, in requiring that diseased nonambulatory animals be condemned and kept out of human food, USDA failed to require that brains from all such animals be tested for mad cow disease.[759] If the reason for such drastic action, which has serious adverse economic consequences for the owner of the condemned animal, is the risk that the cow is a carrier of mad cow disease, it makes sense to find out for sure by conducting a quick and relatively inexpensive test on the animal.[760]

---

755 *See* Jo Dee Black, *Rehberg Wants Downer Cattle Redefined*, Great Falls Tribune, May 18, 2004 (Rep. Rehberg introduced legislation redefining "downer"); Frederic J. Frommer, *USDA Urged to Weaken Ban on Disabled Cows*, Los Angeles Times, May 16, 2004 (reporting comments of many states and cattle groups); Letter to FSIS Docket Clerk from Anne B. Tantum, Association Manager, Pennsylvania Association of Meat Processors, dated April 4, 2004 ("the ban should not extent to animals that have injuries such as broken extremities or injuries suffered during birthing"); Letter to FSIS Docket Clerk from Philip Nelson, President, Illinois Farm Bureau, dated February 29, 2004 (cattle that have broken a limb during transport should not be included in definition of "downer" cattle).

756 A professor of veterinary medicine at the University of California, Davis 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." Pasternak, *Disease Heightens Beef Debate*, *supra*.

757 An overview of the Minnesota animal disposal rules relates that burying dead animals is a lawful option:

Burying- carcass must be buried 5 feet above seasonal high water table and covered by dirt. Sandy and gravelly areas within 10 ft of bedrock and areas subject to flooding should be avoided. Do not place near lakes, ponds, rivers, streams, wetlands, ditches, or wells. Recommended for small amounts of materials, not for large facilities/operations with catastrophic losses. All sites should be marked for safety. Minnesota regulations- accessed on Minnesota Board of Animal Health website www.bah.state.mn.us/animals/carcass%20disposal/carcass_disposal.htm (updated June 2004).

An overview of the Missouri Dead Animal Disposal Law provides that "onsite burial" is an "acceptable disposal method" for animal carcasses, but recommends against it "due to potential water pollution." When it is employed, "[d]ead animals must be immediately covered with a minimum of 6 inches of soil, and a final cover of a minimum of 30 inches of soil." Missouri Dead Animal Disposal Law- outlined in Missouri Water Quality Initiative publication WQ216, available at website http://muextension.missouri.edu/xplor/envqual/wq0216.htm.

758 Shannon Dininny, *Mad-cow likely to force higher rendering costs*, Seattle Times, January 26, 2004 (relating discovery of dozens of dead cattle along rural Washington roadside).

759 *See* Editorial, *Testing All Beef*, Boston Globe, January 3, 2004 (Failure to require testing of all downer cattle "forfeits a chance to monitor the pervasiveness of the disease").

760 *See supra* Section XI.D.1.e.

Finally, the ban still allows downer cattle to be sold to renderers for processing into feed for nonruminants and other products. As previously discussed, "condemnation" can be accomplished through technologies (incineration and denaturing) that will destroy mad cow prions, but it can also be accomplished by simply rendering condemned animals into protein for animal feed.[761] If, as should usually be the case, the owner elects the second option, the protein, with mad cow prions still intact, may be fed to poultry and pigs, the protein of which may be rendered into cattle feed. In addition, poultry litter containing bits of unconsumed poultry feed may be rendered into cattle feed. FDA could eliminate this route of transmission of mad cow disease from downer cows to healthy cows by amending its feed rule, but it has not yet done so.[762]

F. The SRM Restrictions Firewall.

The SRM firewall was an attempt to protect human food from especially risky materials found in cattle that might be infected by mad cow disease. Keeping risky material out of the food supply is a commendable ideal if the universe of risky material is properly identified and if the restrictions are effective. Unfortunately, the requirements that FSIS enacted in January 2004 meet neither of these conditions. They define "specified risk material" far too narrowly, much more narrowly than most other countries that have experienced mad cow disease outbreaks, and they are written as highly flexible "performance standards" that give the operators of slaughterhouses and meat processing establishments far too much leeway in deciding how to comply with their 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."

The regulations prohibit the use in human food of "specified risk material," which, among other things, includes brain, skull, eyes, trigeminal ganglia, and spinal cord of cattle more than 30 months old, and tonsils and lower intestines of all slaughtered animals.[763] USDA's conclusion that BSE "infectivity has been confirmed" in these materials is well-supported in the existing science. The regulations, however, contain two significant loopholes that should give pause to consumers of beef and beef products.

a) <u>The 30-Month Loophole.</u>

761 *See supra* Section VII.E.

762 *See supra* Section IV.B.1.

763 *See supra* Section VII.B.

The loophole for cattle less than 30 months old is not well supported in the existing literature. Infected animals may not show clinical signs of the disease until long after they have become infected.[764] USDA's analysis of data from the mad cow outbreak in England found "a gradual increase in the number of clinical BSE cases with increasing age," with a peak at 5 years of age.[765] The age at which potential infectivity should be sufficient to warrant regulatory action, however, is a topic for legitimate scientific and debate. Unfortunately, not enough is known about TSE as a strictly scientific matter 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 under 30 months of age.[766] In Japan, where all cattle are tested for BSE prior to slaughter, animals aging only 21 and 23 months have tested positive for BSE,[767] and USDA expressed some concern about these reports in the preamble to the SRM rule.[768] Other countries, including England and Slovakia have reported detecting BSE in cattle younger than 24 months.[769]

The preamble to the SRM Rule attempts 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 for sufficiently long that it is highly unlikely that an animal of less than 30 months in age will be BSE-positive.[770] This explanation, however, is unpersuasive. While it may be true that younger cattle pose fewer risks, they are not risk-free.[771] Indeed, 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 "specified risk material" to include "brain and spinal cord from cattle aged 24 months and older and downer cattle regardless of age."[772] 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 FDA's own monitoring indicates that compliance with its feed restrictions has been spotty.[773] The preamble does not explain why U.S. consumers should be intentionally subjected to such a high-consequence risk, even if the probability is low.

---

764 Harvard Center for Risk Analysis BSE Report, *supra*, at 36.

765 USDA SRM Interim Final Rule, *supra*, at 1863.

766 Center for Science in the Public Interest, CSPI Reacts to New BSE Safeguards, Press Release, December 31, 2003.

767 *See* T. Ling Chwang, *Mad Cow Demands Respect*, Dallas Morning News, January 2, 2004.

768 USDA SRM Interim Final Rule, *supra*, at 1863 (noting that "[t]he lower ranges of this age distribution include some cattle younger than 30 months of age").

769 Blakeslee, *Jumble of Tests May Slow Mad Cow Solution*, *supra*.

770 USDA SRM Interim Final Rule, *supra*, at 1864.

771 *See* Letter to FSIS Docket Clerk from Karen L. Egbert, Center for Science in the Public Interest, dated April 7, 2004 (taking the position that a 12-month age cutoff should be employed in defining SRM); Letter to Docket Clerk from Steven Roach, Food Animal Concerns Trust, dated April 9, 2004 (same).

772 USDA Current Thinking Paper, *supra*, at 11.

773 *See supra* Section IV.B.2.

FSIS appears to have engaged in an implicit cost-benefit analysis in deciding to draw the line at 30 months rather than at 12 or 24 months. The FMIA, however, does not allow FDA to determine whether food is adulterated on the basis of cost-benefit considerations. Under the statute meat is adulterated if it contains a deleterious substance that "*may* render it injurious to health."[774] Meat is also adulterated if it is "unhealthful, unwholesome or unfit for human food."[775] That it may cost a lot to remove a deleterious substance from food or to render food fit for human consumption is clearly not a factor that the statute allows FSIS to consider.

Given the high infectivity of the tissues that FSIS has identified in the SRM rule, FSIS has determined that such tissues are "unfit for human food" when they come from animals greater than 30 months of age. Since the same tissues can be infective when they come from cattle less than 30 months of age, there is no good reason why they should not be considered unfit for human food as well so long as they pose a credible risk to humans. Although 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.

b) <u>The Bone Marrow Loophole.</u>

FSIS's failure to include bone marrow in the definition of SRM is not well justified. The agency recognized that one study had shown that bone marrow from infected cattle could spread mad cow disease, but it concluded that the findings of that study were "not conclusive."[776] At the same time, the AMR rule did limit the presence of bone marrow in meat produced by AMR systems. That requirement, however, was "not a food safety measure" but was instead "related to misbranding."[777] 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 statute requires only that the meat contain a deleterious substance that "*may* render it injurious to health."[778] Meat is also adulterated if it is "unhealthful, unwholesome or unfit for human food."[779] Meat that may be contaminated with BSE prions may be unhealthful, unwholesome or unfit," even if it has not been shown conclusively to be infective. Given even a small risk of contracting BSE from bone marrow, there is no plausible rationale for FSIS's failure to include it in the definition of SRM other than cost-benefit considerations, which, as discussed above, are not appropriately considered in determining whether food is "adulterated."

2. Zero Tolerance with Maximum Flexibility.

---

774 21 U.S.C. § 601(m)(1).

775 *Id*. § 601(m)(3).

776 USDA SRM Interim Final Rule, *supra*, at 1864.

777 *Id*.

778 21 U.S.C. § 601(m)(1).

779 *Id*. § 601(m)(3).

In addition to shifting from USDA's traditional "organoleptic" approach to a heavier reliance on scientific analysis and testing, the 1996 HACCP regulations also represented a major move away from what critics had called a "command and control" regulatory approach to "performance-based" regulation. The preamble to the HACCP regulations explained that "[p]erformance standards . . . prescribe the objectives or levels of performance (such as pathogen reduction standards for raw product) establishments must achieve, but afford establishments flexibility in determining how to achieve those performance objectives."[780] At the same time, performance standards "rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety."[781]

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.[782] The SRM Rule gives establishments "the flexibility to implement the most appropriate procedures that will best achieve"[783] its zero-tolerance performance standard for SRM through HACCP plans, Sanitation SOPs or prerequisite programs.[784] The primary constraint on that flexibility is the rule's insistence that the part of the plan devoted to SRM be committed to writing.[785]

At the core of the performance-based HACCP program is a company-prepared plan for ensuring that critical limits are not exceeded at critical control points. Although the operator bears the initial responsibility for identifying the critical control points, setting the critical limits and monitoring for exceedences, the plan and major revisions to the plan must ultimately be approved by FSIS.[786] Sanitation SOPs and other prerequisite programs, by contrast, do not require FSIS approval.[787] As discussed above, there is no

---

780 USDA HACCP Final Rule, *supra*, at 38817.

781 *Id*. at 38818.

782 Fox, *Spoiled*, *supra*, 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." NAS Safe Food Report, *supra*, 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. Fox, *Spoiled*, *supra*, at 258. 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 0157:H7: Reviewing the Role of Pathogen Testing in HACCP (February 29, 2000), available at http://www.cspinet.org/foodsafety/fsis_policy.html (last visited February 20, 2004); CRS Issue Brief 8/1/03, *supra*, at CRS-5 (relating support for HACCP of the Center for Science in the Public Interest and Safe Tables Our Priority).

783 USDA SRM Interim Final Rule, *supra*, at 1869.

784 9 C.F.R. § 310.22(d)(1).

785 *Id*. § 310.22(d)(1).

786 *See supra* Section on XI.F.2.a.2.

787 Email to Elizabeth Duffy from Jennifer Beasley-McKean, Staff Officer, Technical Assistance & Correlations, Technical Service, Food Safety and Inspection Service, Omaha, Nebraska, dated March 24, 2004, at 2, [hereinafter cited as Beasley-McKean/Duffy Email, 3/24/04] ("Inspectors do not 'approve' GMPs or other written prerequisite programs."). *See also* USDA HACCP Final Rule, *supra*, at 38832 ("FSIS will not approve Sanitation SOP's"); *id*. at 38834 ("FSIS inspectors will not be tasked with directing an establishment's sanitation procedures, nor with "approving" the establishment's Sanitation SOP's.").

legal requirement that companies adopt any particular approach to writing and implementing prerequisite programs.

Despite its theoretical advantages, it is not at all clear that the HACCP process, as currently implemented, is up to the task of preventing human beings from contracting vCJD from meat from mad cows. First, the HACCP approach incorporates the notion of "prerequisite programs" for which no critical control points are identified and for which no quantitative critical limits are established. Second, because the primary culprits addressed by USDA's HACCP regulations are well-understood microorganisms that can be eliminated by properly cooking the product, the regulations have a high tolerance for imperfection. Third, by failing to prescribe the performance and measurement criteria that are essential to a functional performance-based regime the SRM rule has created a verification vacuum that may effectively render it unenforceable. Fourth, the flexibility of HACCP programs, and especially the prerequisite programs envisioned by the HACCP regulations, leaves the regulated establishments with far too much discretion to draft and implement their own procedures for removing SRMs from meat. Fifth, the consequences of repeated failure to remove SRMs from meat products are so minimal and the likelihood of getting caught is so low that SRM-contaminated meat is virtually certain to enter the food supply in substantial amounts under those regulations. Sixth, the SRM rule appears to allow a slaughterhouse to shift responsibility for removing SRMs from its meat to downstream meat processors when its product will undergo further processing prior to sale. Seventh, the performance-based approach does not take into account the very real impediments that FSIS inspectors face in trying to enforce a performance-based legal requirement. Finally, there may be some lingering uncertainty over the agency's legal authority to adapt a flexible performance-based approach to the mad cow problem.

a) Industry Reliance on Prerequisite Programs.

(1) The Industry's Choice of Prerequisite Programs and Sanitation SOPs over HACCP.

The SRM Rule requires establishments to "develop, implement, and maintain 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.[788] 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 speak directly to this choice.

The HACCP regulations require each establishment to conduct a hazard analysis to determine the "food safety hazards reasonably likely to occur in the production process."[789] HACCP plans must specify control measures for every food safety hazard that the hazard analysis determines is "reasonably likely to occur."[790] The regulations go

788 9 C.F.R. § 310.22(d)(1).

789 *Id*. § 417.2(a)(1).

790 *Id*. § 417.2(b), (c). *See* United States Department of Agriculture, Food Safety and Inspection Service, Review of Establishment Data by Inspection Program Personnel, 69 Fed. Reg. 24556 (May 4, 2004), at 24556-57 [hereinafter cited as USDA Establishment Data Review Notice] ("Whenever a hazard

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."[791] Establishments must "reassess the adequacy" of their HACCP plans "whenever any changes occur that could affect the hazard analysis or alter the HACCP plan."[792]

The preamble to the SRM Rule states that "FSIS expects that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with" the HACCP reassessment requirements "to address SRMs."[793] According to a widely circulated FSIS Notice, its inspectors must to verify that each establishment dealing with SRM "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."[794] The 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."[795] 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."[796] The Notice does not, however, require the inspector to approve or otherwise verify the accuracy of the establishment's determination that a Sanitation SOP or a prerequisite procedure renders SRMs a hazard that is not reasonably likely to occur.

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.[797] 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,

---

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").

791 9 C.F.R. § 417.2(a)(1).

792 *Id*. 417.4(a)(3).

793 USDA SRM Interim Final Rule, *supra*, at 1863.

794 United States Department of Agriculture, Food Safety and Inspection Service, FSIS Notice 9-04, January 23, 2004, at 2 [hereinafter cited as FSIS Notice 9-04].

795 *Id*.

796 *Id*.

797 Thomas O. McGarity, Telephone Interview with Mr. Dennis Johnson, Olsson, Frank & Weeda, July 1, 2004 [hereinafter cited as Johnson Interview, 7/1/04] ("all the companies that I know of are using prerequisite programs"); Burson Interview 5/4/04, *supra*; Email to Elizabeth Duffy from Jennifer Beasley-McKean, Staff Officer, Technical Assistance & Correlations, Technical Service, Food Safety and Inspection Service, Omaha, Nebraska, dated March 24, 2004, at 2 [hereinafter cited as Beasley-McKean/Duffy Email, 3/24/04] ("I would say more plants are addressing Sims in their hazard analysis through prerequisite programs rather than SSOPs or CCPs.").

and concluded that it is therefore unnecessary to establish critical control points and critical control limits for SRMs in their operations.[798] 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.[799] FSIS has apparently acquiesced in this response so long as the prerequisite programs are reduced to writing,[800] and it currently has no plans to draft model HACCP plans identifying critical control points and suggesting critical limits for SRMs.[801]

(2) The Amorphous Nature of Prerequisite Programs.

Since nearly all establishments appear to be implementing the zero tolerance requirement for SRMs through Sanitation SOPs and other prerequisite programs, it is important to gain an understanding of how those requirements are interpreted and implemented in the industry and enforced by FSIS. 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."[802] 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.[803]

The preamble to an FDA proposed regulation establishing HACCP requirements for juice provides some guidance on the meaning of "prerequisite program" in the HACCP context. In FDA's view, a "prerequisite program is an appropriate mechanism for a situation, such as sanitation, that does not lend itself well to HACCP controls."[804] Prerequisite programs are meant to "cover a range of processing factors, not just CCPs."[805] According to FDA, "prerequisite programs" come in two varieties: (1) Sanitation SOPs (of the sort directly addressed in USDA's HACCP regulations) and (2)

---

798 Johnson Interview, 7/1/04, *supra*; Email to Elizabeth Duffy from Dennis Johnson, dated March 31, 2004 [hereinafter cited as 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.").

799 Burson Interview 5/4/04, *supra* ("HACCP should be looked at as a food safety program. I think of mad cow as an animal health analysis.").

800 Beasley-McKean/Duffy Email, 5/3/04, *supra*, at 2 ("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 prerequisite program.").

801 Beasley-McKean/Duffy Email, 3/24/04, *supra*, at 2.

802 USDA HACCP Proposed Rule, *supra*, at 6785.

803 United States Department of Agriculture, Food Safety and Inspection Service, E. coli O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62325 (October 7, 2002), at 62330 [hereinafter cited as USDA E. coli O157:H7 Notice] ("Current regulations do not include specific requirements for prerequisite programs other than Sanitation SOPs.").

804 Department of Health and Human Services, Food and Drug Administration, Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 63 Fed. Reg. 20450 (April 24, 1998), at 20465 [hereinafter cited as FDA Juice NPRM, 4/24/98].

805 *Id*. at 20465.

programs that provide "control over materials that are entering the plant."[806] For example, the purity of the water used to clean final product might be a critical control point requiring bacterial testing if the water comes directly from a river, but could be treated as a prerequisite program for which no testing is required if the water comes from a treated municipal water supply.[807]

If 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.[808]

In connection with its HACCP rules, FSIS proposed regulations would have codified sanitation SOPs for various aspects of the beef production process, thereby providing "an effective means to hold all establishments accountable for meeting them."[809] As discussed above, however, the agency ultimately elected not to codify these "essential prerequisites," and instead required establishments merely to draft and implement written sanitation SOPs on a case-by-case basis. Two years later the agency went to the trouble of replacing a pre-existing set of prescriptive sanitation regulations with a set of "performance-based" aspirations that vaguely told establishments to clean up facilities "to the extent necessary to prevent product adulteration and the creation of insanitary conditions."[810]

(3) Why the Choice Matters.

The industry's decision to address SRMs through Sanitation SOPs and prerequisite programs has enormous consequences for the integrity of the SRM Rule's zero-tolerance performance standard for SRMs in edible meat. Some of the critical 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 outlined below.

- *USDA Approval*. Perhaps the most important practical difference between HACCP programs and prerequisite programs (including Sanitation SOPs) is the role played by the government. Whereas FSIS inspectors must approve HACCP programs under USDA's HACCP regulations, they do not approve prerequisite programs.[811] They merely verify compliance with the procedures of the

---

806 *Id*.

807 Burson Interview, *supra*.

808 The latter prerequisite program, however, is currently not allowed by USDA for dubious reasons discussed above. *See supra* Section XI.D.2.

809 USDA HACCP Proposed Rule, *supra*, at 6786.

810 9 C.F.R. § 416.2(b)(4), (d). *See supra* Section IV.A.1.b.

811 USDA HACCP Final Rule, *supra*, at 38818 (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"); Beasley-McKean/Duffy Email, 5/3/04,

prerequisite program written by the relevant establishment. If the establishment is following the procedures set out in the prerequisite program and the performance based standard (in the case of SRMs, the zero-tolerance requirement) is repeatedly violated, the FSIS inspector does not shut the plant down; he or she merely requires the establishment to revisit its determination in its hazard analysis that the relevant food safety hazard was not "reasonably likely to occur" under the prerequisite program.[812]

- *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 often consist of vague aspirational statements. Even informal "good manufacturing practices" (GMPs), which are little more than industry-generated guidelines, can constitute valid prerequisite programs, so long as they are contained in a written document and generate periodic written monitoring reports.[813]

- *Triviality*. Prerequisite programs are probably so ill-defined because they are generally used to "address issues that are not of high importance from the standpoint of food safety."[814] Instead, they address food safety risks that are viewed as "marginal" by the industry.[815] The goal of prerequisite programs is to reduce relevant sanitation-related risks to such low levels that critical control points are not required.[816] In the words of an author of model HACCP programs and Sanitation SOPs for the industry, "[p]rerequisite programs and SOPs are usually for things that you don't have to worry about very much."[817] For consumers who worry about mad cow disease, the decision by the industry to address SRMs through prerequisite programs should be deeply disturbing.

- *Consequences of Failure*. Another important difference between Sanitation SOPs and HACCP programs is the consequences of failing to achieve the performance goal. For HACCP plans, the performance goal is the national "baseline"

---

supra, at 2 ("Inspectors do not 'approve' GMPs or other written prerequisite programs."). *See also* USDA HACCP Final Rule, *supra*, at 38832 ("FSIS will not approve Sanitation SOP's"); *id*. at 38834 ("FSIS inspectors will not be tasked with directing an establishment's sanitation procedures, nor with "approving" the establishment's Sanitation SOP's.").

812 9 C.F.R. § 417.2(a)(1).

813 Burson Interview, *supra*; Beasley-McKean/Duffy Email, 5/3/04, *supra*, at 2 ("Written BMPs that generate written documents can be used as a prerequisite program.").

814 Burson Interview, *supra*.

815 *Id*.

816 *Id*.

817 *Id*.

incidence of Salmonella in the end product.[818] Although the *Supreme Beef* opinion casts some doubt on the continuing vitality of this standard,[819] it was intended to be a legally binding "standard," and establishments were required to "meet the standard consistently over time as a condition of maintaining inspection."[820] An exceedence of a critical limit at a critical control point requires corrective action and a reassessment of the HACCP plan,[821] and may precipitate an enforcement action on the part of FSIS.[822] For Sanitation SOPs, there are no performance standards, and any given failure to maintain sanitary conditions at a plant is not necessarily a violation of law and does not require any particular action.[823] As a practical matter, "[i]t is a lot harder to get closed under a prerequisite program."[824]

- *Documentation*. A related difference between HACCP plans and prerequisite programs is the amount of documentation required for observed violations of the standard.[825] In administering a HACCP program, an establishment must document the monitoring that it undertakes at critical control points.[826] Every exceedence of a critical control limit at any critical control point must be documented along with the required corrective action.[827] Exceedences also require operators to perform or obtain a reassessment of the HACCP plan that must also be fully documented.[828] The requirements for Sanitation SOPs do not require extensive documentation of deviations from the SOPs and resulting corrective actions, and operators who rely upon prerequisite programs instead of critical control points can thereby avoid the paperwork "nightmare" that can result from the exceedence of a critical limit at a critical control point.[829]

---

818 USDA HACCP Final Rule, *supra*, at 38838.

819 *See supra* Section IV.A.1.f.

820 USDA HACCP Final Rule, *supra*, at 38838.

821 7 C.F.R. § 417.3(b)(4). *See* Johnson Interview, 7/1/04, *supra* (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").

822 *Id*. § 417.3.

823 The HACCP Rule provides performance "criteria" for E. coli contamination based on the prevalence of contamination of E. coli on carcasses produced nationwide, but a failure to meet the criteria is merely an indication that greater sanitation efforts are necessary and not a violation of law. USDA HACCP Final Rule, *supra*, at 38838.

824 Johnson Interview, 7/1/04, *supra*. This important difference in the legal consequences of a detected violation appears to be an important 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*.

825 *Id*. ("The documentation required for a HACCP is extensive. If you don't treat it as a CCP and you catch some spinal cord, you can have someone trim it up and talk to Joe up the line about the fact that he missed some spinal cord, and you are done.").

826 7 C.F.R. § 417.5(a)(3)

827 *Id*. § 417.3(c).

828 *Id*. § 417.3(4), 417.4(a)(3).

829 Johnson Interview, 7/1/04, *supra*.

The industry's decision to rely upon Sanitation SOPs and prerequisite programs, rather than establishing and monitoring critical limits at critical control points will result in a much lower likelihood of achieving the regulatory goal of keeping SRMs out of edible meat. After the promulgation of the FSIS SRM Rule in January 2004, specialists at the University of Nebraska prepared model Sanitation SOPs for the control of SRMs in cattle slaughter operations and in beef carcass receiving and fabrication operations.[830] Each document consists of two pages of text, a worksheet and a checklist. For the most part, the documents set out in layperson language the requirements of the January 2004 interim final rules. Although written in mandatory terms, the requirements are actually highly discretionary. For example, the SOP for segregating older cattle provides: "If possible, any beef animal(s) determined to be ≥ 30 months of age will be held for slaughtering after young age documented animals are slaughtered."[831] Similarly, "grossly identifiable spinal cord material spread by the splitting process" on any carcasses of animals 30 months and older should "be trimmed from the carcass with a knife."[832] The suggested SOP does not require (or even suggest) any monitoring for SRMs in finished product beyond the requirement that "[v]isual observation will be conducted once per day during slaughter operations."[833] No quantitative testing of any sort for SRMs is required or suggested. Corrective actions are limited to retraining slaughter operators in SRM control procedures and properly disposing of SRMs.[834]

If the prerequisite programs that slaughterhouses are using are anything like the model SOPs described above, it seems highly unlikely that the zero-tolerance for SRM performance requirement of the SRM rule is being met in practice. Although FSIS has for years touted the virtues of quantitative tests at critical control points in HACCP programs, the move by the industry to 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 minimal suggestions contained in the recommended SOPs. This is of more than modest concern, because, as one FSIS technical advisor laments, "[s]ome of the people writing

---

830 Ryan R. Baumert & Dennis Burson, Cattle Slaughter Standard Operating Procedures (SOP) for Control of Specified Risk Materials (SRMs), February 17, 2004 [hereinafter cited as Nebraska Cattle Slaughter SRM SOPs]. 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 for 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*, at 1.

831 Nebraska Cattle Slaughter SRM SOPs, *supra*, at 1.

832 *Id*. at 1.

833 *Id*. at 2.

834 *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), February 17, 2004

the prerequisite programs really do not understand how to support decisions made in their hazard analysis."[835]

That FSIS advisor suggests, however, that the differences may not have a significant real-world effect, because the requirement that establishments take corrective action applies to failures of prerequisite programs as well as full-fledged HACCP plans.[836] The HACCP regulations require that plans for implementing Sanitation SOPs make the establishment responsible for taking corrective action when either the establishment or FSIS determines that the sanitation SOPs or their implementation "may have failed to prevent direct product contamination or adulteration."[837] Although the HACCP regulations do not contain a similar corrective action requirement for other 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 be considered a 'deviation not covered by a specified corrective action' or an 'unforeseen hazard'" under the HACCP rule requiring corrective action.[838] FSIS is apparently adopting the same approach with respect to prerequisite programs that implement SRMs.[839]

Although the corrective action requirement does provide some measure of comfort, 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 a 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 amorphous prerequisite programs. 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.

In sum, it does not appear that prerequisite programs are up to the task of ensuring compliance with a zero-tolerance rule. Rather than establishing critical control points for

---

835 Beasley-McKean/Duffy Email, 3/24/04, *supra*, at 2.

836 *Id*. ("There really aren't any benefits to a prerequisite program versus a CCP. They still have to meet 417.3 if there is a deviation from either a prerequisite program or a CCP.").

837 USDA HACCP Final Rule, *supra*, at App A, B.

838 USDA E. coli O157:H7 Notice, *supra*, at 62330. *See also* United States Department of Agriculture, Food Safety and Inspection Service, Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products, Interim Final Rule, 68 Fed. Reg. 34208 (June 6, 2003), at 34214 [hereinafter cited as 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.").

839 Beasley-McKean/Duffy Email, 5/3/04, *supra*, 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).").

detecting and eliminating SRM contamination of meat destined for human consumption, the companies are electing to deal with SRMs as an utterly ordinary aspect of day-to-day sanitation. In short, the companies, with the passive acquiescence of FSIS, have decided that SRMs are not sufficiently risky to warrant the special treatment afforded by HACCP plans. This cavalier treatment, in turn, stems from the firmly held conclusion of the industry and FSIS leadership that mad cow disease in the United States is primarily an animal health concern and not a human health problem.

(4) The Dubious Legal Rationale.

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."[840] 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."[841]

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.[842] Given the various "firewalls" in place, including the FDA feed ban and the sanitation 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.[843] 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 SRMs because they have apparently concluded that SRMs *per se* are not "food safety hazards."[844]

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

---

840 9 C.F.R. § 417.2(a)(1).

841 *Id*. § 417.1.

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

843 Johnson Interview, 7/1/04, *supra* (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"); Johnson/Duffy Email, 3/31/04, *supra*, at 1. *See also* Burson Interview, *supra*.

844 Johnson/Duffy Email, 3/31/04, *supra*, 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."). *See also* Burson Interview, *supra* ("We have other [restrictions] in place so that the occurrence of the prion is very low. . . . If SRM got on the meat, the chance of a person eating a prion is still very, very small.").

appropriate to find that such materials are unfit for human food."[845] FSIS apparently concluded that SRMs are "unfit for human food" because they may present a "food safety hazard."[846] 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."[847] 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 if SRMs are reasonably likely to occur in the food manufacturing process.[848]

Furthermore, it seems reasonably clear that the presence of *SRMs* in 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 that have for several years been subject to a requirement that finished product contain no spinal cord material indicates 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.[849]

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.[850] 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 innovative reading of the SRM and HACCP regulations, however, does not square with the above-quoted language in the preamble to the SRM rule. Indeed, since companies typically do address

---

845 USDA SRM Interim Final Rule, *supra*, at 1869.

846 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, FDA stated that "a food can be 'otherwise unfit for food' based on health risks." FDA Food and Cosmetics Rule, *supra*, at ___. It further stated that "[b]ecause 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.*

847 FSIS Notice 9-04, *supra*, at 2 (emphasis added).

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

849 Zitner, *Bovine Disease Surfaces in U.S.*, *supra*; USDA AMR Interim Final Rule, *supra*, at 1876. *See supra* Section III.C.1.

850 Johnson Interview, 7/1/04, *supra*.

fecal matter in HACCP programs through critical control points,[851] the argument may prove too much.

Despite its clearly articulated legal position, FSIS has tolerated a wholesale adoption by the industry of an approach to meeting the zero-tolerance requirement for SRMs that is based upon the opposite legal conclusion. One close observer suggests that FSIS may be tolerating this interpretation because to conclude otherwise is to acknowledge that the government's firewalls have failed and the presence of SRMs in food indicates the presence of mad cow prions.[852] Whatever the reason, FSIS is tolerating industry practices that do not actually test for SRM in food and that attempt to achieve compliance through visible inspection for SRMs during slaughter and processing operations, an approach that does not in fact result in the removal of all SRM from edible food.

b) HACCP's High Tolerance for Contamination.

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."[853] Given HACCP's historical focus on controlling bacteria, FSIS's conclusion that HACCP is capable of controlling mad cow prions involved a considerable leap of faith. The agency did not explain how a system designed to ensure that Salmonella levels in finished product do not exceed the national average would be capable of ensuring that SRM levels in finished product could meet a zero-tolerance performance standard. Whether or not 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 that piece of beef edible. 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."[854] 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. One observer notes that the fact that the overall percentage of contaminated beef should be creeping downward "may not instill the confidence the

---

851 *Id*.

852 *Id.* ("If they say that meat containing SRMs is adulterated, then that acknowledges that the firewalls are not working" and "USDA does not acknowledge that the firewalls are not working.").

853 USDA HACCP Final Rule, *supra*, at 38811.

854 *Id*. at 38848.

USDA is hoping for in consumers, who cook individual [pieces of meat], not percentages."[855]

Nevertheless, the goal of reducing the prevalence of Salmonella-contaminated meat may have been acceptable from a public health perspective, because the agency could reasonably assume that any contaminated meat would be cooked prior to consumption.[856] A reasonable assumption in the context of microorganisms like Salmonella, however, may be a reckless gamble in the context of mad cow disease. Unlike microorganisms, the preparation and cooking of meat containing the mad cow prion will not destroy the prion, and the risk of contracting vCJD will remain. The HACCP regulations are ultimately built on the assumption that the preparer of food is the "primary defense" against foodborne illness. Since the preparer of the food cannot be the "primary line of defense" from mad cow disease, greater efforts will be necessary at points earlier in the process. The next clear line of defense is the slaughterhouse.

c) A Verification Vacuum.

The SRM Rule provides that SRMs "are inedible and shall not be used for human food,"[857] and it requires establishments to "develop, implement, and maintain written procedures for the removal, segregation, and disposition" of SRMs and to include those procedures in their HACCP plans, Sanitation SOPs or other prerequisite programs."[858] The regulations do not specify acceptable technologies for monitoring for SRM, nor do they specify a generic level of sensitivity for testing technologies. As noted above, establishments may avoid the testing requirement altogether by addressing SRMs through prerequisite programs rather than in HACCP plans.

(1) The Critical Importance of Quantitative Monitoring.

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. The FSIS Guidebook for preparing HACCP plans states that "[m]onitoring is essential to a HACCP system."[859] 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

---

855 Fox, *Spoiled*, *supra*, at 356.

856 *See* Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001), at 439 (agreeing with 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.")

857 7 C.F.R. § 310.22(b).

858 *Id*. § 310.22(d)(1).

859 United States Department of Agriculture, Food Safety and Inspection Service, Guidebook for the Preparation of HACCP Plans (April, 1997), at C-18 [hereinafter cited as FSIS HACCP Plan Guidebook].

regulations,[860] and it was the promise of quantitative monitoring that persuaded consumer advocates to support the HACCP approach when USDA initially proposed it.[861] In the words of an industry spokesperson "[y]ou have to test to make sure that your systems have been effective."[862]

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

> 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 data, except that laboratory methods for quantification may be more time and resource intensive for certain pathogens.[863]

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.

(2) The Vagueness of Zero.

The HACCP regulations require the incidence of positive Salmonella tests to be no higher than the average incidence nationwide, which initially meant an incidence of no more than 7.5 percent of the samples taken. Although the SRM Rule declares SRMs to be "inedible" and provides that SRMs "shall not be used for human food,"[864] it does not

---

860 *Frontline* Interview with Elsa Murano, Undersecretary for Food Safety, USDA, undated, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews, at 4 [hereinafter cited as Murano Interview].

861 *Frontline* Interview with Carol Tucker Foreman, undated, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews [hereinafter cited as Foreman Interview] (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."). *Id*. at 6 ("The key change that was made that made it possible for us to support HACCP was the creation of an objective measure.").

862 *See Frontline*, *Modern Meat*, *supra*, at 10 (quoting Dave Theno, Scientist in charge of meat safety for Jack-In-The-Box).

863 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 (October 8, 2003), available at http://www.fsis.usda.gov/OPHS/nacmcf/rep_stand.htm (last visited May 21, 2004).

864 7 C.F.R. § 310.22(b).

provide even a hint as to how establishments and USDA should go about determining whether or not otherwise edible meat has become contaminated with SRMs. FSIS decided not to prescribe "specific procedures that establishments must follow because FSIS believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule."[865]

A zero-tolerance is easily prescribed and popular with the citizenry, but it may be impossible to achieve in practice. Scientists often question zero-tolerance policies in the context of human food, because they "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."[866] It is, at best, an ideal to be strived for but perhaps never completely achieved.[867] 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."[868] Whether a particular establishment complies with the SRM Rule's zero tolerance requirement thus depends upon the ability of the monitoring tool to detect SRM in the final product, a matter that the rule leaves up to the establishment. The Department has delegated the critical process of determining just how hard to look for SRM to the operators of establishments that have every reason not to find it.

(3) The Lack of a Monitoring Requirement.

The preferable form of monitoring under the FSIS HACCP regulations consists of taking continuous quantitative measurements for the relevant characteristic(s) at the critical control points.[869] When continuous monitoring is not feasible, non-continuous monitoring is appropriate if it is undertaken with sufficient frequency.[870] The regulations further envision the possibility of "visual examination" as a form of non-continuous monitoring.[871] 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."[872] Because companies have the option of addressing SRMs

---

865 USDA SRM Interim Final Rule, *supra*, at 1869.

866 NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 25.

867 *Id*. (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").

868 USDA E. coli O157:H7 Notice, *supra*, at 62329.

869 FSIS HACCP Plan Guidebook, *supra*, 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.").

870 *Id*. at C-19. The NAS Scientific Criteria to Ensure Safe Food Report complained about the "lack of a generally accepted approach to setting regulatory controls and performance standards that result in a reduction of human disease," NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 22, and 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.

871 FSIS HACCP Plan Guidebook, *supra*, at C-19.

872 Nebraska Cattle Slaughter SRM SOPs, *supra*, at 2.

through their prerequisite programs, which do not require any testing at all, this is perfectly legal.[873]

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., verify adequacy of Sanitation SOP procedures)."[874] Since establishments that rely entirely upon prerequisite programs will have no "HACCP monitoring records," the FSIS inspectors must rely upon physical observations.

The agency's tolerance of visual inspection as an appropriate monitoring technique represents a reversion to the organoleptic approach to meat safety. Worse, the regulations apparently substitute a company employee who is otherwise occupied by work-related activities for an FSIS inspector who is concerned primarily for safety. Even assuming that company laborers are more adept at detecting carcasses containing SRMs than trained FSIS inspectors, the pressure on the employee to "see no evil" and thereby keep the production line flowing unimpeded without wasting valuable time and product will almost certainly be greater than the pressures on FSIS inspectors. The ability of establishments to substitute subjective observations for quantitative measurements belies the argument that HACCP is "science-based."

This rather cavalier implementation of the "critical" monitoring function through visual observation is distressing in light of readily available tests for 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.[875] Because USDA prohibits spinal cord in AMR product, USDA has promulgated guidelines for conducting Glial Fibrillary Acidic Protein Analysis for CNS tissues in the product of AMR operations.[876] 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

---

873 It should be noted, however, that the legality of this approach depends upon the legality of the decision to address SRMs through prerequisite programs rather than with HACCP programs. The questionable legality of that election is discussed above. *See supra* Section XI.F.2.a.4.

874 FSIS Notice 9-04, *supra*, at 3.

875 Email to Elizabeth Duffy from Gregorio Rivera, ABC Research, dated April 5, 2004, at 1[hereinafter cited as Rivera/Duffy Email, 4/5/04] ("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* Burson Interview, *supra* (noting that "there are some tests for spinal cord in meat"); David Kelly, *For Some, Mad Cow Disease All in a Day's Work*, Los Angeles Times, January 4, 2004 (quoting Kim Hossner, a biochemist for the Center for Red Meat Safety at Colorado State University).

876 United States Department of Agriculture, Food Safety and Inspection Service, 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, dated February 14, 2002, at 3 [hereinafter cited as USDA Testing GMPs, 2/14/02].

the market.[877] Their competitors, however, are free to rely upon visual inspections for SRMs by company employees.

d) Technological Torpidity.

In promulgating the original HACCP Rule, FSIS expressed confidence that operators could comply with the national baseline prevalence performance standard for Salmonella because it was aware of many existing technologies that were capable of reducing pathogens in meat. It went to some effort to list and discuss various technologies capable of achieving the standard in its proposed rule and in the preamble to the final rule.[878] The agency was careful, however, not to prescribe any particular technology, leaving those critical decisions up to the establishments. The proof would ultimately be in the results of the periodic tests for Salmonella in the resulting product.

The HACCP, Sanitation SOP, and prerequisite programs were not, however, designed with zero tolerance policies in mind.[879] 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 the assumption on the part of FSIS that the person who ultimately prepares meat for consumption is the primary defense against foodborne illness. It may be, as Nobel Laureate Dr. Stanley Pruisner maintains, that "U.S.D.A. scientists and veterinarians, who grew up learning about viruses, have difficulty comprehending the novel concepts of prion biology."[880] 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 is 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 not to require companies to use them.

(1) Running Hot and Cold on Technology Prescriptions.

USDA did in fact depart 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 cattle[881] and on mechanical separation technologies for removing meat from bones.[882] Similarly, the preamble to the SRM Rule is quite prescriptive in specifying how the FSIS inspectors must go about making the critical age determination. In cases in which

---

877 Kelly, *For Some, Mad Cow Disease All in a Day's Work*, *supra* (quoting Dell Allen, Vice-President for Technical Services at Excel Corporation, "We now have labs in all of our facilities where we test all the tissue.").

878 USDA HACCP Final Rule, *supra*, at 38846.

879 *See* NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 8 (noting that "[w]hen zero tolerance is used as a performance standard, unique methodology issues need to be considered").

880 Blakeslee, *Expert Warned That Mad Cow Was Imminent*, *supra*.

881 9 C.F.R. § 313.15(b)(2)(ii).

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

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.[883] In the absence of accurate and reliable records, however, inspectors at slaughterhouses must verify the age of cattle through the specific technique of dental examination.[884]

At the same time, 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. Operators have generally elected to address SRMs in their prerequisite programs, and those company-promulgated programs often do identify specific technologies and techniques. Requirements in prerequisite programs are not, however, directly enforceable by FSIS inspectors who may only withdraw inspection upon a determination that repeated failures of the prerequisite programs to achieve the zero-tolerance goal indicate that the facility is not maintaining sanitary conditions and that the resulting product is therefore adulterated.[885]

(2) Obsolete Sanitation Requirements.

USDA's sanitation regulations provide that "[e]quipment and utensils must be maintained in sanitary condition so as not to adulterate product."[886] Surfaces of utensils and equipment "must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product."[887] The recommended Sanitation SOPs likewise require that steps be taken to "sanitize" tools and equipment that have been used to remove SRMs from cattle more than 30 months of age. Neither the SRM Rule nor the model Sanitation SOPs, however, provide any guidance on how one would go about "sanitizing" equipment that has become contaminated with the mad cow prion.

The highly regarded author of one of the few existing model Sanitation SOPs for SRM materials suggests that as a practical matter, companies will "sanitize" equipment that may be contaminated with SRMs from older cattle by using the same technique (spraying or dipping edible meat in water heated to greater than 180 degrees) that they have always used to rid meat of potentially harmful microorganisms.[888]

---

883 *Id*. at 1869.

884 *Id*. An FSIS Directive specifies that inspectors are to consider cattle to be 30 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 a depiction of that event in an attached chart. United States Department of Agriculture, Food Safety and Inspection Service, FSIS Notice 5-04, January 12, 2004, at 4 [hereinafter cited as FSIS Notice 5-04]. Again, these procedures are quite prescriptive.

885 *See supra* Section on IV.A.1.b.

886 7 C.F.R. § 416.3(a).

887 *Id*. § 416.4(a), (b).

888 Burson Interview, *supra* ("As a practical matter, companies require a 180 degree water step in the process. You either spray the meat with water at 180 degrees or your dip the meat into water at 180 degrees. This is what is normally done to kill bacteria.").

It is well-known, however, that hot water will not kill mad cow prions. Only relatively severe treatments, such as dipping in a 40 percent chlorine solution, are efficacious against mad cow prions, and companies are apparently not willing to go that far for practical reasons.[889] Apparently, the goal is not so much to kill prions as it is to ensure that material that may be contaminated with prions is removed from the implements that are used for processing edible meat.[890] Since the Sanitation SOPs that most companies use typically provide for cleaning implements between animals,[891] the assumption must be that this degree of sanitation will suffice.

This reluctance to change standard operating procedures to meet the unique risks posed by mad cow prions is another manifestation of an industry conclusion that mad cow disease is primarily an animal health problem and does not pose a serious human health risk. While it is true that rinsing implements in hot water, if done carefully, will physically remove most of any SRM material present on the implement, it will not destroy any mad cow prions that may be present in that SRM material. Any prion-containing SRM material that remains on the implement will still contain prions. As importantly, any prion-containing SRM material that is removed from the implements will also contain prions that may not be destroyed by any sewage treatment technologies that are employed prior to discharge of liquids into a river or lake and use or disposal of the resulting sludge. EPA has only recently commissioned a study on the likelihood that mad cow prions could survive common sewage treatment technologies.[892]

(3) The "Reconditioning" Option.

When SRMs are detected on edible meat, the establishment is not required to destroy the contaminated meat. Instead, it has the option of "reconditioning" the meat by trimming off the tissue that has become contaminated.[893] This reconditioning option is especially problematic because of its heavy dependence on the judgment of the establishment employee performing the reconditioning operation. SRMs on meat may be detected by an employee located farther down the line than the point at which the contamination occurred or by a quality assurance employee making a periodic inspection.[894] It is, however, possible that the very employee whose actions (whether or not negligent)

---

889 *Id*. ("FSIS admits that the only way to kill the prion is a high concentration of chlorine, (e.g., 40%) that is really too high to be of practical use.").

890 *Id*. ("The goal is not to kill the prion. It is as much to wash the material off the implements as it is to kill anything.").

891 *Id*. ("Most companies sanitize their implements between animals on the line.").

892 University of Wisconsin-Madison, News Release, Researchers To Study Fate Of Prions In Wastewater, May 27, 2004. Ironically, the economic distress caused by the mad cow discovery could dissuade EPA from promulgating more stringent technology-based standards for conventional pollutants, because such standards must meet an industry-wide cost-effectiveness test. *See Mad Cow Discovery May Prompt EPA Review of Meat Industry Water Rule*, Inside EPA Weekly Report, January 9, 2004, at 1.

893 FSIS Notice 9-04, *supra*, at 4.

894 Burson Interview, *supra* ("The guy who causes the material to get on the carcass (*e.g.*, the one with the saw cutting the spine) does not trim the contaminated material. That would be an employee further down the line who has been trained to look for it.").

resulted in the edible meat becoming contaminated with the SRMs in the first place will have the responsibility for reconditioning the meat.[895]

The more edible tissue that is lost to reconditioning, the less is available for sale and the more has to be disposed of or specially rendered for non-ruminant uses. Obviously, the employees of the establishment, and especially the employee who was responsible for contaminating the edible meat in the first place, will want to minimize the amount of tissue lost to reconditioning. This incentive may be desirable from the standpoint of efficiency, but it is not likely to yield the safest meat supply.

e) Sticky Enforcement Triggers.

Under the general HACCP regulations, failure to meet the Salmonella standard results not in an enforcement action, but in company implemented "corrective actions to lower the incidence of Salmonella on all such product" that the establishment produces.[896] The regulations make it clear that variations from the national baseline prevalence of Salmonella only trigger a withdrawal of inspectors 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," the agency considers it to be in compliance with the Sanitation SOP's regulations.[897]

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)."[898] Only when the VMO or other off-line official 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 an Noncompliance Record (NR).[899] An NR is "an official letter of noncompliance with one or more regulatory requirements" that "could result in additional regulatory and administrative action."[900]

The consequences of an establishment's repeated failure to keep SRMs out of finished product are even more limited when, as is apparently generally the case, the establishment elects to address SRMs through prerequisite programs. The Notice to inspectors provides

---

[895] FSIS regulations governing Sanitation SOPs contemplate that the employee who is responsible for the implementation and maintenance of the standard operating procedures may be the employee who is also responsible for carrying out the procedures. USDA HACCP Final Rule, *supra*, at 38830.

[896] *Id*. at 38848.

[897] *Id*. at 38834.

[898] FSIS Notice 9-04, *supra*, at 4.

[899] *Id*. *See* United States Department of Agriculture, Food Safety and Inspection Service, FSIS Directive 5000.1, as amended (July 15, 2003), at 41 [hereinafter cited as FSIS Directive 5000.1].

[900] United States Department of Agriculture, Food Safety and Inspection Service, FSIS Directive 5400.5, undated, at 106.

that when they find that the procedures under a prerequisite program have "failed to prevent SRMs from adulterating product," they must merely "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."[901] 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."[902]

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,[903] but it is entirely inconsistent with the zero-tolerance policy articulated in the SRM rule. As previously discussed, the general HACCP regulations are built upon the assumption that someone will properly cook the meat prior to its consumption. As a practical matter, the packing and processing establishments cannot guarantee "sterile" meat, and they do not pretend to do so. In the case of mad cow disease and the risk of foodborne vCJD, however, sterility is precisely what is required of an adequate regulatory system. 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. A three-strike rule is too lenient for mad cow disease.

f) Shirking Responsibility.

A commercial slaughterhouse rarely sells meat directly to the consumers to be cooked and eaten. There is usually an intermediary processor or butcher 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 could avoid responsibility for removing SRMs from meat that it sells to downstream processors if it determined that "the SRMs are removed at the receiving establishment."[904] At least one State Department of Agriculture has read this FSIS Notice to allow "an official establishment" to "ship out carcasses which contain SRMs."[905]

This 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 before it is consumed as food will virtually guarantee that human beings

---

901 FSIS Notice 9-04, *supra*, at 4.

902 9 C.F.R. § 417.2(a)(1).

903 USDA HACCP Final Rule, *supra*, at 38849.

904 FSIS Notice 9-04, *supra*, at 5.

905 Letter to FSIS Docket Clerk from Gus R. Douglass, West Virginia Department of Agriculture, dated April 5, 2004, at 1.

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.

g) USDA'S Limited Legal Authority.

USDA's legal authority may not be sufficiently broad to protect the public from the risk of contracting mad cow disease. Although the authorities granted by the FMIA are in many ways quite broad, the statute is based upon outdated assumptions about the nature of foodborne diseases. In the modern slaughterhouse, regulating meat safety requires more than keeping carcasses clean and fresh.

(1) Authority to Implement HACCP.

The *Butz* and *Supreme Beef* cases raise serious questions concerning USDA's legal authority to enforce requirements that operators include in their HACCP programs to ensure that meat is free of SRM.[906] The *Butz* case, which was decided in 1974, long before the discovery of prion-based diseases, ratified USDA's position that meat is not *per se* adulterated merely because it contains pathogenic organisms.[907] 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."[908] The *Supreme Beef* opinion reaffirmed the *Butz* conclusion in the HACCP context, concluding that so long as there was a credible possibility that bacteria contaminated the meat entering a facility, FSIS could not insist that meat leaving the facility met the HACCP nationwide average prevalence test for Salmonella.[909]

Although there is no reason to believe that 21st Century housewives are any more ignorant or stupid than 20th Century housewives, it is clear that their methods of preparing and cooking meat will not remove mad cow prions, because they are not destroyed at normal cooking temperatures.[910] 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 reasoning underlying *Butz* is wholly inapplicable to FSIS's regulatory efforts to protect consumers from foodborne TSEs.

---

906 *See* NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 5 (noting that "[l]egal challenges to action s taken by regulatory agencies in response to violations of established food safety criteria have cast doubts on the agencies' authority to enforce [HACCP] criteria").

907 American Public Health Ass'n v. Butz, 511 F.2d 331, 333 (DC Cir. 1974).

908 *Id*. at 334. The Fifth Circuit reaffirmed the *Butz* holding that Salmonella is not a per se adulterant in Supreme Beef Processors, Inc. v. USDA, 275 F.3d 432, 439 (quoting *Butz* at 334).

909 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001). *See* Lassiter, *Hoof to Hamburger*, *supra*, at 454.

910 *See* Harvard Center for Risk Analysis BSE Report, *supra*, at 38.

If FSIS cannot assume that the preparer will take any steps to remove mad cow prions from meat, it must assume responsibility for ensuring that steps are taken upstream in the meat production process to remove any material that may contain mad cow prions. The SRM Rule should therefore be immune from a legal attack based upon the *Butz* precedent. Since ordinary food preparation practices will not remove either SRMs or mad cow prions from SRM-contaminated meat, FSIS may properly conclude that any SRM-contaminated meat exiting the slaughterhouse or food processing plant is adulterated.

USDA's conclusion that SRM is "unfit for human food" under section 601(m)(3) of FMIA and is therefore adulterated could potentially salvage the HACCP regulations in the context of mad cow disease. If USDA can successfully defend that determination, then it should be able to require operators to use zero SRM as a critical control level at critical control points in their HACCP programs or ensure that prerequisite programs (e.g., Sanitation SOPs) achieve the zero-tolerance standard without establishing critical control points. USDA could take the position that since SRM, unlike Salmonella, is in fact an adulterant, its presence in meat is sufficient to permit FSIS "to refuse to stamp such meat 'inspected and passed.'"[911] Although the *Supreme Beef* court made it clear that USDA has no authority to "regulate the levels of non-adulterant pathogens," it clearly does have the authority to regulate adulterants in meat.

A conclusion that SRM is an adulterant may not, however, be easy to support. The Department relies upon the definition of adulterated in section 601(m)(3) of the FMIA, under which meat is adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food."[912] The Department bases its determination that SRM is adulterated on its conclusion that SRM is "for any other reason . . . otherwise unfit for human food." 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 within the meaning of section [601](m)(3) of the FMIA."[913] FSIS concludes that SRMs present "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 can therefore "unknowingly be exposed to the BSE agent through consumption of these materials."[914]

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 SRM to the BSE agent, SRM "is . . . otherwise unfit for human food."[915] First, SRM is clearly not a complete proxy for prion-containing tissue. The Secretary of Agriculture and Department spokespersons

---

911 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001), at 439.

912 21 U.S.C. § 601(m)(3).

913 USDA SRM Interim Final Rule, *supra*, at 1869.

914 *Id*.

915 21 U.S.C. § 601(m)(3).

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 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.[916] Otherwise, a much larger proportion of the population of England would have contracted vCJD.[917]

It is abundantly clear, on the other hand, that consuming meat that is infected with the mad cow prion does pose 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 meat contaminated with SRM "is . . . unfit for human food," just as it concluded that meat contaminated with any detectable amount of E. coli O157:H7 is 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 all doubt about this by amending the FMIA to provide clear authority to USDA to regulate SRMs.[918]

Another unresolved question is the extent to which USDA's SRM regulations, which incorporate all of the legal infirmities of the HACCP regulations, can be applied to downstream entities like grinders after *Supreme Beef*. That court's broad statement 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"[919] strongly suggests that the HACCP regulations are irrelevant to the meat production process downstream of the slaughterhouse. Thus, grinders like Supreme Beef will probably not be subject to enforcement actions if they decline to incorporate testing for SRM in their HACCP programs. This is not a serious problem from the mad cow perspective, because any SRM that gets into meat intended for human consumption will get there during the process of killing and processing carcasses at the slaughterhouse. It does, however, eliminate one potential backup defense against vCJD.

(2) Authority over On-Farm Practices.

USDA lacks direct authority to regulate what ranchers do to cattle. In the notice proposing the HACCP regulations, USDA noted that it did "not currently have and does

---

916 *See* 2002 GAO Mad Cow Report, *supra*, at 32 ("Many experts believe that vCJD is difficult to contract and, therefore, that relatively few people would develop the disease.").

917 *See* FDA Food and Cosmetics Rule, *supra*, at ___[section on "Requirements for Prohibited Cattle Materials"] ("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.").

918 *See infra* Section XVI.E.

919 Supreme Beef Processors, Inc, v. USDA, 275 F.3d 432 (5th Cir. 2001), at 440.

not anticipate on-farm inspectional authority."[920] Thus, it appears that USDA lacks authority to require a rancher who suspects that one of his cows is afflicted with mad cow disease to either report that fact to the government or to refrain from killing and burying it. Until the long awaited universal identification system is fully implemented, there is no way for the department to ascertain independently whether or not suspect cattle are being secretly destroyed. Again, this is something that Congress could easily correct with amendments to the FMIA.

3. The Advanced Meat Recovery Rule

The AMR Rule addresses a modern technique that uses pressurized water to separate meat from bone. In the 1990s, USDA concluded that AMR techniques were sufficiently like hand deboning from a public health perspective that the product resulting from AMR techniques could properly be labeled "meat." After scientists determined that BSE-positive cattle could transmit vCJD to human beings, FSIS on April 13, 1998 proposed a requirement that the product of AMR devices could not contain any spinal cord material and still be labeled "meat."[921] While the proposal languished for years in the agency, FSIS continued to find spinal cord in the product of the 30 or so plants that employ AMR technologies. A 2002 survey of those facilities discovered that 35 percent of the AMR product sampled did, in fact, contain spinal cord or other prohibited material.[922]

The January 2004 AMR regulations extended the SRM Rule to prohibit the use of the word "meat" to describe the output of any AMR process applied to any spinal cord or dorsal root ganglia. They also apply the same labeling restriction to skulls and vertebral column bones from cattle that are 30 months of age or older. As a legal matter, the regulations are a labeling requirement, and not strictly a safety regulation. Like the SRM rule, the AMR rule gives operators the option to implement the zero-tolerance requirement through scientific testing or through more subjective prerequisite programs. They are therefore subject to many of the same criticisms that apply to the SRM rule.

G. Faux Firewalls -- Supporting Protective Rhetoric with Regulations that Don't Matter.

Two of the announced actions were almost certainly included solely for their "public relations" value. Both the ban on air injection stunning and the ban on mechanically separated meat imposed no burden whatsoever on the cattle industry, because neither technology had been used in the United States since soon after the outbreak of mad cow disease in England in 1996.

XII Faulty Responses to Firewall Failure.

---

920 USDA HACCP Proposed Rule, *supra*, at 6829. *See also* CRS Issue Brief 8/1/03, *supra*, at CRS-3.

921 63 Fed. Reg. 17959 (1998).

922 Zitner, *Bovine Disease Surfaces in U.S.*, *supra*. *See supra* Section III.C.1.

No firewall designed and implemented by human beings can be 100 percent effective 100 percent of the time. Sadly, the previous analysis of the existing and recently enhanced firewalls strongly suggests that firewall failure is not only possible, but probable. 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. As the Mabton mad cow experience demonstrated, USDA is not fully prepared to address firewall failure with effective recalls and a universal cattle identification program.

A. A Perverse Recall Policy.

One perennially mentioned impediment to effective protection of the public health from food-borne disease is USDA's lack of authority to order manufacturers to recall contaminated beef and beef products.[923] Companies are generally sufficiently concerned about the public relations impacts of a failure to recall potentially adulterated meat that they are willing to recall it voluntarily,[924] and that is what happened to most of the meat that may have become contaminated by tissue from the Mabton mad cow.[925] Nevertheless, a firm is completely free to decline a request if it decides not to go to the expense and effort of a recall.[926] If it does so, FSIS's only recourse is to seek a court order to seize and detain adulterated products in a proceeding in which the agency has the burden of proving that the product is adulterated and that seizure is the appropriate remedy.[927] 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 not likely to produce a very high yield.[928]

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.[929] FSIS bears only the costs of issuing the voluntary recall statement, informing the public of the recall, and ensuring

---

923 *See* USDA Food Safety and Inspection Service, Fact Sheet on FSIS Food Recalls, available at http://www.fsis.usda.gov/fact_sheets/fsis_food_recalls/index.asp (last visited on June 17, 2004).

924 Boyle Interview, *supra*, at 5-6.

925 *See supra* Section VI.A.

926 CRS Issue Brief 8/1/03, *supra*, at CRS-10.

927 U.S. v. Lexington Mill & E Co., 232 U.S. 399, (1914); 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) ("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"). *See also* CRS Issue Brief 8/1/03, *supra*, at CRS-10.

928 *Frontline*, *Modern Meat*, *supra*, at 14 (quoting Carol Tucker Foreman). *See also Frontline* Interview with Eric Schlosser, undated, available at http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews, at 14 [hereinafter cited as Schlosser Interview] ("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 the meat.").

929 Michelle Avallone, Telephone Interview with Hany Sidrak, Deputy Director of Recall Management Division, Food Safety and Inspection Service, USDA, June 15, 2004.

its effectiveness by inspecting the facilities subject to the recall.[930] Although this policy may appear sensible for huge operations that can easily afford the expense of a recall, smaller establishments, like the Vern's Moses Lake facility, do not have abundant resources available to support such recalls.[931] The significant expense of product recalls and USDA's unwillingness to defray the entire costs of a recall may dissuade small companies in the future from participating voluntarily.[932] 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 Washington 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.[933] 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.[934] 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.[935] By the time that USDA halted its investigation, only 29 of the 81 cows in the birth herd had been accounted for.[936] A functioning animal ID program would no doubt have increased that number dramatically. The precautionary slaughter of 450 head of cattle was no doubt fully warranted, but it could have been avoided if the United States had previously implemented a mandatory cattle identification program.[937] 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."[938]

Animal identification is defined as the "permanent marking of individual farm animals, or a group or lot of animals, so that they can be tracked from place of birth to slaughter."[939] It is one component of the broader goal of meat traceability, which is the comprehensive

---

930 *Id*.

931 The American Meat Institute offers recall insurance to companies to cover recall costs. *See* www.meatami.com/Content/NavigationMenu/CrisisCenter/AMICrisisManagementResources/AMIProductRecallInsurance/AMIProductRecallInsurance.htm.

932 *See* Ellestad Affidavit, *supra*, at 15-16.

933 Guy Gugliotta & Dan Morgan, *Inspection Practices Examined*, Washington Post, December 25, 2003, at A16.

934 *Id*.

935 Vedantam & Harden, *Probe of Infected Cow Spreads, So Does Worry*, *supra*.

936 *U.S. Ends Its Hunt for More Cases of Mad Cow Disease*, *supra*.

937 Lisa M. Krieger, *National ID Plan Would Protect Against Disease*, San Jose Mercury News, Jan. 13, 2004 (quoting Ken Foster, a Purdue University agricultural economist).

938 Shankar Vedantam, *U.S. Ends Investigation of Mad Cow Case*, *supra*.

939 Geoffrey S. Becker, *Animal Identification and Meat Traceability*, CRS Report for Congress, Code RL32012, Dec. 31, 2003 at 1.

tracking of meat products through the entire life cycle from birth to consumption.[940] The 1999 NAS Ensuring Safe Food Report complained that "mechanisms are lacking for tracing a diseased animal back to point of production on the farm," a situation that "prevent[ed] the ability to reduce the likelihood of future incidents."[941]

When Secretary Veneman promised on December 30, 2003 to "begin immediate implementation of a verifiable system of national animal identification,"[942] 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.[943] As discussed above, USDA had been working with state agencies and industry groups since 2002 to come up with an acceptable Animal Identification Plan.[944] 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.[945] This was, of course, a highly optimistic prediction that depended upon a smoothly functioning rulemaking process in which the comments did not force the Department to rethink any significant aspect of the program and in which no one sought judicial review of the final rule. Other estimates have the identification system in place by July 2006.[946] When pressed for a timeline in January 21, 2004 congressional hearings, Secretary Veneman explained that the Department found itself in the midst of an ongoing debate over how the ID system should be organized and who should fund it, and she did not have an estimate for when the plan would be ready.[947]

Although consumer groups have advocated mandatory animal tracking for many years,[948] industry groups have generally resisted such efforts.[949] Only recently, in light of consumer fears and the negative effect on foreign trade generated by the Washington mad cow, have industry groups actively begun to support a voluntary animal identification program.[950]

---

940 *Id*. at 2.

941 NAS Safe Food Report, *supra*, at 83.

942 Veneman Announces Additional Protection Measures To Guard Against BSE, *supra*.

943 *See* Denise Grady, *Way to Track U.S. Cattle Isn't Ready for Quick Use*, New York Times, January 3, 2004.

944 *See supra* Section IV.A.2.d.

945 *USDA Creating National Livestock ID System*, AgOnline, December 8, 2004.

946 Hileman, *Mad Cow Disease*, *supra*, at 24.

947 Testimony of Ann M. Veneman, Secretary, Department of Agriculture before the Senate Committee on Agriculture, January 21, 2004. *See also* Ira Dreyfuss, *National Animal-Tracking System Still Years Away*, Seattle Times, February 9, 2004 (no timeline); Marc Kaufman, *Cattle IDs to Combat Mad Cow*, Atlanta Journal-Constitution, January 22, 2004 (ongoing debate).

948 Consumer Federation of America, A Mandatory Animal Identification System Capable of Tracing All Animals Back to the Farm of Origin is Essential to Protect Public and Animal Health, Jan. 23, 2004.

949 Stephanie Simon, *USDA Plans to Beef Up Livestock ID System*, *supra*; Margaret Webb Pressler, *Cattle-Tracing System Will Face Obstacles*, Washington Post, January 3, 2004, at E1.

950 Charles Abbott, *U.S. Cattle Tracing Will Calm Beef Fears*, Reuters, Jan. 20, 2004; *USDA Creating National Livestock ID System*, *supra* (quoting John Wiemers, National ID Coordinator for USDA-APHIS) ("Just recently, in the last two to three years, it (animal ID) has become more of a 'have-to' kind of

One unresolved issue is whether animal identification will be voluntary or mandatory.[951] Most countries that have animal identification programs in place make them mandatory, and Canada reports that animal registration did not rise above 75% participation until the program became mandatory.[952] To provide a comprehensive tracking system, animal identification must be mandatory to prevent gaps in coverage from defeating the program's purpose.

Another contentious issue is who should pay the cost of 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.[953] Cost estimates for workable identification devices range from $5 to $20 per head.[954] Startup costs for the program would be about $600 million, and annual costs are estimated to range from $70 to $122 million annually.[955] 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.[956]

The cattle industry would, of course, prefer to have the government foot the bill for any universal animal identification program, but the Bush administration has reportedly requested $33 million for animal identification as part of the FY 2005 budget.[957] While this represents a substantial increase over the zero budget for the animal identification program in prior years, it will still be insufficient for an effective program without substantial industry contributions. Meanwhile, mad cow disease in the United States is predicted to cost the cattle industry up to $2 billion.[958]

Another industry concern has been the potential of an identification program to decrease protections for confidential business information and increase the risk of tort liability.[959] A National Cattlemen's Beef Association spokesmen hoped that "we're not creating

---

thing as we're faced with foreign animal diseases, such as foot-and-mouth and mad cow disease, that are knocking at our doorstep.")

951 Charles Abbott, *After Mad Cow, U.S. Farmers Warily Back Animal ID*, Reuters Health, Jan. 9, 2004.

952 Abbott, *U.S. Cattle Tracing Will Calm Beef Fears*, *supra*.

953 Michelle Cole, *Reliable Tracking of Cattle Could Be Years Away*, Newhouse News Service, March 8, 2004; Pressler, *Cattle-Tracing System Will Face Obstacles*, *supra*; Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, *supra*.

954 *A High-Tech Race To Corral Mad Cow*, Business Week, March 1, 2004.

955 Draft U.S. Animal Identification Plan, *supra*, at 45. *See also* Pressler, *Cattle-Tracing System Will Face Obstacles*, *supra*.

956 Simon, *USDA Plans to Beef Up Livestock ID System*, *supra*.

957 Cole, *Reliable Tracking of Cattle Could Be Years Away*, Newhouse News Service, March 8, 2004; Les Blumenthal, *No Wider Testing for Mad Cow Disease But Bush Will Seek an Extra $47 million for Meat Safety*, Sacramento Bee, Jan. 30, 2004, available at http://www.sacbee.com/content/politics/story/8184979p-9116306c.html.

958 Purdue University Cooperative Extension Service, *Economist: Mad Cow Case Could Cost Beef Industry $2 Billion*, Dec. 24, 2003, available at http://www.ces.purdue.edu/madcow/industry.html.

959 Simon, *USDA Plans to Beef Up Livestock ID System*, *supra* ("Many ranchers worry that farm-to-plate tracking will leave them vulnerable to consumer lawsuits.").

something for trial lawyer's heaven."[960] It is very difficult 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 identification program: "We have lost the right to anonymity if we're food producers."[961] The fact that an identification program could be used to hold a negligent producer liable for damage caused by its negligence is a reason to support such a program, not reject it.

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.[962] In England, cattle must be individually identified and reported by producers to the national tracing system run by the government.[963] Compliance is apparently high, perhaps because EU agricultural subsidies are contingent upon maintaining accurate producer records.[964] Additionally, the government makes regular inspections and slaughterhouses can only accept properly identified cattle.[965] Costs are shared between the government and producers, with the government providing approximately 30 million out of 55 million pounds annually.[966] Other EU countries have cattle identification systems run by private companies and funded by farmers. In Denmark, for example, a farmer-owned private company manages a national database that is funded by an annual fee on farmers.[967] Canada also has had an animal identification system in place since 2001 that is run jointly by the Canadian Cattle Identification Agency, an industry group, and the Canadian Food Inspection Agency.[968] All Canadian cattle must be tagged before leaving their herd of origin and their identification numbers are tracked through an agency database and recorded at slaughter.[969]

XIII Why the Firewalls Are Failing -- Underlying Causes of Inadequate Regulation.

Many of the underlying causes of firewall failure were addressed in the particular critiques detailed above. Several additional underlying causes of the failure cut across many of the individual firewalls. Both USDA and FDA have engaged in a sustained and

---

960 Andrew Martin, *The Race to Trace Food Disease, U.S. Government Tries to Catch Up*, Chicago Tribune, Jan. 31, 2004.

961 Pressler, *Cattle-Tracing System Will Face Obstacles*, *supra*.

962 Drew, Becker & Blakeslee, *Despite Mad-Cow Warnings, Industry Resisted Safeguards*, *supra*.

963 National Audit Office, Identifying and Tracking Livestock in England, at 2, Nov. 2003, London, England, available at http://www.nao.gov.uk/publications/nao_reports/02-03/02031144.pdf.

964 *Id*. at 14.

965 *Id*.

966 *Id*. at 12.

967 *Id*. at 49.

968 Canadian Cattle Identification Agency, Report from the Canadian Cattle Identification Agency, Sept. 2002, available at http://www.canadaid.com/publications/From_GM/Sept_10_2002.shtm.

969 National Audit Office, *Identifying and Tracking Livestock in England* at 2, Nov. 2003, London, England available at http://www.nao.gov.uk/publications/nao_reports/02-03/02031144.pdf.

ultimately deceptive campaign to characterize their faulty regulatory choices as "science-based" when in fact they have clearly been dominated by economic and political considerations. Although robust public debates might have helped avoid many of the problems that plague the current firewalls, USDA has vigorously shielded the industry and its own deliberations from public scrutiny and criticism. Both FDA and USDA face numerous legal and resource constraints that hamper effective enforcement of the regulatory requirements out of which the firewalls are built. Finally, several institutional and structural deficiencies in the current regulatory regime, such as institutional conflicts-of-interest, the revolving door, and the great influence that the industry has over USDA and its oversight committees in Congress, greatly hamper the government's efforts to maintain adequate firewalls against the spread of mad cow disease.

A. Abuse of "Science" to Advance Economic and Political Goals.

Appeals to science are generally more politically salable than appeals to economics. Characterizing decisions as "science-based" suggests that they will be determined by objective criteria, solid empirical data and rational analysis. Most people believe that society is better off when safety regulations are based upon sound science, rather than unfounded emotions. People recognize that appeals to economics, on the other hand, are nearly always motivated by self-interest. It is therefore politically wise to frame self-interested appeals not as appeals to economics, but as appeals to science.

This fundamental political reality was captured very nicely in a recently leaked memorandum from political consultant Frank Luntz (the originator of the "Contract with America") to Republican leaders. In discussing the global warming debate, Luntz observed:

> The economic argument should be secondary. Many of you will want to focus on the higher prices and lost jobs that would result from complying with Kyoto, but you can do better. Yes, when put in specific terms (food and fuel prices, for example) on an individual-by-individual basis, this argument does resonate. Yes, the fact that Kyoto would hurt the economic well being of seniors and the poor is of particular concern. However, the economic argument is less effective than [other listed arguments].
>
> The most important principle in any discussion of global warming is your commitment to sound science. Americans unanimously believe all environmental rules and regulations should be based on sound science and common sense. Similarly, our confidence in the ability of science and technology to solve our nation's ills is second to none. Both perceptions will work in your favor if properly cultivated.[970]

In addressing recent public concern over mad cow disease, the Bush Administration has apparently followed Mr. Luntz's advice very closely, never missing an opportunity to praise its own initiatives, however much driven by economic considerations, as "science-

---

[970] Frank Lutz, *Straight Talk, The Environment: A Cleaner, Safer, Healthier America*, at 137-38, available at http://www.luntzspeak.com/graphics/LuntzResearch.Memo.pdf.

based" and criticizing suggestions for more stringent regulations as not based on "sound science."[971]

Testifying to the House Agriculture Committee, Secretary Veneman assured the public that the United States was "leading the effort to ensure that the international response to BSE is science-based."[972] She strenuously objected to the Japanese insistence that USDA follow that country's practice of testing all animals for BSE prior to slaughter on the ground that universal testing would not be based on "sound science."[973] At a press luncheon in April 2004, Secretary Veneman explained that the United States was, instead, employing "sound science" to pressure Japan and 57 other countries to resume imports of U.S. beef.[974] At the same luncheon, Secretary Veneman explained that "sound science" would also guide her decision whether to allow imports from Canada to resume after a mad cow was discovered in that country, a decision that has still not been made.[975] Apparently, "sound science" dictates one result when the issue is the safety of U.S. cattle but a different result when the issue is the safety of Canadian cattle.

In reality, the Bush Administration's reaction to the discovery of the Washington State mad cow has very little to do with science and a great deal to do with economics and politics. A former head of FSIS and current director of the Consumer Federation of America's Food Policy Institute concludes that "USDA has chosen in every instance since the issue of BSE arose to look at the available science and then take the course of action that will impose the least possible cost on the industry and provide the least reassurance and protection to consumers."[976] A long-time observer of the public relations industry notes that "[t]he United States has spent millions of dollars on PR convincing Americans that mad cow could never happen here, and now the USDA is engaged in a crisis management plan that has federal and state officials, livestock industry flacks, scientists and other trusted experts assuring the public that this is no big deal."[977]

In its constant reiteration of the "sound science" theme, the Bush Administration has relied time and again on the HCRA Risk Assessment or, as various spokespersons invariably describe it, the "Harvard Study." Seldom has the product of an industry

---

971 The demand for "sound science" in regulating mad cow risks has been bi-partisan. At the House hearings, Rep. Charles W. Stenholm (D-Tex) stressed that USDA "must make objective decisions based on sound science alone." Opening Statement of Hon. Charles W. Stenholm, *Hearings on Review of the U.S. Department of Agriculture's Bovine Spongiform Encephalopathy (BSE) Response*, January 21, 2004, at 1. Senator Max Baucus (D-Mont) later emphasized to Japanese government officials the need to employ "sound science" in deciding whether to withdraw their import restrictions on U.S. beef. *Japan Mad Cow Barriers May Bring More Conflict*, Reuters, March 15, 2004.

972 Testimony of Ann M. Veneman, Secretary, Department of Agriculture before the Senate Committee on Agriculture, January 21, 2004.

973 USDA Veneman sees no need for blanket mad cow tests, *supra*.

974 Jim Barnett, *"Sound Science" Should Guide Other Nations In Reviving U.S. Beef Imports, Official Says*, The Oregonian, April 7, 2004.

975 *Id*.

976 Hileman, *Mad Cow Disease*, *supra*, at 22.

977 John Stauber, *U.S. Needs To Do Right Thing To Stop Mad Cow Disease*, Madison.com, January 5, 2004.

funded think tank had such a powerful effect on public policymaking. The HCRA risk assessment, however, does not on its own terms support the broad and comforting conclusions that USDA and FDA officials frequently attribute to it, and it does not really support even its own much more limited conclusions. As discussed above,[978] the HCRA risk assessment posits hypothetical scenarios and draws conclusions about those scenarios based upon assumption-driven models and very little raw data. It is filled with caveats, and it forthrightly admits that its conclusions are "not amenable to formal validation." It is, in short, a gedanken exercise, and cannot honestly be portrayed as more than that.[979]

Perhaps the starkest example of the misuse of the "sound science" appellation to justify a policy that was based entirely upon economic and political considerations is USDA's refusal to allow a company to test all of its cattle for mad cow disease at its own expense.[980] The head of APHIS justified USDA's decision with the unenlightening explanation that the Department had to "stick to the science."[981] Aside from alluding to USDA's belief that younger cattle could not contract mad cow disease, an assertion that is belied by the facts in other countries, he did not explain how universal testing could possibly be contrary to science.[982] The evidence is, in fact, quite to the contrary. In Italy, where universal testing of all animals greater than 30 months of age is the practice, scientists are gaining a much better understanding of the incidence of mad cow disease in that country and are in fact learning more about the disease itself and its relationship to CJD in humans.[983]

In truth, so little is known about TSEs, CJD, and the meaning of "infectivity" in the context of a disease that may not be transmitted through a living organism that "sound science" cannot possibly dictate the proper regulatory approach.[984] In such situations,

---

978 *See supra* Section V.

979 A review by *The Oregonian* of the study and statements by Administration officials about the study concluded that "in their rush to embrace 'sound science,' Veneman and others at times mischaracterized the study's purpose, recommendations or conclusions." Jim Barnett, *Bush Officials Overstated Findings Of Risk Study*, The Oregonian, January 27, 2004. For example, although agency spokespersons have frequently told the public that actions taken by their agencies were consistent with the recommendations of the "Harvard study," the HCRA risk assessment did not make *any* recommendations, as the director of the Center is frequently at pains to relate. *Id*. Frequent references to the conclusion that widespread contamination of the meat supply would be "extremely unlikely" (based on a hypothetical introduction of 500 BSE-positive animals and effective enforcement of the 1997 FDA Feed Rules) are made without mentioning the caveat that the conclusion was "not amenable to formal validation." *Id*. Another review by the *Oregonian* noted that Secretary Veneman had repeatedly mischaracterized the HCRA report in telling the public that "early government protection systems have been largely responsible for keeping BSE out of the United States." *Id*. The authors of the study, however, have consistently been at pains to caution that the risk assessment did not attempt to assess the risk that infected cows or cattle feed would be imported into the U.S. *Id*.

980 *USDA Veneman Sees No Need For Blanket Mad Cow Tests*, *supra*. *See supra* Section XI.D.2.

981 Kaufman, *Company's Mad Cow Tests Blocked*, *supra*.

982 *Id*.

983 McNeil, Jr., *Research in Italy Turns Up a New Form of Mad Cow Disease*, *supra*; *New Form Of Mad Cow Disease Found*, *supra*.

984 Hileman, *Mad Cow Disease*, *supra*, at 21 ("Because so little is known about prion diseases, it is hard to determine a regulatory approach that is based on sound science"). If "sound science" requires unanimity in the scientific community, then no governmental action would ever be supported by "sound

policy considerations must determine the extent to which the government intervenes into private market arrangements to protect public health and the environment.[985] The FMIA and the FDCA both rather clearly articulate a precautionary policy of erring on the side of safety in situations, like the regulation of TSE risks, where science alone cannot determine the proper regulatory response. USDA has, for unexpressed extra-statutory policy reasons of its own, decided to err on the side of protecting the dominant firms in the beef industry from economic loss.

B. 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. Critical matters of great public concern are worked out between industry representatives and government officials without any participation by representatives of consumers who are supposed to be the beneficiaries of the regulatory protections. One observer of the meat industry has concluded that it "maintains a level of secrecy that far exceeds that of nuclear power plants."[986] And the federal government has frequently aided and abetted the industry's passion for secrecy.

1. Lack of Transparency in the Import Restriction Program.

The first firewall in the defense against an outbreak of mad cow disease in the United States is the restrictions in place on imports from countries in which BSE has been reported. 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 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 USDA had put in place after the discovery of a mad cow in Canada in May 2003.[987] Although a public outcry forced USDA to back away from that proposal once the media publicized it, public trust in the transparency of USDA's import program was shattered by reports in May 2004 that APHIS had for months already been allowing imports of up to 33 million pounds of restricted beef products, including hamburger meat and processed meat containing offal,

---

science." As if to prove the point, citing a single aberrational article in the British Medical Journal, Steven Milloy, a Cato Institute fellow, has concluded that the widely accepted conclusion that TSEs are transmissible from mad cows to humans is not based on "sound science." Steven Milloy, *Don't Have a Cow*, Los Angeles Times, January 2, 2004. Instead, "variant Creutzfeldt-Jakob is a rare, isolated and apparently random disease of unknown origin," and the discovery of the Washington mad cow does not "justify the current panic about the safety of the beef supply." *Id.*

985 *See* Committee on the Institutional Means for Assessment of Risks to Public Health, National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983); Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo. L.J. 729 (1979); Wendy E. Wagner, *The Science Charade In Toxic Risk Regulation*, 95 Colum. L. Rev. 1613 (1995).

986 Fox, *Spoiled*, *supra*, at 357.

987 *See supra* Section XI.B.

from Canada under a secretly administered "exemption" process.[988] Perhaps even more outrageous was USDA's refusal even to name the U.S. meat producers that had secured the secret permits.[989]

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

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.[990] 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 involving suspect HACCP programs, for 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.[991] An inquiry to one of the largest meat processors in the United States seeking information on the steps that it was taking to implement the January 2004 regulations resulted in the following curt response: "[O]ur HACCP plans are proprietary and so we are unable to provide you with the information you requested."[992]

The product 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 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 quid pro quo is some vehicle for assuring a sometimes skeptical public that the performance goals are in fact being met. In the case of USDA's HACCP program, the government is not fulfilling its side of the bargain.

3. Lack of Transparency in the Animal Identification Program.

Although the nationwide animal identification program that Secretary Veneman promised would be forthcoming in the very near future may be years away, there are already ominous 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. 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

---

988 *See* Kaufman & Skrzycki, *USDA Rescinds Policy Allowing Sale of Canadian Beef*, *supra*; *See supra* Section XI.B.

989 Kaufman, *USDA Allowed Canadian Beef In Despite Ban*, *supra*.

990 *See supra* Section IV.A.1.d.

991 USDA HACCP Proposed Rule, *supra*, at 6818.

992 Email to Elizabeth Duffy from Mark Klein, Cargill Corporation, dated March 31, 2004.

well be protected from release under the Freedom of Information Act (FOIA).[993] It did not take long before a bill was introduced in Congress to exempt animal identification information from FOIA disclosure altogether.[994]

4. Lack of Transparency in the Recall Process.

In order to encourage industry participation in recalls, USDA has implemented a policy of keeping the details and results of recalls secret.[995] 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 five 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 consumers.[996] 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 with USDA. Under that memorandum of understanding, which USDA demands of all states participating in such recalls, federal officials agree to share with state officials the names of stores and restaurants to which recalled meat has been shipped, but the state may not reveal those names to the public.[997] Interpreting the memorandum broadly, state officials refused to reveal critical recall information even to the counties in which the meat had been sold.[998] Worse, the State Department of Health Services did not find out about the recall until a week after USDA had implemented it.[999] USDA's insistence upon keeping the recall process secret has been driven by its need to secure the voluntary cooperation of the companies engaged in the recall. If USDA had mandatory recall authority, privacy would no longer be necessary.

C. Practical Enforcement Difficulties.

Consumer groups and food safety advocates were generally supportive of USDA's attempts to adopt a HACCP-based approach to meat safety, but they were concerned that the "performance-based" aspects of that approach would not be enforceable.[1000] This general concern was shared by the authors of the NAS report on Scientific Criteria to Ensure Safe Food, 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

---

993 Nelson Antosh, *Tracking of Cattle Becomes Key Goal*, Houston Chronicle, March 5, 2004.

994 *Id*.

995 Jon Ortiz, *State Wants To Revisit Beef-Recall Secrecy Pact*, Sacramento Bee, February 18, 2004.

996 Sabin Russell, *Mad Cow Censoring Gets Legislators' Goat*, San Francisco Chronicle, February 25, 2004.

997 *Id*.

998 *Id*.

999 Jon Ortiz, *State Hit A Wall On Beef Recall*, Sacramento Bee, May 10, 2004.

1000 USDA HACCP Proposed Rule, *supra*, at 6784.

controlling old and emergent foodborne hazards and have prompted many to question the effectiveness and appropriateness of the current system."[1001]

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."[1002] Unfortunately, the weaknesses of the performance-based approach adopted in the FSIS HACCP regulations are especially clear when viewed through the enforcement lens.[1003] 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 limited.

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.[1004] 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.[1005] 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.[1006] 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.[1007]

One of the primary purposes of adopting the 1996 HACCP regulations was to put the 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.[1008] As part of their HACCP inspection duties, in-plant FSIS Consumer Safety Inspectors regularly review their assigned plant's hazard analysis,

---

[1001] NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 2.

[1002] Lassiter, *Hoof to Hamburger*, *supra*, at 444. Professor Lassiter has concluded that the HACCP regulations "are significantly flawed because the imposed enforcement mechanisms are weak and inadequate." *Id*. at 446.

[1003] Lassiter, *Hoof to Hamburger*, *supra*, at 446.

[1004] Burson Interview, *supra* ("The inspector can look at the head very easily. The inspector visually inspects the spinal cord removal process.").

[1005] *Id*. ("There is a physical inspection at the end of the process that is mostly relied on to detect SRM in muscle tissue.").

[1006] *Frontline*, *Modern Meat*, *supra*, at 7.

[1007] McNeil, Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*.

[1008] Fox, *Spoiled*, *supra*, at 356.

HACCP Plan, prerequisite programs, and all supporting documentation.[1009] 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.[1010] It is always possible that a company "whistleblower" will bring such fraud to the agency's attention, but the fact that the FMIA fails to provide whistleblower protections greatly reduces the likelihood of that ever happening.[1011]

FSIS inspectors do conduct unannounced inspections during which they undertake their own testing at critical points.[1012] 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 verify "the proper execution of the HACCP plans or the prerequisite programs."[1013] In particular, the inspector is 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., verify adequacy of Sanitation SOP procedures)."[1014] On-line inspections of individual carcasses or heads should attempt to "observe visible (readily identifiable) SRMs on edible portions of the product."[1015]

It is not at all clear that 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.[1016] The NAS Ensure Safe Foods committee concluded that "[a]dequate resources have not been provided to enable the implementation of HACCP-based inspection effectively, efficiently, and without disruption."[1017] Nevertheless, Congress has not significantly added to USDA's

---

1009 Beasley-McKean/Duffy Email, 5/3/04, *supra*, at 2.

1010 *See* Lassiter, *Hoof to Hamburger*, *supra*, at 446, 455 ("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.").

1011 *Id*. at 453 ("To date, Congress has not granted whistle-blower protection to meat industry employees").

1012 9 C.F.R. 310.25(b)(2), 381.94(b)(2), 417.8. The frequency of unannounced inspections, however, depends upon the number of violations reported in the producer's records.

1013 FSIS Notice 9-04, *supra*, at 3.

1014 *Id*.

1015 *Id*. at 4.

1016 CRS Issue Brief 8/1/03, *supra*, at CRS-6.

1017 NAS Safe Food Report, *supra*, at 31.

appropriation for inspection activities, and it has steadfastly refused to allow FSIS to charge establishments user fees to cover the cost of inspections.[1018]

2. Pressures on USDA Inspectors.

Even if USDA inspectors could be everywhere, they face strong pressure from the facilities they inspect and sometimes from their superiors at 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.[1019] 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.[1020]

FSIS inspectors can theoretically exercise the option of shutting down facilities that fail "to ensure that product is not adulterated" or fail to maintain sanitary conditions, even if the failure in question is not specifically prohibited in the regulations.[1021] FSIS instructions for inspectors, however, make it very clear that stopping a moving production line is a very 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."[1022] The instructions warn inspectors that "[s]topping production for 'possible' cross contamination is unjustifiable unless you can verify that there is direct product contamination."[1023] Clearly, FSIS inspectors face pressure from upstairs to keep the lines moving, even in the face of serious safety concerns.

3. Lack of Civil Penalty Authority.

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 inspectors, thereby effectively closing the plant down. 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. Notably, 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.[1024]

1018 CRS Issue Brief 8/1/03, *supra*, at CRS-7.

1019 McNeil Jr., *Mad Cow Case May Bring More Meat Testing*, *supra*.

1020 *See*, *e.g.*, *id*. (reporting complaints of Dr. Lester Friedlander, a former USDA veterinarian).

1021 USDA Sanitation Requirements Final Rule, *supra*, at 56402.

1022 *It's What's For Dinner*, Harper's Magazine, April 2003.

1023 *Id*.

1024 CRS Issue Brief 8/1/03, *supra*, at CRS-10.

The withdrawal of inspectors is the regulatory equivalent of dropping the atomic bomb, because the economic consequences of an FSIS withdrawal for a large slaughterhouse or meat processing plant are so high that the agency is necessarily very reluctant to consider it. Since the establishments know that withdrawal is not a serious option, the reality is that most detected violations lead at most to the filing of an 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. None of this should put consumers' minds at ease about the safety of the meat that comes out of plants run by routine violators of USDA safety regulations. Again, this state of affairs could be easily remedied by providing FSIS with civil penalty authority.

D. Institutional Conflict of Interest.

A fundamental underlying problem with USDA's approach to mad cow disease is its narrow view of its primary mission. Many USDA officials see its primary role as the pre-eminent 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. APHIS is an animal-and-plant agency."[1025] 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 in part attributable to the fact that USDA suffers from an "institutional conflict of interest" of the sort that characterized the old Atomic Energy Commission.[1026] USDA's primary task has always been to advance the interests of American agriculture.[1027] As such, USDA has been the country's chief spokesperson, advocate and apologist for agricultural economic interests. At the same time, Congress has charged 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.[1028] On those relatively rare occasions when 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.[1029] Professor Marion Nestle observes that "for decades, food

---

1025 Henderson, *USDA's Selective Screens Aren't Enough, Say Some Firms, Scientists*, *supra*.

1026 *See generally* Karen Shrader-Frechette, *Nuclear Power and Public Policy* (1980); E. Rolph, *Nuclear Power and the Public Safety* (1979); Shrader-Frechette, *Nuclear Power and Public Policy*, *supra*.

1027 Nestle, *Safe Food*, *supra*, at 63.

1028 *See* Eric Schlosser, *The Cow Jumped Over the U.S.D.A.*, *supra* ("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. Ref. 1089 (1987), at 1089.

1029 Nestle, *Safe Food*, *supra*, at 64.

producers, USDA staff, and members of the House and Senate agriculture committees constitute what was universally understood to be the 'agricultural establishment.'"[1030]

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.[1031] 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.[1032] The strong tendency to elevate "flexibility" over protection in its promulgation and administration of the SRM regulations also suggests institutional bias.[1033]

E. The revolving Door.

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.[1034] A young political appointee with a mid-level supervisory job at USDA may with a change in Administrations find him or herself working for an industry trade association. A young Hill staffer, after acquiring expertise in complex agricultural legislation and accumulating many useful contacts, may decide to abandon the cramped quarters and low salary of the legislative branch for a large office in USDA or the considerably more lucrative lifestyle of a corporate lobbyist.

On rare occasions, consumer advocates have been appointed to high positions in USDA,[1035] and once in awhile champions of consumer interests have served on one of the congressional agriculture committees.[1036] These people, however, are the exceptions to the rule, and they frequently grow frustrated with the difficulty of moving against the constant pressures generated by a very powerful industry and its allies in both Congress and the Executive Branch.

1030 *Id*.

1031 Matthew Daly, *Consumer Groups Want More Cattle Testing*, Associated Press, Jan. 16, 2004 (consumer group complaints).

1032 *See supra* Section IV.A.1.d.

1033 *See supra* Section XI.F.2.

1034 Nestle, *Safe Food*, *supra*, at 64.

1035 Carole Tucker Foreman, who is 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. Pew Initiative on Food and Biotechnology, http://pewagbiotech.org/events/1121/bios/foreman.php.

1036 Congressman George Brown, who chaired the House Agriculture Committee from 1991 to 1994, was generally regarded as a friend to consumer and environmental groups. *See* http://www.house.gov/science_democrats/releases/99jul16.htm.

The "revolving door" was spinning especially rapidly at the outset of the Bush Administration. Secretary Ann Veneman 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.[1037] Her predecessor as Secretary of Agriculture, Dan Glickman, left USDA to join a law firm that lobbies for the food and agriculture industries.[1038] Veneman appointed a lobbyist for the National Cattleman's Beef Association, Dale Moore, to be her chief of staff.[1039] Moore was 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 1993-1994.[1040] Charles Lambert, Deputy Under Secretary for Marketing and Regulatory Programs at the USDA, had been a lobbyist for the National Cattlemen's Beef Association for 15 years before joining USDA.[1041]

F. Money and Politics.

One consideration that rather clearly appears to be guiding the Administration's policy choices is the welfare of large agricultural interests. In the years since World War II, the beef industry has become a highly concentrated, but intensely competitive subsector of the U.S. economy in which profits are maximized by using every gram of protein available as efficiently as possible. Although it claims to be a strong proponent of food safety and has struggled mightily to create and maintain the public perception that domestic beef is the "safest in the world," the beef industry has doggedly resisted efforts by consumer groups and the federal government to enhance safety when such improvement comes at the expense of efficiency.[1042] Many observers believe that the

---

[1037] Center for Responsive Politics, http://www.opensecrets.org/bush/cabinet/cabinet.veneman.asp.

[1038] Harvard University, Kennedy School of Government Faculty Page, available at http://ksgnotes1.harvard.edu/degreeprog/courses.nsf/wzByDirectoryName/DanGlickman

[1039] Nestle, *Safe Food*, *supra*, at 65.

[1040] USDA People in the News, USDA News, 60(1), 2001, available at http://www.usda.gov/news/pubs/newslett/old/vol60no1/moore.htm

[1041] Anne C. Mulkern, *When Advocates Become Regulators*, Denver Post, May 23, 2004, available at www.denverpost.com/Stories/0,1413,26~11676~2164693,00.html. Other revolving door notables include L. Val Giddings, a biotechnology regulator and biosafety negotiator at the USDA who became Vice President for Food and Agriculture of the Biotechnology Industry Organization (BIO); Terry Medley, a former administrator of APHIS and chair of the USDA Biotechnology Council who became Director of Regulatory and External Affairs of DuPont Corporation's Agricultural Enterprise; Margaret Miller, a former chemical laboratory supervisor for Monsanto who became Deputy Director of Human Food Safety and Consultative Services, New Animal Drug Evaluation Office, Center for Veterinary Medicine in the USDA; Michael Taylor, a former partner at the law firm of King & Spaulding, whose clients included Monsanto, and who became Deputy Commissioner for Policy at the USDA and later head of Monsanto Corporation's Washington D.C. office; and Clayton Yeutter, former Secretary of the USDA who became a member of the Board of Directors for Mycogen Corporation, whose majority owner is Dow Agrosciences. The Edmonds Institute, www.edmonds-institute.org/olddoor.html

[1042] *See* Michael Moss, Richard A. Oppel Jr. & Simon Romero, *Mad Cow Forces Beef Industry to Change Course*, New York Times, January 5, 2004 ("For years, the industry had a simple strategy: Fight proposals that would crimp its ability to squeeze as much revenue as possible from each cow.").

best explanation for the federal government's anemic response to the discovery of the Washington State mad cow is that "powerful livestock and animal feed industries continue to call the shots at FDA and USDA."[1043]

The agriculture and food industries also have a great deal of influence over the House and Senate Agriculture Committees and Appropriations Committees, all of which in turn have a powerful influence on USDA policy choices. Both industries are consistent and large contributors of campaign dollars to the members of all of these committees. According to the Center for Responsive Politics, individual and PAC contributions from agribusiness are among the top contributors to members of the Senate and House committees on agriculture and appropriations.[1044] In fact, agribusiness was the largest single contributor to members of the House Agriculture Committee during the 2001-2002 election cycle.[1045]

XIV Additional Actions that USDA Should Take.

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. This section of the report and the one that follows it outline changes that USDA and FDA can implement on their own with little or no assistance from Congress other than supplying much needed additional resources. The section after that suggests reforms that will probably require legislation and are therefore properly addressed to Congress.

A. Ensure that Imported Beef Complies with U.S. Requirements.

One of the most disturbing of USDA's many troubling responses to the mad cow problem was its secret grant of exemptions for 33 million pounds of beef imports from Canada that circumvented its otherwise applicable import restrictions on Canadian beef. This 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. 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 process for granting any import exemptions in which the public

---

1043 John Stauber, *It's the Cow Feed, Stupid!*, CommonDreams.org, December 31, 2003.

1044 Center for Responsive Politics, www.opensecrets.org/cmteprofiles/overview. Corporate campaign contributions from the food and agriculture industries are almost exclusively devoted to Republican candidates. In 2001, the National Cattlemen's Beef Association donated 82 percent of its total campaign contributions to Republicans, the National Food Processors Association 96 percent and the United Dairy Farmers 100 percent. Anne Lappe, *Last Meals? How Corporate Power Taints Safety Rules*, San Francisco Chronicle, March 30, 2003.

1045 Center for Responsive Politics, www.opensecrets.org/overview.

receives notice of exemption requests and is provided an opportunity to comment on those requests.

USDA should also take steps to ensure that beef and beef products imported into this country comply with the January 2004 regulations. By law, meat imported for human consumption must be slaughtered and processed in accordance with U.S. laws and regulations.[1046] Soon after issuing the January 2004 rules, USDA sent a letter to the 10 relevant importing countries informing them of their obligation to adopt the same or equivalent rules,[1047] and it later reported to Congress that all of the countries had done so and were 100 percent compliant.[1048] The Department did not, however, indicate what steps it took to ascertain the accuracy of compliance determinations.

USDA does in fact have inspectors in place in plants in countries that import meat into the United States, and they should be monitoring compliance with the U.S. rules. As with U.S. companies, however, "compliance" with broad and flexible "performance-based" standards is a vaguely defined concept. With respect to the SRM zero-tolerance rule in particular, it should be possible to put an independent surveillance program into place that tests meat and meat products for the presence of SRMs as they exit the foreign plants. Furthermore, FDA could provide a strong incentive to importers to comply with the SRM regulations if it tested a significant percentage of imported meat for the presence of SRMs at the time it is imported into this country.

B. Increase Surveillance.

USDA should follow the example of the EU and test all cattle of greater than 30 months in age for BSE prior to slaughter for human consumption.[1049] If, however, the Department persists in its stubborn refusal to consider a program for universal testing of all cattle or all cattle in some age-determined subcategory, it should at the very least radically revise its current "see no evil" policy. First, FSIS inspectors should continue to take samples from suspect cattle, and APHIS laboratories should not have the option of declining to test those samples for BSE. In addition to testing all FSIS-submitted samples, APHIS should, with the help of an expert advisory committee, design a comprehensive random sampling program under which APHIS personnel simply show up at slaughterhouses and rendering facilities and randomly select cattle brains for sampling. This necessarily means that the program may no longer be voluntary. It is painfully clear that the voluntary testing program under which operators are essentially bribed to allow testing of downer cattle has been an abject failure.[1050] USDA clearly has the authority

---

[1046] 21 U.S.C. § 620.

[1047] Charles Abbott, *U.S. Expects Beef Nations To Adopt Its Mad Cow Rules*, Reuters, January 21, 2004.

[1048] *All Beef Exporters to U.S. Adopt Mad Cow Rule-USDA*, Reuters, January 27, 2004.

[1049] See supra Section XI.D.1.f; Letter to Docket Clerk from Steven Roach, Food Animal Concerns Trust, dated April 9, 2004 (recommending testing of all cattle above thirty months).

[1050] Shannon Dininny, *Mad Cow Surveillance System Criticized*, Boston Globe, March 15, 2004 (quoting Sen. Patty Murray (D-Washington) ("I think it is clear that a system that is entirely voluntary is not working").

under the Federal Meat Inspection Act to implement a program of mandatory testing, and it should do so forthwith.[1051]

Second, USDA should sample and test all downer cattle, no matter how old. Because it is not clear that USDA currently has the authority to require producers and renderers to notify USDA of the fact that an animal is a downer animal and to hold that animal for testing, Congress will have to address this recommendation as discussed below.

Third, USDA should continue its expanded surveillance program beyond the 1.5 years that it is currently anticipated to operate and convert it into a permanent surveillance program of all suspect animals and a random selection of healthy animals. 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 go up as the age category gets higher.[1052]

APHIS's adoption of a more extensive surveillance program will necessarily raise the question of what should be done with the carcasses of sampled animals. Pursuant to the policy that USDA adopted in January 2004, carcasses of suspect animals that are tested should be held until the tests are completed. Carcasses from all cattle that test positive should not be rendered, but should be disposed of by incineration or by some other process capable of destroying mad cow prions. Randomly selected cattle that test negative and are otherwise unadulterated could be slaughtered for human food or rendered into feed for nonruminant animals. Carcasses from downer cattle that test negative could be rendered, but not processed for human consumption.

C. Decentralize Surveillance.

The fact that a single laboratory has historically done all of the BSE testing for the entire country has given rise to suspicions on the part of many FSIS inspectors that the APHIS Ames, Iowa laboratory has been doctoring the results.[1053] Since that laboratory has historically had a monopoly on mad cow testing, there is no way to know whether these suspicions are justified. The International Panel Report recommended that APHIS decentralize mad cow testing,[1054] and the agency has recently authorized several state

---

1051 USDA has recently promulgated a final rule requiring slaughterhouses and rendering plants to grant access to APHIS personnel for the purpose of collecting samples for BSE testing and other purposes. Animal and Plant Health Inspection Service, Blood and Tissue Collection at Slaughtering and Rendering Establishments, 69 Fed. Reg. 10137 (2004).

1052 The International Panel urged USDA to consider testing a random sample of healthy slaughter cattle over 30 months of age. International Panel Report, *supra*, at 7. 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.

1053 Mitchell, *USDA Vets Question Agency's Mad Cow Lab*, *supra* (quoting a USDA veterinarian).

1054 International Panel Report, *supra*, at 8 (panel recommends that "a number of laboratories throughout the country be governmentally approved to conduct screening tests as part of the national surveillance program").

agencies to begin BSE testing.[1055] USDA should continue to decentralize testing for BSE.

D. Permit Voluntary Testing.

USDA's adamant refusal to allow private companies to test their cattle for BSE is simply inexplicable. The rationale that voluntary testing will give consumers a false sense of security because no test is one hundred percent accurate is wholly implausible. It betrays a contempt for the intelligence of consumers that is appalling in a governmental department that is charged with protecting the health of those very consumers. The only plausible explanation for USDA's position is an unshakable desire to protect the big five beef processors from competition. Nothing in 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.

E. 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 is to be done with the condemned animals. Technologies are available that will guarantee the destruction of prions in infected tissue. 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 300 degrees.[1056] 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.[1057] Scientists are also working on a promising technology for cheaply disposing of downer cattle through composting.[1058]

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

---

1055 *See supra* Section VII.H.

1056 Comments on Proposed Rule by Waste Reduction by Waste Reduction, Inc., Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species, dated March 24, 2004; Denise Grady, *With Diseased Animals, Disposal Isn't Simple*, New York Times, January 6, 2004. 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 digestors using this process that can process up to 40,000 pounds of potentially contaminated tissue in a single batch for about $1.5 - 2.0 million apiece. *Id*.

1057 Comments on Proposed Rule by Waste Reduction by Waste Reduction, Inc., *supra* ("alkaline hydrolysis Tissue Digestor manufacturing has not yet benefited from the significant cost reductions that will accompany high volume requirements for these machines").

1058 *Mad Cow Ban Could Prompt More Cow Composts*, Associated Press, April 11, 2004. The effectiveness of composting in destroying mad cow prions, however, has not been demonstrated scientifically. Comments on Proposed Rule by Waste Reduction by Waste Reduction, Inc., *supra* ("there is no evidence that composting destroys the infectivity of BSE prions").

cattle in ways that could lead to transfer of mad cow disease to other animals. This incentive will dramatically increase if FDA ever implements 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 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.[1059] USDA officials have indicated that the Department is willing to consider a similar option, but it has not yet implemented it.[1060]

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, USDA should seek authority from Congress to regulate the disposal of downer and other cattle that die from diseases that pose a threat to human and animal health.[1061]

F. Establish an Effective Animal Identification and Tracking Program.

With the help of state agencies and industry groups, 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.[1062] 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.[1063] A Purdue University economist forecasts that animal identification will reduce costs for both consumers and producers because it will minimize numbers of animals lost by more

---

1059 *New Incentive Offered for Mad-Cow Vigilance*, Chicago Tribune, March 15, 2004.

1060 Randy Fabi & Charles Abbott, *U.S. May Pay Farmers to Test for Mad Cow*, Reuters, January 2, 2004.

1061 *See* Letter to Docket Clerk from Steven Roach, Food Animal Concerns Trust, dated April 9, 2004 (urging USDA to exercise its existing authority to "require licensing of all entities including farms and ranches that dispose of cattle").

1062 Simon, *USDA Plans to Beef Up Livestock ID System*, Los Angeles Times, January 11, 2004. *See supra* Section IV.A.2.d.

1063 *See* Jill E. Hobbs, *Traceability and Country of Origin Labeling*, Presented at the Policy Dispute Information Consortium 9th Agricultural and Food Policy Information Workshop, Montreal, available at http://www.farmfoundation.org/farmpolicy/hobbs.pdf. 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, July 2002 at 5.

quickly interrupting the cycle of disease.[1064] And it is critical that the program be mandatory. Noting that Canada's initial voluntary testing program attained a poor 75 percent compliance, the chairman of the Canadian agency responsible for that country's cattle identification program, reported that compliance climbed to 99 percent once the program became mandatory.[1065]

USDA should implement an effective mandatory animal identification system as expeditiously as possible. Syringe-injectable radio-frequency and digital data chips about the size of a grain of rice are readily available on the U.S. market.[1066] In fact, such chips have already been implanted in millions of wild salmon to facilitate tracking them around hydroelectric dams in the Northwest.[1067] Another technology that scans the retinas of cattle is also available for universal identification purposes.[1068] The latter technology would avoid the risk of a microchip winding up in someone's hamburger.[1069]

USDA has sufficient legal authority to promulgate regulations implementing a nationwide cattle identification system. USDA has for many years employed animal identification tools, such as tattoos, eartags, and other comparatively crude identification devices, to trace diseased animals as part of its ongoing outbreak and eradication programs.[1070] USDA's current cattle identification regulations cite the Animal Health Protection Act (AHPA)[1071] as authority for these programs. That statute authorizes the USDA to regulate interstate movement of animals for purposes of detection, control and eradication of disease.[1072] To establish an animal tracking and identification system, USDA could use its authority to promulgate new regulations to "carry out operations and measures to detect, control, or eradicate any pest or disease of livestock."[1073] Animal identification and tracking for BSE (and other diseases) should easily fall within this authority to "detect" and "control" livestock disease.[1074]

1064 *Economist: Animal Identification Benefits Livestock Industry*, Newswise Business Wire, Jan. 6, 2004, available at http://www.mycattle.com/news/dsp_national_article.cfm?storyid=12154.

1065 *Mad Cow Could Keep Cattle Prices Lower for Months*, Los Angeles Times, January 12, 2004.

1066 Cole, *Reliable Tracking of Cattle Could Be Years Away*, *supra*; Sherrie Gossett, *Bill Proposes Federal Monitoring Using Digital Angle Technology*, WorldNet Daily, February 28, 2004.

1067 Simon, *USDA Plans to Beef Up Livestock ID System*, *supra*.

1068 *A High-Tech Race To Corral Mad Cow*, Business Week, March 1, 2004.

1069 *Id*.

1070 Animal and Plant Health Inspection Services, Animal Identification, available at http://www.aphis.usda.gov/vs/nahps/animal_id/.

1071 Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, §10410 et seq.

1072 *Id*. at §8305, 8306.

1073 *Id*. at §8315, 8308(a).

1074 The Federal Meat Inspection Act (FMIA) empowers USDA to ensure meat safety through inspection and recordkeeping requirements. 21 U.S.C. §601 et seq. (2004). The statute requires slaughterhouses, meat brokers and wholesalers, renderers, and others to maintain records to "disclose all transactions involved in their businesses." *Id*. at §642. This would appear to provide authority for 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, USDA rather clearly has the authority to promulgate regulations requiring companies to keep such records and make them available to USDA inspectors.

G. Eliminate the Specified Risk Material Loopholes.

Although BSE has undeniably been found in cattle much younger that the 30-month cut-off that the SRM Rule establishes for many categories of risky tissues, FSIS decided to allow such materials from younger cattle to be used in human food and animal feed in spite of the risk that they pose of spreading mad cow disease.[1075] The USDA International Panel recommended that FSIS redefine SRM to include brain and spinal cord of all cattle over 12 months of age, skull and vertebral column of cattle over 12 months of age, and lower intestines of all cattle.[1076] The panel noted that the suggested 12-month cut-off represented "a recognition of the fact that some cattle under 30 months of age may be slaughtered with infectivity present in the tissues."[1077] The European Union has defined SRM to include risky tissues of animals imported from the U.K. and Portugal greater than 6 months old and of all animals from other EU countries greater than 12 months old.[1078]

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 the very slight loss of protein to the food supply. The Federal Meat Inspection Act, 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.[1079] 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 12 months of age.[1080]

Furthermore, FSIS should not simply walk away from its decision to exclude bone marrow from the definition of "specified risk material." USDA recognizes one study has shown that bone marrow can transmit BSE, but it has concluded that the findings of that study were "not conclusive."[1081] Although it is not clear that the public should have to wait for a "conclusive" study before it can expect protection from this potentially risky material, 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.

H. Remove the Option of Relying upon Prerequisite Programs.

1075 *See supra* Section XI.F.1.a.

1076 International Panel Report, *supra*, at 5.

1077 *Id*.

1078 *See* Food Standards Agency, Specified Risk Material from October 2003, available at www.food.gov.uk/multimedia/webpage/srmoct03; *see also* Questions and Answers on BSE (Memo/03/3), available at http://europa.eu/int/comm/food/food/biosafety/bse/m03_3_en.pdf [last visited June 4, 2004].

1079 *See supra* Section XI.F.1.a.

1080 *See* Letter to FSIS Docket Clerk from Karen L. Egbert, Center for Science in the Public Interest, dated April 7, 2004 (taking the position that a 12-month age cutoff should be employed in defining SRM).

1081 USDA SRM Interim Final Rule, *supra*, at 1864.

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. It seems reasonably clear that establishments do not behave as if prerequisite programs are as important as HACCP programs because they are designed for "things that you don't have to worry about very much."[1082] FSIS apparently harbors the same belief, because, unlike HACCP programs, prerequisite programs do not require FSIS approval.[1083] In addition, FSIS apparently 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.[1084] Also, much more documentation is required for HACCP programs than for prerequisite programs.[1085] 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 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. Rather than taking samples at critical control points as they do in enforcing HACCP programs, FSIS inspectors are relegated to conducting spot checks for the visible presence of SRMs on edible meat.[1086]

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.

I. 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.[1087] 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. Tests for the presence of some, if not all, SRMs are readily available,[1088] and the sorry experience of the industry 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

---

1082 Burson Interview, *supra*.

1083 *See supra* Section XI.F.2.a.2.

1084 *See supra* Section XI.F.2.a.2.

1085 *See supra* Section XI.F.2.a.2.

1086 *See supra* Section XIII.C.1.

1087 Nebraska Cattle Slaughter SRM SOPs, *supra*, at 2.

1088 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* Section XI.F.2.c.3.

HACCP programs are not periodically undertaken.[1089] 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.[1090] In the absence of objective tests at critical points, the prerequisite programs operate on the "honor system."[1091] If some companies can test for SRMs, then all should. Otherwise, the laggards obtain a competitive advantage in an intensely competitive market.

Finally, FSIS should modify its own testing program to require FSIS inspectors to periodically test random samples of final product 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.[1092] This second layer of testing would provide a needed level of redundancy while at the same time serving as a vehicle for detecting fraud or incompetence in company-administered testing programs.

J. Write Protective Standards for SRM Removal.

The most effective environmental laws often articulate high health and environmental goals, but also charge the implementing agencies with promulgating standards aimed at inducing regulatees to install the best available technologies.[1093] Although the aspirational goals may be achievable over the 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 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. The current FSIS regulations allow FSIS and regulated establishments to give the

---

1089 *See supra* Section XI.F.2.c.3.

1090 USDA Listeria Rule, *supra*, at 34215 ("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* (FSIS "could test for SRMs at the rail under either HACCP or Prerequisite programs").

1091 *See* Foreman Interview, *supra*, at 6 ("If you do away with the [objective] pathogen standards, then the HACCP truly becomes what its critics have charged -- an honor system.").

1092 Letter to Docket Clerk from Steven Roach, Food Animal Concerns Trust, dated April 9, 2004 (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").

1093 *See* Wendy Wagner, *The Triumph of Technology-Based Standards*, 2000 U. Il. L Rev. 83 (2000); Rena Steinzor, *Reinventing Environmental Regulation: The Dangerous Journey from Command to Self-Control*, 22 Harv. Env. L. Rev. 103 (1998).

appearance of adhering to a zero-tolerance policy while actually doing very little in the real world to ensure that SRMs stay out of the food supply.

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.

USDA should 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 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.[1094] In addition, it could promulgate mandatory requirements for sanitizing equipment used on edible tissues that might come into contact with SRMs.[1095] FSIS should also reconsider its willingness to allow regulatees to elect the "reconditioning" option under which company employees can salvage otherwise inedible meat by slicing off areas that are visibly contaminated with SRMs. Finally, 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.

The performance-based HACCP approach provides a useful backup to a system for which adequate safety technologies are already in place. It is not an adequate substitute for the technologies themselves. To fulfill its statutory obligation to protect the public health, 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.

K. 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. If an establishment incorporates the SRM Rule into its HACCP program, the FSIS inspector may issue a Noncompliance Record (NR) to the facility only when the Veterinary Medical Officer or other off-line official determines that "the *process* failed to prevent SRMs from

---

1094 *See supra* Section VII.B.2.

1095 *See supra* Section XI.F.2.d.2.

adulterating product."[1096] When the establishment relies upon prerequisite programs, the only consequence of repeated violations of the zero-tolerance SRM requirement is that the FSIS inspector must "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."[1097]

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.

L. 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 customers if they determine that the customers will detect and remove the SRMs prior to human consumption.[1098] This highly questionable signal to large slaughterhouses to shift their responsibility for keeping SRMs out of meat to their customers should be immediately 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.

M. Consider Banning Advanced Meat Recovery Technologies.

FSIS has since the late 1990s been concerned about the potential for AMR technologies to contaminate edible meat with spinal cord and other CNS material. A 2002 survey revealed that 35 percent of the AMR product sampled contained spinal cord or other prohibited material.[1099] This is not a record to inspire confidence in AMR technologies. The January 2004 AMR Rule prohibits the use of the word "meat" to describe any AMR product that contains any CNS SRM, but given the history of AMR technologies, that is probably not enough. The USDA International Panel recommended that USDA prohibit the processing of all skulls and vertebral columns of cattle over 30 months of age via

---

1096 FSIS Notice 9-04, *supra*, at 4 (emphasis added).

1097 *Id*.

1098 *See supra* Section VII.B.2.

1099 Aaron Zitner, *Bovine Disease Surfaces in U.S.*, *supra*.

AMR technologies, and it further recommended that USDA consider banning AMR technologies altogether.[1100]

FSIS should initiate a rulemaking to solicit public comment on whether it should implement a complete or partial ban of AMR technologies. If FSIS decides not to ban AMR techniques, it should require that labels of meat containing AMR product bear the statement that: "This meat product contains tissue from Advanced Meat Recovery processes and may include small amounts of materials from the central nervous systems of cattle."

N. Increase Transparency.

When the issue is something as important as mad cow disease, USDA's frequent invocation of the "mushroom" theory of public participation in agency decisionmaking is entirely unacceptable. USDA's frequent attempts to make mad cow regulation a matter of private negotiations between it and the industry are inconsistent with modern administrative law concepts of "open government" and depart drastically from the way other agencies, like EPA, implement their statutes.[1101] The public has a right to know when USDA grants "exemptions" to companies to import beef into the United States in contravention of import bans, and it has a right to know whether the operators of slaughterhouses have effective HACCP plans in place.

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 USDA grants them. Both the substance of the request and the identity of the requesting entity should be available for public scrutiny and comment, and the Department should not grant or deny such requests until it has reviewed and prepared a response to relevant public comments.

USDA should also amend its HACCP regulations to require that all written HACCP plans and prerequisite programs be submitted to FSIS for its files where they will be available for public inspection. Like NPDES discharge permits that EPA issues under the Clean Water Act,[1102] 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 USDA inspectors are doing their jobs. If USDA has a serious concern about whether such plans are legitimate trade secrets, it should seek

---

1100 International Panel Report, *supra*, at 6.

1101 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) (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").

1102 *Id*.

legislation specifying that such plans are not trade secret and are fully disclosable to the public.

O. More Effective Enforcement.

Effective enforcement is a necessity 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. If adequately enforced, a performance-based approach may be superior to a system that relies upon the ability of a single overworked FSIS on-line inspector to detect every animal displaying signs of CNS disorder and every instance in which SRM is splashed on edible carcasses. Yet the public cannot depend exclusively on the regulated establishments to see to it that all of the relevant standards and requirements are observed.

As discussed above, 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."[1103] In addition to seeking authority to levy civil penalties, USDA should seek additional resources 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 whether the ultimate product has become contaminated with SRMs or other unsafe material. To the contrary, upper-level supervisors should be supportive of their inspectors in the field and thereby send a message to the regulated establishments that FSIS takes its public health responsibilities seriously.

XV Additional Actions that FDA Should Take.

A. Expand the Feed Ban.

On January 26, 2004, 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.[1104] 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 cease its efforts to mollify its industry constituents and proceed ahead with the publication of a Notice of Proposed Rulemaking (NPRM) requesting public comment on the changes that it promised in January.

[1103] CRS Issue Brief 8/1/03, *supra*, at CRS-6. *See supra* Section XIII.C.1.

[1104] Food and Drug Administration, Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission, Press Release, January 26, 2004.

The NPRM should, however, go much farther than the rather timid steps mentioned in the January 26 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.[1105] 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.[1106] A broader prohibition would considerably enhance 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.[1107] If FDA expanded the Feed Rule to ban protein from all animals, including pigs, in animal feed, direct enforcement of the regulations could serve as a powerful backup to enforcement based exclusively upon a paper trail.

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."[1108] It could, however, adversely affect the dairy industry, which relies more heavily upon protein supplements to sustain high levels of milk production.[1109] 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 otherwise disposed of in landfills.[1110] 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.

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.[1111] Consumer groups in the United

---

[1105] *See supra* Section XI.C.1. *See also* Rampton & Stauber, *Mad Cow U.S.A.*, *supra*, at 5 ("simple common sense tells most people that this practice of animal cannibalism is a bad idea").

[1106] See International Panel Report, *supra*, 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."); Doughton, *Should U.S. follow U.K. on Mad Cow?*, *supra* ("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").

[1107] *See supra* Section XI.C.2.

[1108] Denise Grady, *Mad Cow Quandary: Making Animal Feed*, New York Times, February 6, 2004 (quoting Dr. Gary Weber).

[1109] *Id*. (quoting Dr. Gary Weber).

[1110] *Id*. (quoting Tom Cook, president of the National Renderers Association).

[1111] European Commission, Commission Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001, available at http://europa.eu/int/comm/food/food/biosafety/bse/ban_en.htm and www.defra.gov.uk/animalh/bse/animal-health/feedban-legislation.html#euro [last visited June 3, 2004]. Processed animal proteins include the following: meat and bone meal, meat meal, bone meal, blood meal, dried plasma and other blood products, hydrolysed protein, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatin and any other similar products including mixtures, feeding stuffs, feed additives, and premixtures containing these products. *Id*.

States have long urged FDA to expand its Feed Rule to "ban the feeding of all rendered animal remains to food animals."[1112] USDA's own International Expert Panel recommended that "the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds."[1113] FDA's proposal should encompass the EU model as well to attract a full range of public comment.

B. Better Enforcement of the Feed Ban.

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 FDA and the states had done a very poor job of enforcing the 1997 feed ban, the U.S. General Accounting Office recommended that FDA develop "a strategy, working with states, to ensure that the information FDA needs to oversee compliance is collected and that all firms subject to the feed ban are identified and inspected in a timely fashion."[1114] It further recommended that 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."[1115] USDA's International Panel recommended that the feed ban "be strongly enforced" through "an inspection program including sampling and testing of feed."[1116]

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. As discussed above, accurate sampling should be possible once FDA puts into place a ban on feeding all animal protein to animals that could be consumed as food or rendered into animal feed. The inspection program could be modeled on the OSHA inspection program, which has two components -- a complaint inspection element to deal with specific complaints of unlawful conditions and a random element in which facilities are randomly selected for inspection.

XVI Additional Actions Congress Should Take.

Although many of the reforms advocated here can easily be implemented by USDA and FDA, some of them do not clearly come within the aging authorizing legislation under which those agencies regulate meat and feed. These reforms will require congressional attention. Without attempting to prescribe the contents of specific legislation, the following section of this Report 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.

1112 Consumers Union, Consumers Union: USDA Proposals to Prevent Spread of Mad Cow Disease Inadequate to Protect Public Health. Press Release, January 8, 2004.

1113 International Panel Report, *supra*, at 9.

1114 2002 GAO Mad Cow Report, *supra*, at 37.

1115 *Id*. at 38.

1116 International Panel Report, *supra*, at 9.

A. 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,[1117] and USDA has decided to 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. 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.[1118] Congress should amend the FMIA to require any owner of an animal that becomes nonambulatory to notify 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. Renderers 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 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."[1119] The panel recognized that this "most likely would involve expending resources to assist with costs associated with sampling, transport and disposal."[1120] 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.[1121]

B. Require Additional BSE Testing.

Now that mad cow disease has invaded the United States, some consumer groups have urged USDA to follow Japan's lead and implement a universal BSE testing requirement for cattle brought to slaughter or rendering.[1122] Although USDA has increased its testing program, it is still very far behind the surveillance efforts of other countries. If USDA persists in restricting its BSE testing program to downer cattle and a few nonrandomly selected healthy cattle, Congress should require the Department to follow the example of

---

1117 *See* International Panel Report, *supra*, at 6.

1118 *See supra* Section XI.F.2.g.2.

1119 International Panel Report, *supra*, at 6.

1120 *Id*.

1121 *Id*. (invoking the concept of "facilitated pathways").

1122 Consumers Union, Consumers Union: USDA Proposals to Prevent Spread of Mad Cow Disease Inadequate to Protect Public Health, *supra* ("Consumers Union urges USDA to require testing of all animals at slaughter, as they do in Japan.").

the EU and test all cattle of greater than 30 months in age for BSE prior to slaughter for human consumption.[1123] To eliminate any doubt, Congress should clearly grant USDA explicit authority to make such testing mandatory.

C. Allow Voluntary BSE Testing.

If USDA does not discontinue its incomprehensible efforts to protect the five dominant meat producing companies from competition by preventing companies like Creekstone Farms from testing some or all of their cattle for mad cow disease, Congress should intervene. Congress should amend the aging Virus, Serum and Toxin Act to provide that any company may use USDA-approved tests to test some or all of its meat for food-borne diseases. If deemed necessary, Congress could further provide legal authority to USDA or (preferably) the Federal Trade Commission to prevent companies from relying upon such tests to provide misleading characterizations of the safety of their products.

D. Set Deadlines for Creating an Effective Animal Identification Program.

Two years ago, USDA formed a consortium to draft a national cattle identification program. That effort has moved at a snail's pace as the various governmental and industry actors have attempted to negotiate consensus positions. The consortium does not include any representatives of consumer groups. With the discovery of the Mabton mad cow, USDA must now take charge of the process and bring it to a rapid completion. Unfortunately, there is little indication that the Department is taking the lead in getting an effective animal ID program in place.

Congress should therefore enact legislation establishing enforceable deadlines for writing proposed and final regulations establishing a national cattle identification program.[1124] In light of suggestions that the negotiations have been slowed by questions concerning who should pay for the program, Congress should allocate sufficient funds for USDA to manage the program. Bills currently pending in Congress provide a specific mandate for USDA to implement animal identification and tracking.[1125] Congress could kill two birds with one stone by requiring the cattle identification program to be financed from monies collected under the beef check-off program.

E. Clarify USDA Authority to Enforce HACCP Programs for SRMs.

1123 *See supra* Section XI.D.1.f.

1124 *See* Consumer Federation of America, A Mandatory Animal Identification System Capable of Tracing All Animals Back to the Farm of Origin Is Essential To Protect Public and Animal Health, Press Release, January 23, 2004 ("Congress should act immediately to establish a mandatory, uniform animal identification and tracking system capable of tracing all animals from the slaughterhouse back to the farm of origin.").

1125 *See* Sen. Bill 2008, 108th Cong. (2004) and H.R. 3787, 108th Cong. (2004) (both bills amend the Animal Health Protection Act, requiring USDA Secretary to establish electronic nationwide livestock identification system within 90 days of enactment).

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 aggressive challenge to USDA's authority to close down a plant that supplied ground beef containing the deadly pathogen E. coli O157:H7 suggests that the industry is likely to challenge FSIS authority to enforce the HACCP regulations any time it contemplates more serious enforcement action than a slap on the wrist.[1126]

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."[1127] Today, we know that diseases like vCJD are caused by infectious agents.[1128] 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.

The NAS Scientific Criteria to Ensure Safe Food Report 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."[1129] This is very good advice. Congress should amend the FMIA to authorize 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.

F. Recall Legislation.

Although companies generally comply with FSIS requests to recall potentially adulterated product, they are under no obligation to do so. As discussed above, companies are becoming much more aggressive in challenging USDA's authority to implement the HACCP regulations, and 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 the recall to bear the bulk of the costs incurred makes it even more likely that small facilities will resist voluntary compliance in the future.[1130]

1126 *See* CRS Issue Brief 8/1/03, *supra*, at CRS-9.

1127 NAS Scientific Criteria to Ensure Safe Food Report, *supra*, at 19.

1128 *Id*.

1129 *Id*. at 5.

1130 See supra Section XII.A.

Consumer groups have for many years strongly urged Congress to enact legislation giving the Department this authority, but so far to no avail.[1131] Congress should as quickly as possible supply FSIS with the legal authority to order recalls of contaminated meat and poultry products.[1132] Mandatory recalls should be conducted at the expense of the companies ordered to participate in the recalls, but USDA should have a fund available for hardship cases. Hardship cases would generally consist of small companies that could demonstrate that they are not able to afford available recall insurance.[1133] Congress should not wait until a company has refused to recall meat potentially contaminated with mad cow prions before giving USDA the authority to issue mandatory recall orders.[1134]

G. Country of Origin Legislation.

Congress has 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.[1135] Had the unnamed meat processors who secretly imported 33 million pounds of otherwise banned beef from Canada pursuant to special exemptions complied with that law, the fact that the massive importation of Canadian beef was taking place would have been obvious to U.S. consumers.[1136] Unfortunately, those processors did not have to comply with the law, because Congress in

---

[1131] Consumer advocacy organizations advocating recall legislation include Center for Science in the Public Interest, Support HR 1612 and S. 908 -- The Consumer Food Safety Act of 1999 Make the Food and Drug Administration the Food-Poisoning-Prevention Police, available at http://www.cspinet.org/foodsafety/hr1612.html; Consumer Federation of America, USDA hears suggestions for improving product recall procedures, available at http://www.cidrap.umn.edu/cidrap/content/fs/food-disease/news/recallmeet.html; Consumers Union, Beef recall process draws criticism USDA lacks power to inform public, mandate returns, available at http://inspectorsunited.com/beefrecall.htm; and Safe Tables Our Priority (STOP), Comments on Recall Policies and Procedures, available at http://www.safetables.org/Policy_&_Outreach/Public_Comments/pc_98029n_recall_10_1998.html.

[1132] *See* Statement of CFA's Carol Tucker Foreman on USDA's Additional Protections to Prevent Bovine Spongiform Encephalopathy, December 31, 2003, available at http://www.consumerfed.org/usdarelease123003.html.

[1133] The American Meat Institute offers recall insurance to companies to cover recall costs. *See* www.meatami.com/Content/NavigationMenu/CrisisCenter/AMICrisisManagementResources/AMIProductRecallInsurance/AMIProductRecallInsurance.htm.

[1134] A recall bill is pending in the 108th Congress, but the House leadership has not seen fit to allow it to go forward. H.R. 2273 - 108th Congress, 2d Sess. "Unsafe Meat and Poultry Recall Act"; introduced May 22, 2003, sponsor Tom Udall (D-NM).

[1135] 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. CRS Report for Congress, Country-of-Origin Labeling for Foods, available at www.ncseonline.org/nle/crsreports/03Feb/97-508.pdf. 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* www.ams.usda.gov/cool for country of origin labeling details.

[1136] Barrie McKenna, *Canada Fears Fallout Over U.S. Beef Gaffe*, Montreal Globe and Mail, May 21, 2004, at B4

its wisdom enacted a rider in January 2004 that made the program voluntary until 2006.[1137] It is now time to eliminate the rider and allow previously enacted mandatory country of origin labeling to go into effect.

H. Civil Penalty Power.

USDA currently lacks authority to levy civil penalties for violations of its regulations.[1138] 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 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 USDA the authority to collect penalties in civil proceedings subject to judicial review.

Congress could address the particular infirmities of the HACCP programs as applied to the threat of mad cow disease by requiring mandatory penalties for uncorrected violations of HACCP plans or prerequisite programs addressing SRMs in beef and processed meats. This would require FSIS to seek a civil penalty every time an establishment reported (or an FSIS inspector discovered) a violation of the relevant SRM requirement and failed to establish convincingly that the violation had been immediately corrected. In addition, Congress should mandate civil penalties for repeated violations of HACCP plans, even if the establishment undertakes corrective actions for individual violations. This would give establishments an incentive to revisit their hazard analyses and fix broken HACCP or prerequisite programs to ensure that violations do not continue indefinitely.

I. User Fees.

Although most administrations during the last 20 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.[1139] 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. 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.

1137 The 2002 Farm Bill requires retailers to provide country of origin labeling on covered commodities starting September 30, 2004. CRS Report for Congress, Country-of-Origin Labeling for Foods, available at, www.ncseonline.org/nle/crsreports/03Feb/97-508.pdf. 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. *See* Agricultural Marketing Service, USDA, Current Status of Country of Origin Labeling, available at www.ams.usda.gov/cool/status.htm.

1138 *See supra* Section XIII.C.3.

1139 CRS Issue Brief 8/1/03, *supra*, at CRS-7.

J. Greater transparency.

If 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 is highly dubious and should be rejected out of hand. Likewise, if USDA neglects to make the process of granting import exemptions more transparent, Congress should do that for the Department.

Animal identification programs should also be transparent. Concerned about the possibility of "frivolous" lawsuits, the industry has strongly resisted public disclosure of animal identification information, and a bill has recently been introduced in Congress to exempt animal identification information from FOIA disclosure.[1140] Congress should not enact a bill that will allow the cattle industry to cloak itself in secrecy. Instead, it 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 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.

USDA's current recall policy is to keep the details and results of its recalls confidential. The Department further insists that state agencies that assist in such recalls likewise keep information about those recalls confidential.[1141] Consequently, the public in the California counties in which meat from the Washington state mad cow was recalled remained unaware of that fact, and even the state's Department of Health Services was kept in the dark. When Congress enacts legislation to provide mandatory recall authority to USDA, it should also require that the terms and conditions of all recalls be a matter of public record and that USDA and state implementing agencies make the details of such recalls available to the print media, local television and local radio.

K. 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

---

1140 Nelson Antosh, *Tracking of Cattle Becomes Key Goal*, Houston Chronicle, March 5, 2004.

1141 *See supra* Section XIII.B.4.

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.[1142]

L. Citizen Enforcement.

Because FSIS suffers from an institutional conflict-of-interest, it cannot be trusted to conduct adequate investigations and enforcement activities. The natural tendency for an agency in such a setting is to make its peace with the only entity that can make life difficult for it. If, however, citizens may act as private attorneys general to bring their own enforcement actions, the industry will have a much more powerful incentive to toe the line. Most of the modern environmental statutes allow affected citizens to seek injunctive relief or civil penalties (to be paid to the U.S. treasury) for violations of specific regulatory requirements.[1143] In cases, such as mad cow disease, where the public rightly demands a low tolerance for violations of protective regulatory requirements, the added incentive of a private citizen suit is absolutely critical. Congress should enact legislation providing for citizen enforcement of FSIS safety requirements.

XVII Conclusions.

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, USDA told the American public that it will never happen again, but it will.[1144] USDA expanded its BSE testing program to persuade Japan and other countries to re-open their markets to U.S. beef, but they didn't. To calm consumer fears, USDA promulgated a set of regulations built on the assumption that mad cow disease is primarily an animal health problem, but it isn't.

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. The same "pernicious, pervasive and deeply corrupt antigovernment fanaticism that ha[d] taken hold in Britain"[1145] in the mid-1990s has now taken hold in the United States, and the results could be equally devastating. As in England, the deeply imbedded problem in the U.S. is that "the meat industry and its allies in government assess the risk

---

1142 *See* Lassiter, *Hoof to Hamburger*, *supra*, at 458. Professor Lassiter has suggested 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 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*.

1143 *See*, *e.g.*, 42 U.S.C. § 7604.

1144 Secretary Veneman has recently acknowledged the likelihood that the expanded program will uncover additional cases of mad cow disease in the U.S. *Veneman: We Expect Further Cases of BSE to be Found*, USAgNet, May 27, 2004.

1145 Rhodes, *Deadly Feasts*, *supra*, at 231.

differently from the scientists and physicians who know most about the transmissible spongiform encephalopathies."[1146]

It is time for USDA and 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.

1146 *Id*. at 232.