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Mad Cow Disease: An Approach to its Containment

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MAD COW DISEASE: AN APPROACH TO ITS CONTAINMENT

MICHAEL B. ABRAMSON*

INTRODUCTION

On December 23, 2003, the United States Department of Agriculture (“USDA”) announced that a Holstein cow in Washington tested positive for Mad Cow Disease.¹ The cow was slaughtered at Verns Moses Lake Meats in Moses Lake, Washington.² Ultimately, it was determined that the cow was born on a dairy farm in Alberta, Canada, and imported into the United States in September 2001.³ While the USDA conducted a recall on certain meat products,⁴ it determined that the United States’ meat supply was safe.⁵ The presence of Mad Cow Disease on American soil sparked a flurry of attention to the safety of meat in the United States.

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1. Matthew L. Wald & Eric Lichtblau, *U.S. is Examining a Mad Cow Case, First in Country*, N.Y. TIMES, Dec. 24, 2003, at A1.

2. U.S. DEP’T OF AGRIC., CASE OF BSE IN THE UNITED STATES CHRONOLOGY OF EVENTS, at <http://www.usda.gov/news/releases/2003/12/bsechronology.htm> (last visited June 19, 2004).

3. U.S. DEP’T OF AGRIC., COMMONLY ASKED QUESTIONS ABOUT BSE IN PRODUCTS REGULATED BY FDA’S CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), at <http://www.cfsan.fda.gov/~comm/bsefaq.html> (last updated Jan. 30, 2004); Elizabeth Becker, *Test Confirms Infected Cow Was Born on Canada Farm*, N.Y. TIMES, Jan. 7, 2004, at A14. Because the cow was born in Canada and imported into the United States, it may be debated whether Mad Cow Disease has occurred in an animal born and raised in the United States. See Sarah Kershaw & Bernard Simon, *What’s a Canadian Cow? Trade Blurred Distinctions*, N.Y. TIMES, Jan. 6, 2004, at A14 (noting the debate surrounding whether Mad Cow Disease has developed in the United States). This article will not address this argument but merely states that Mad Cow Disease has occurred in the United States. The infected cow was likely born prior to the U.S. and Canadian bans concerning mammalian protein in cattle feed. Jerry Adler, *Mad Cow: What’s Safe Now?*, NEWSWEEK, Jan. 12, 2004, at 42. See *infra* notes 161-77 and accompanying text for information on the American ban.

4. FOOD SAFETY & INSPECTION SERV. (FSIS), USDA, RECALL NOTIFICATION REPORT 067-2003, at <http://www.fsis.usda.gov/Oa/recalls/rnrfiles/rnr067-2003.htm> (last visited June 19, 2004). The Class II recall was a voluntary recall (all recalls are voluntary), and it recalled “approximately 10,410 pounds of raw beef that may have been exposed to tissues containing the infectious agent that causes bovine spongiform encephalopathy (BSE).” Adler, *supra* note 3. Class II recalls are recalls for a “low health risk.” Adler, *supra* note 3.

5. Wald & Lichtblau, *supra* note 1.

The incidence of Mad Cow in the United States had three effects. First, the meat industry suffered economically. Over forty nations including Japan, Mexico, and South Korea have banned the sale of United States' meat resulting in decreased meat industry revenues.⁶ Japan, Mexico, and South Korea account for over eighty percent of U.S. beef exports.⁷ Furthermore, cattle prices plunged twenty percent,⁸ and stock prices for meat producers declined.⁹ Second, the USDA and Food and Drug Administration ("FDA") created regulations in response to the recent outbreak.¹⁰ Third, consumers and the general public developed an increased awareness of both Mad Cow Disease in the United States as well as steps that could and should be taken to prevent an outbreak.

Mad Cow Disease is a neurological disease that affects cattle.¹¹ The first outbreak of Mad Cow Disease was in 1986, and cases still occur today.¹² Cases of Mad Cow Disease are increasing in parts of Europe outside of the United Kingdom.¹³ On May 21, 2003, a cow was diagnosed with the disease in Canada.¹⁴

A human disease is purportedly linked to Mad Cow Disease,¹⁵ and it has resulted in the death of over one hundred people.¹⁶ In 2002, the first case of the

6. Wald & Lichtblau, *supra* note 1; ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, BSE TRADE BAN STATUS AS OF 3-31-04, at http://www.aphis.usda.gov/lpa/issues/bse/trade/bse_trade_ban_status.html (last visited June 19, 2004).

7. See ECON. RESEARCH SERV., USDA, NEWSROOM: BACKGROUND STATISTICS ON U.S. BEEF AND CATTLE INDUSTRY, at <http://www.ers.usda.gov/news/BSECoverage.htm> (last visited June 19, 2004).

8. Michael Moss et al., *Mad Cow Forces Beef Industry to Change Course*, N.Y. TIMES, Jan. 5, 2004, at A1.

9. *The Markets: Stocks & Bonds; Nasdaq Tops 2,000; Other Major Gauges at 2003 Highs*, N.Y. TIMES, Dec. 30, 2003, at C7. See also Jennifer Bayot, *Mad Cow Disease in the United States: The Market; Many Stocks Linked to Beef Continue Fall*, N.Y. TIMES, Dec. 27, 2003, at A14.

10. See *infra* notes 263-72 and accompanying text.

11. ANIMAL AND PLANT HEALTH INSPECTION SERV., USDA, BOVINE SPONGIFORM ENCEPHALOPATHY (BSE), at <http://www.aphis.usda.gov/lpa/issues/bse/bse-overview.html> (last visited June 19, 2004) [hereinafter APHIS].

12. *Id.*

13. CTR. FOR BIOLOGICS, EVALUATION AND RESEARCH, FDA, QUESTIONS AND ANSWERS ON FDA GUIDANCE ENTITLED "REVISED PREVENTIVE MEASURES TO REDUCE THE POSSIBLE RISK OF TRANSMISSION OF CREUTZFELDT-JAKOB DISEASE (CJD) AND VARIANT CREUTZFELDT-JAKOB DISEASE (VCJD) BY BLOOD AND BLOOD PRODUCTS," at <http://www.fda.gov/cber/gdlns/cjdvcjdq&a.htm> (last visited June 19, 2004) [hereinafter Q&A on FDA Guidance].

14. Clifford Krauss & Sandra Blakeslee, *Case of Mad Cow in Canada Prompts U.S. to Ban Its Beef*, N.Y. TIMES, May 21, 2003, at A1.

15. APHIS, *supra* note 11. See discussion *infra* Part I.E for a detailed description of new variant Creutzfeldt-Jakob Disease.

16. Wald & Lichtblau, *supra* note 1.

human disease in the United States was diagnosed in a British woman living in Florida,¹⁷ and, in July 2003, the first person in Italy died from the human disease.¹⁸

Mad Cow Disease has affected numerous countries throughout the world and has the potential to affect many more. Although there are measures to prevent the emergence and spread of the disease, these regulations are often flawed or inadequately enforced.¹⁹ Moreover, statutes and oversight concerning meat are not present in every country where meat is produced, and, due to the unregulated production of beef, the meat may be unsafe. With the continued rise of global trade,²⁰ unsafe meat produced in one country could be consumed in any country. Even in countries that have domestic precautions against unsafe meat, the importation of meat and the meat that citizens eat in foreign countries might result in these precautions being insufficient to completely protect the populace from Mad Cow Disease.

Prior to December 23, 2003, most Americans likely did not worry about Mad Cow Disease and felt that America was immune from it.²¹ Americans' feelings of protection probably resulted from the geographic path of Mad Cow Disease (previously, Mad Cow Disease had never been found in the United States)²² as well as faith in U. S. government actions concerning public health²³ and the

17. *National Briefing Science and Health: Woman Has Human Form of Mad Cow Disease*, N.Y. TIMES, Oct. 18, 2002, at A21. The CDC stated that she had probably been exposed to the human disease prior to moving to Florida in 1992. *Id.*

18. Agence France-Presse, *Mad Cow Disease Kills First Human in Italy*, N.Y. TIMES, Aug. 7, 2003, at A11.

19. See *infra* Part II (evaluating the strengths and weaknesses of the existing regulations for preventing the spread of Mad Cow Disease.); see also Steve Stecklow, *Porous Borders: Despite Assurances, U.S. Could be at Risk for Mad-Cow Disease*, WALL ST. J., Nov. 28, 2001, at A6 (evaluating U.S. efforts to prevent the occurrence of Mad Cow Disease).

20. In the United States alone, beef is a \$56 billion per year industry. GEN. ACCOUNTING OFFICE, PUB. NO. GAO-02-183, *MAD COW DISEASE: IMPROVEMENTS IN THE ANIMAL FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S. PREVENTION EFFORTS 4* (2002), available at <http://www.gao.gov/new.items/d02183.pdf> (last visited June 19, 2004) [hereinafter GAO].

21. Other countries previously free from Mad Cow Disease did not fear the disease until it appeared in their nations. The United States could have the same experience:

Like a mantra, federal officials and beef-industry executives are fond of repeating that there has never been a case of Mad-Cow Disease in the United States. It's the same claim that Germany, Italy, Spain, and Japan used to make—until the disease showed up in their cattle, instantly resulting in plunging beef sales. Will the U.S. go down the same road?

Stecklow, *supra* note 19.

22. Wald & Lichtblau, *supra* note 1.

23. The U. S. government oversees a large portion of those entities which can affect public health. The U.S. Geological Survey, along with the Department of the Interior, oversees aspects of water safety, and the Department of Health and Human Services helps ensure that medicines and food products are safe. See generally U.S. GEOLOGICAL SURVEY, at <http://www.usgs.gov> (last visited June 19, 2004); U.S. DEP'T OF THE INTERIOR, at <http://www.interior.gov> (last visited June 19, 2004); U.S. DEP'T OF HEALTH and HUMAN SERVS., at <http://www.os.dhhs.gov/drugs/index.shtml> (last visited June 19, 2004).

prevention of Mad Cow Disease.²⁴ The discovery of Mad Cow Disease in Washington and the resultant effects of the outbreak had vast consequences.²⁵ These effects resulted from the discovery of only one case of Mad Cow Disease. If a widespread outbreak of the disease occurred on American soil, it is safe to assume that the consequences, reactions to, and impact of the disease would be catastrophic. Aside from the death and suffering directly related to the disease, the public would panic wondering whether they or their loved ones had ingested food which could cause a terminal illness; food would be recalled and cattle destroyed; farmers and beef producers would be out of jobs; restaurants, such as steakhouses, would close; supermarkets' sales, especially of those specializing in beef, would decrease; and other economic blows would impact the shipping industry and the beef futures market. The scourge of the illness itself would be horrendous, and the disease's other effects would be devastating as well.

To date, Americans have not been clamoring for reform in government regulation of the meat industry, probably because of previous attitudes about the disease and the Department of Agriculture's assurances that the meat in the United States is safe.²⁶ As the discovery of Mad Cow Disease in Washington indicates, an outbreak of Mad Cow Disease in the United States is a real possibility and must be addressed if it is to be avoided. Americans must decide either to develop and implement strategies to prevent problems from occurring or to accept the consequences of inaction.

As a consequence of Mad Cow Disease and its purported link to a human disease, thousands of cattle have been destroyed,²⁷ over one hundred people have died,²⁸ and the meat industry has suffered economically.²⁹ Now, at the beginning of the 21st century, the world is at a crossroads with its meat industry. It must choose to act with vigilance and prudent measures in defeating the disease and preventing the catastrophic effects that are associated with its outbreak.

This article discusses Mad Cow Disease and one of the leading contributors to the disease, the presence of mammalian protein in cattle feed. Ultimately, the article offers methods to decrease the manufacture and use of harmful cattle feed, help eliminate the presence of Mad Cow Disease, and inform consumers about the content of the meat they consume.

Part I addresses the veterinary and medical background of Mad Cow Disease and related diseases. A scientific background of the diseases is a prerequisite to

24. See *infra* Part II.B for a discussion of United States actions to combat Mad Cow Disease.

25. See *supra* notes 6-10 and accompanying text.

26. Wald & Lichtblau, *supra* note 1.

27. Wald & Lichtblau, *supra* note 1.

28. Wald & Lichtblau, *supra* note 1.

29. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; 62 Fed. Reg. 552, 575 (proposed Jan. 3, 1997) (to be codified at 21 C.F.R. pt. 589).

evaluating laws and proposals because they must reflect a scientific understanding of the diseases.

Part II examines statutes and recommendations banning the use of mammalian protein in cattle feed in the United Kingdom, United States, European Union, World Health Organization, and in the General Agreement on Tariffs and Trade/World Trade Organization. This part also evaluates relevant statutes and recommendations of these bodies, noting any benefits and drawbacks. Particular attention is placed on the inner-workings and efficacy of the U.S.'s ban on mammalian protein in cattle feed. Further, to provide context to the fight against Mad Cow Disease, the article addresses other governmental and private actions against the disease in the United Kingdom and the United States.

Part III proposes a meat certification program to verify that harmful mammalian protein is not used in the production of meat products. Certified meat would have a stamp on its packaging indicating its compliance with procedures necessary for certification, providing a way for food markets and restaurants to advertise that they sell certified meat. The article addresses two possible models for implementing this certification program: a governmental scheme and a private system. The private system would be independent and financed by producers and consumers, similar to the process of declaring food items kosher. Each model has its advantages and disadvantages, and the article analyzes the costs and benefits of each approach.

I. VETERINARY AND MEDICAL BACKGROUND

In order to fully comprehend the legal and political issues surrounding Mad Cow Disease (clinically referred to as bovine spongiform encephalopathy, "BSE") and new variant Creutzfeldt-Jakob Disease ("vCJD", the human disease purportedly arising after consumption of meat from a cow infected with Mad Cow Disease), it is important to understand the veterinary and medical background of the diseases. This part will analyze the diseases, other similar illnesses, and the commonalities between the illnesses. Specifically, this part will describe the basic pathology of the transmissible spongiform encephalopathies, scrapie, bovine spongiform encephalopathy, Creutzfeldt-Jakob Disease, and new variant Creutzfeldt-Jakob Disease.

A. The Basic Pathology of Transmissible Spongiform Encephalopathies

At their basic level, the diseases discussed below are similar and are classified as transmissible spongiform encephalopathies (“TSEs”).³⁰ For years, they have remained a mystery because they can be both infectious and hereditary in both humans and animals.³¹ Common characteristics include vacuolation (the development of tiny holes) of nerve cell bodies and the grey matter neuropil (a part of the brain).³² Starting in the mid-1970s, scientists believed they uncovered the mechanisms behind this strange molecular behavior.³³ They determined that the cause of the diseases was a particle which they termed a *prion*, a contraction of the words “proteinaceous” and “infectious.”³⁴ In 1982, scientists proposed that, during the diseases, protein in the brain becomes prions which transform other protein into abnormal configurations that are both infectious and capable of causing neurodegenerative disorders.³⁵ These prions are shaped as beta sheets (flat sheets) and alpha helixes (spiral shapes).³⁶ They have a dual behavior, causing disease via infection and/or through genetics, and they also spread disease through a sporadic process which is neither infectious nor genetic but spontaneous.³⁷ While the processes of TSEs (also known as “prion diseases”) are understood after humans or animals have contracted the diseases, scientists do not understand how the diseases and prions are acquired.³⁸

30. Stephen J. Dearmond et al., *Prion Diseases*, in 2 GREENFIELD’S NEUROPATHOLOGY 273, 273 (David I. Graham & Peter L. Lantos eds., 7th ed. 2002).

31. *Id.*

32. *Id.*

33. *Id.* at 273-76.

34. *Id.* at 273-74. The prion theory is one of the more popular explanations for the cause of TSEs. It should be noted, however, that the prion theory is not the only possible explanation for these diseases. See *infra* note 38 for a discussion of other theories behind TSEs.

35. *Id.* at 275.

36. *Id.*

37. *Id.*

38. See *id.* Based upon the author’s research, the most common explanation for TSEs is the prion theory. See also Steven Dealler, *Can the Spread of BSE and CJD Be Predicted?*, in THE MAD COW CRISIS: HEALTH AND THE PUBLIC GOOD 35, 35-42 (Scott C. Ratzan ed., 1998); Michael D. Lemonick, *Can It Happen Here? Panic Over Mad Cow Has Already Infected Europe. Now It’s Our Turn*, TIME, Jan. 29, 2001, at 58, 59; FOOD & DRUG ADMIN., ACTION PLAN: TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES INCLUDING BOVINE SPONGIFORM ENCEPHALOPATHY AND CHRONIC WASTING DISEASE, available at http://www.fda.gov/oc/oca/roundtable/bse/FDA_actionplan.html (last visited June 19, 2004); APHIS *supra* note 11; U.K. DEP’T OF ENV’T, FOOD, & RURAL AFFAIRS (DEFRA), BSE: SCIENCE-RESEARCH INTO BSE - PATHOGENESIS, at <http://www.defra.gov.uk/animalh/bse/bse-science/level-4-pathog.html> (last modified Apr. 30, 2001) [hereinafter BSE - PATHOGENESIS]; WORLD HEALTH ORG., FACT SHEET NO. 113, BOVINE SPONGIFORM ENCEPHALOPATHY (2002), at <http://www.who.int/mediacentre/factsheets/fs113/en/> (last revised Nov. 2002) [hereinafter WHO]; However, the prion theory is not 100% certain, and there are other possible explanations for the disease. These include, among others, a theory of an unconventional virus and a theory of a virino or “incomplete” virus made of nucleic acid protected by a host protein. Lester M. Crawford, *BSE: A Veterinary History*, in THE MAD COW CRISIS: HEALTH AND THE PUBLIC GOOD, *supra*, at 11; Lemonick,

B. Scrapie

Scrapie is a prion disease that affects sheep and goats.³⁹ The first recorded incidence was in the 1700s, but cases of scrapie may have occurred unreported for years.⁴⁰ Scrapie is present in Great Britain but is rare in the United States.⁴¹

Scrapie displays the same changes in the brain as other TSEs.⁴² Affected sheep and goats experience neuronal degeneration and vacuolation of neurons.⁴³ Once infected, symptoms include tremors, weakness, thirst, wasting, ataxia, and itching.⁴⁴ The itching causes sheep to scrape their bodies against objects, giving the disease its name “scrapie.”⁴⁵

C. Bovine Spongiform Encephalopathy

Bovine spongiform encephalopathy is the veterinary term for Mad Cow Disease.⁴⁶ It is a disease that infects cattle.⁴⁷ Scientists at Great Britain’s Central Veterinary Laboratory discovered the disease in November 1986 while studying cows sent there for investigation.⁴⁸ In April 1987, epidemiological studies began, and the disease has been studied and closely monitored ever since.⁴⁹

BSE continues to the present day and cows are still being infected.⁵⁰ The BSE epidemic reached its highest levels in January 1993 in the United Kingdom, with approximately 1,000 new cases per week.⁵¹ Since 1986, over 180,000 cattle

supra, at 59; APHIS, *supra* note 11; WHO, *supra*. See also BSE - Pathogenesis, *supra* (detailing reasons why the prion theory may not be correct).

39. Dearmond et al., *supra* note 30, at 278.

40. Scrapie, though not known by that name, was first recorded in sheep in 1732, and the first references to the term “scrapie” occurred in 1853. U.K. DEP’T OF ENV’T, FOOD, & RURAL AFFAIRS, THE BSE INQUIRY, THE REPORT - THE INQUIRY INTO BSE AND VARIANT CJD IN THE UNITED KINGDOM VOL. 16, (2000) [hereinafter THE BSE INQUIRY], available at <http://www.bseinquiry.gov.uk/report/index.htm> (last visited June 19, 2004).

41. See Lemonick, *supra* note 38, at 58-59.

42. Dearmond et al., *supra* note 30, at 273.

43. Dearmond et al., *supra* note 30, at 279.

44. Dearmond et al., *supra* note 30, at 278.

45. Dearmond et al., *supra* note 30, at 278.

46. APHIS, *supra* note 11.

47. APHIS, *supra* note 11.

48. U.K. DEP’T OF ENV’T, FOOD, & RURAL AFFAIRS, CHRONOLOGY OF EVENTS, BSE HOME PAGE, CHRONOLOGY OF EVENTS, at <http://www.defra.gov.uk/animalh/bse> (last visited June 19, 2004) [hereinafter DEFRA CHRONOLOGY OF EVENTS].

49. *Id.*

50. See Wald & Lichtblau, *supra* note 1.

51. ANIMAL AND PLANT HEALTH INSPECTION SERV., USDA, FACTSHEET: BOVINE SPONGIFORM ENCEPHALOPATHY (Feb. 2002), available at http://www.aphis.usda.gov/lpa/pubs/fsheet_fa_notice/fs_ahbse.html (last visited June 19, 2004) [hereinafter APHIS FACTSHEET].

have been diagnosed with BSE in the United Kingdom.⁵² Over 3,000 additional cases have been found in: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Poland, Portugal, Slovakia, Spain, and Switzerland.⁵³ Canada has reported BSE-positive cattle, and a cow with BSE was found in the United States.⁵⁴ Worldwide, the reported cases of BSE have decreased since 1992.⁵⁵

BSE is a prion disease and is thus similar to other TSEs such as scrapie.⁵⁶ Vacuolation is present in the cell body of neurons and the grey matter neuropil.⁵⁷ Vacuoles are the largest and most numerous in the brainstem and cerebral cortex.⁵⁸ Once infected with BSE, the brain, because of the vacuoles, looks like a sponge, hence the term 'spongiform.'⁵⁹

BSE and scrapie are neurologically similar,⁶⁰ but BSE was first discovered in 1986⁶¹ while scrapie has been a known disease for hundreds of years.⁶² Scientists believe that BSE developed in cattle after consumption of cattle feed which contained a BSE-causing agent.⁶³ The source of the agent in this theory was traced to a food supplement composed of meat and bone meal.⁶⁴

After World War II, cattle raisers began to include mammalian protein in their cattle feed.⁶⁵ While new diseases in cattle did not appear for approximately

52. WHO, *supra* note 11.

53. WHO, *supra* note 11; APHIS, *supra* note 11; APHIS FACTSHEET, *supra* note 51. Slovenia has also been identified as a country with cases of BSE. GAO, *supra* note 20, at 6. Both Canada and the United States are considered to have low risk. U.S. DEP'T OF AGRIC., COMMONLY ASKED QUESTIONS ABOUT BSE IN PRODUCTS REGULATED BY FDA'S CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), at <http://www.cfsan.fda.gov/~comm/bsefaq.html> (last updated Jan. 30, 2004).

54. APHIS, *supra* note 11.

55. WHO, *supra* note 38.

56. Dearmond et al., *supra* note 30, at 273.

57. Dearmond et al., *supra* note 30, at 280.

58. Dearmond et al., *supra* note 30, at 280.

59. APHIS FACTSHEET, *supra* note 51.

60. Dearmond et al., *supra* note 30, at 277.

61. DEFRA, CHRONOLOGY OF EVENTS, *supra* note 48.

62. THE BSE INQUIRY, *supra* note 40, at vol. 16.

63. Dearmond et al., *supra* note 30, at 280. The World Health Organization states: "Transmission of BSE occurs when cattle consume meat and bone meal feed contaminated with the causative agent." WORLD HEALTH ORG., UNDERSTANDING THE BSE THREAT 1, 6 (2002), available at <http://www.who.int/csr/resources/publications/bse/en/BSEthreat.pdf> (last visited June 19, 2004) [hereinafter UNDERSTANDING THE BSE THREAT].

64. UNDERSTANDING THE BSE THREAT, *supra* note 63. 'Meat and bone meal' refers to animals present in animal feed. Telephone Interview with Dr. Neal Bataller, Consumer Safety Officer, FDA Center for Veterinary Medicine (Feb. 25, 2003). The animals in the feed are ground down into a fine powder which is called 'meal.' *Id.*

65. Crawford, *supra* note 38, at 12.

forty years, a significant change in rendering⁶⁶ in the early 1980s, the elimination of solvent extraction, is thought to have created the grounds for the emergence of BSE.⁶⁷ During solvent extraction, solvents such as hexane are used to separate fat from protein.⁶⁸ Once the fat is removed, a high temperature is used to remove the solvent from the protein.⁶⁹ It is believed that this high temperature would inactivate the BSE-causing agent.⁷⁰ Scientists theorize that the new process' lower temperatures allowed the BSE-causing agent to live and be transmitted to cattle.⁷¹

Cows infected with Mad Cow Disease have various clinical signs.⁷² The pathological result of BSE is degeneration of the cow's brain, causing a cow to display "mad" behavior (hence, the colloquial term for the disease, "Mad Cow Disease").⁷³ First, the cows develop apprehensiveness and nervousness.⁷⁴ Second, they experience a deterioration of their bodies which includes skin tremors, high-stepping gait (particularly with their back legs), difficulty in rising, and a reluctance to enter yards, turn corners, cross concrete, go through doorways, or allow milking.⁷⁵ Third, cows often show aggression towards other cows and people and kick manically if milked.⁷⁶ The incubation period⁷⁷ for BSE can last from two to eight years, but the time from the onset of symptoms to death is two

66. "Rendering" is a process that occurs in the production of cattle feed. Telephone Interview with Dr. Burt Pritchett, Veterinary Safety Officer, Division of Animal Feeds, FDA Center for Veterinary Medicine (Feb. 25, 2003). In rendering, the renderer places the animal product in a machine which separates water and fat, leaving meat and bone meal from the animal. *Id.* Eventually (but not part of the actual rendering process), the meat and bone meal is ground into a powder and placed in animal feed. *Id.*

67. Crawford, *supra* note 38, at 12.

68. Crawford, *supra* note 38, at 12.

69. Crawford, *supra* note 38, at 12.

70. Crawford, *supra* note 38, at 12.

71. Crawford, *supra* note 38, at 12. Further evidence adds credence to the theory that the change in rendering allowed for the development of BSE. In Northern England and Scotland, the rendering process remains unchanged since WWII (i.e., no use of solvent extraction), and there have only been a few cases of BSE. Crawford, *supra* note 41, at 12. *See also* Dearmond et al., *supra* note 30, at 280 (maintaining that a change in rendering style, but making no mention the temperature factor, could have contributed to BSE).

72. U. K., DEP'T OF ENV'T, FOOD, AND RURAL AFFAIRS (DEFRA), BSE: SCIENCE – TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES – BSE, at <http://www.defra.gov.uk/animalh/bse/bse-science/level-4-bse.html> (last visited June 19, 2004).

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. "Incubation" is the "the period between the infection of a plant or animal by a pathogen and the manifestation of the disease it causes." PHILLIP BABCOCK GOVE, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 1146 (1993).

weeks to six months.⁷⁸ In Great Britain, the majority of cases have been in dairy cows between three and six years of age.⁷⁹

D. Creutzfeldt-Jakob Disease

Prion diseases also affect humans.⁸⁰ Named for separate discoveries by Drs. Creutzfeldt and Jakob in 1920, 1921, and 1923,⁸¹ Creutzfeldt-Jakob Disease (“CJD”) accounts for ninety to ninety-five percent of all suspected prion disease in humans.⁸² Neurologically, it is similar to prion diseases in animals.⁸³ Prions, it is believed, occur in various regions of the brain⁸⁴ resulting in “spongiform degeneration of neurons and their processes [and] neuronal loss”⁸⁵ As a result, the brain develops holes⁸⁶ and resembles a sponge. CJD can be acquired either by infection or inheritance.⁸⁷

At the onset of the disease, an infected person suffers from fatigue and sleep deprivation and experiences behavioral changes, memory disturbances, and shifts in equilibrium.⁸⁸ As the disease progresses and the protein in the brain changes, the patient’s mental capacity declines, dementia sets in, and motor disturbances become commonplace.⁸⁹ The patient continues to deteriorate, and dementia, along with varied heart rates, accompany the patient to his or her death.⁹⁰ Typically, the disease runs its course within four to twelve months, but disease periods of two to five years have occurred.⁹¹

The death rate for CJD worldwide is 1/1,000,000.⁹² There is no known treatment and the result is invariably death.⁹³ According to the Centers for Disease

78. APHIS, *supra* note 11.

79. APHIS, *supra* note 11.

80. Dearmond et al., *supra* note 30, at 282.

81. Dearmond et al., *supra* note 30, at 282. While the diseases they discovered had similar psychiatric and motor symptoms to CJD, the diseases were not the same as what modern scientists would call CJD. Dearmond et al., *supra* note 30, at 282. CJD, however, is still named after them. Dearmond et al., *supra* note 30, at 282.

82. Dearmond et al., *supra* note 30, at 282.

83. See Dearmond et al., *supra* note 30, at 285.

84. See Dearmond et al., *supra* note 30, at 284.

85. Dearmond et al., *supra* note 30, at 284. Affected regions of the brain include: “the cerebral neocortex, the subiculum of the hippocampus, putamen, caudate nucleus, thalamus and the molecular layer of the cerebellar cortex.” Dearmond et al., *supra* note 30, at 285.

86. Dearmond et al., *supra* note 30, at 285.

87. Dearmond et al., *supra* note 30, at 282.

88. Dearmond et al., *supra* note 30, at 282.

89. Dearmond et al., *supra* note 30, at 282.

90. Dearmond et al., *supra* note 30, at 282.

91. Dearmond et al., *supra* note 30, at 282.

92. Dearmond et al., *supra* note 30, at 283.

Control and Prevention (“CDC”), the average age of death for CJD patients is sixty-seven, and ninety-five percent of deaths occur in those fifty years of age and older.⁹⁴

E. New Variant Creutzfeld-Jakob Disease

In the spring of 1996, scientists at the British National CJD Surveillance Unit reported ten cases of what they thought was CJD but which had distinct features.⁹⁵ On March 20, 1996, scientists at Great Britain’s Spongiform Encephalopathy Advisory Committee (“SEAC”) announced that these ten cases were new forms of CJD that shared similarities with CJD but had different neurological structures and body responses.⁹⁶

Originally, scientists did not know the derivation of this new disease.⁹⁷ They did not believe that the new disease was related to the United Kingdom’s BSE-tainted meat or that the meat was harmful.⁹⁸ This situation changed on March 20, 1996, when SEAC released the following statement:

The Spongiform Encephalopathy Advisory Committee have [sic] considered 10 cases of Creutzfeld-Jakob Disease (CJD) which have occurred in people. . . . Although there is no direct evidence of a link, on current data and in the absence of any credible alternative the most likely explanation at present is that these cases are linked to exposure to BSE before to the introduction of the Specified Bovine Offal Ban (SBO) in 1989. This is a cause of great concern.⁹⁹

Since that statement, a greater body of scientific information suggests that new variant Creutzfeldt-Jakob Disease, (vCJD) is probably caused by ingestion of meat products contaminated with BSE-infected nervous system tissues.¹⁰⁰ While

93. U.S. DEP’T OF HEALTH & HUMAN SERVS., HHS FACT SHEET, FEDERAL AGENCIES TAKE SPECIAL PRECAUTIONS TO KEEP “MAD COW DISEASE” OUT OF THE UNITED STATES (Aug. 23, 2001), available at <http://www.dhhs.gov/news/press/2001pres/01fsbse.html> (last visited June 19, 2004).

94. Dearmond et al., *supra* note 30, at 283. Typically, CJD does not occur in those over 79. Dearmond et al., *supra* note 30, at 284. Scientists believe that an event occurs with age which causes the proper level of energy conversion for prions to operate. Dearmond et al., *supra* note 30, at 284. CJD is also rare in patients under forty years of age. Dearmond et al., *supra* note 30, at 287.

95. Terri L. Harpold et al., *Transmissibility of BSE Across Species*, in THE MAD COW CRISIS: HEALTH AND THE PUBLIC GOOD, *supra* note 38, at 15, 18-19.

96. APHIS, *supra* note 11.

97. See Harpold et al., *supra* note 95, at 18-19.

98. See Harpold et al., *supra* note 95, at 18-19.

99. SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE (SEAC), STATEMENT OF 20 MARCH 1996, available at <http://www.seac.gov.uk/statements/state20mar96.htm> (last visited June 19, 2004).

100. Dearmond et al., *supra* note 30, at 289.

scientists cannot definitively conclude that consumption of BSE-tainted meat is the cause of vCJD, they maintain that several factors point to that conclusion.¹⁰¹

vCJD has neuropathological similarities to CJD but has some differences as well.¹⁰² Like CJD, vacuolation is present resulting in spongiform formations.¹⁰³ In contrast to CJD, vCJD's spongiform degeneration is more intense, its plaque clustering is unique, and its protein deposits are more widespread.¹⁰⁴

vCJD differs from CJD in three clinical manifestations. First, vCJD affects younger patients.¹⁰⁵ The average age of vCJD patients is twenty-eight (with ages ranging from twelve to seventy-four).¹⁰⁶ Second, vCJD lasts longer, and infections typically last fourteen months.¹⁰⁷ Third, the electroencephalographic (EEG) electrical activity in vCJD is different from that of CJD.¹⁰⁸

vCJD is a devastating disease. Its symptoms include mood swings, numbness, hallucinations, and uncontrolled body movements.¹⁰⁹ In its final state, vCJD results in a dementia that is tantamount to the severity of dementia in Alzheimer's Disease.¹¹⁰ The result of vCJD is invariably death.¹¹¹

II. A REVIEW OF LAWS AND REGULATIONS THROUGHOUT THE WORLD

This part will examine statutes and recommendations concerning the use of mammalian protein in cattle feed in the United Kingdom, United States, European Union, World Health Organization, and in the General Agreement on Tariffs and

101. Dearmond et al., *supra* note 30, at 288, 290. These factors are: vCJD appears to be a new form of prion disease which does not resemble other forms of CJD, the majority of patients reside in the UK which is in the same geographic area as the BSE epidemic, the incubation period for other forms of CJD link vCJD with BSE, and experiments performed on mice inoculated with either BSE or vCJD extracts had identical test results to each other but were different from natural sheep scrapie or mice injected with CJD. Dearmond et al., *supra* note 30, at 290. See also APHIS, *supra* note 11 (providing more information on experiments linking BSE with vCJD). Other factors which lead to the connection between BSE and vCJD include the age of vCJD patients (which are much younger than CJD patients), clinical and neuropathological features, and similarities in time period and geography to that of BSE. Dearmond et al., *supra* note 30, at 288. The WHO also concurs that BSE tainted meat is the probable cause of vCJD. WHO, *supra* note 38.

102. See Dearmond et al., *supra* note 30, at 289.

103. See Dearmond et al., *supra* note 30, at 289.

104. See Dearmond et al., *supra* note 30, at 289.

105. APHIS, *supra* note 11.

106. APHIS, *supra* note 11.

107. APHIS, *supra* note 11.

108. APHIS, *supra* note 11.

109. Lemonick, *supra* note 38, at 58.

110. Lemonick, *supra* note 38, at 58.

111. JOSHUA T. COHEN, ET AL., HARVARD CENTER FOR RISK ANALYSIS & HATIM ABDELRAHMAN ET AL., CTR. FOR COMPUTATIONAL EPIDEMIOLOGY, TUSKEGEE UNIVERSITY, EVALUATION OF THE POTENTIAL FOR BOVINE SPONGIFORM ENCEPHALOPATHY IN THE UNITED STATES, I (2003).

Trade/World Trade Organization.¹¹² This part discusses the benefits and drawbacks to each approach. Particular attention will be placed on the processes and efficacy of the United States' protein mammalian ban. Further, to contextualize the fight against Mad Cow Disease, this part will discuss governmental and private actions against Mad Cow Disease in both the United Kingdom and the United States.

A. United Kingdom

Most cases of BSE have occurred in the United Kingdom.¹¹³ An analysis of the United Kingdom's experience is especially relevant because its actions took place in the context of fighting an epidemic of the disease, not merely preventing it or dealing with isolated outbreaks. This section discusses the United Kingdom's mammalian protein ban and other governmental actions. It also analyzes their effectiveness, advantages, and disadvantages by referencing The BSE Inquiry ("Inquiry").¹¹⁴

1. Mammalian Protein Ban

The British Parliament was the first governmental body to pass a law banning the use of mammalian protein in cattle feed.¹¹⁵ The United Kingdom passed its first ban in 1988,¹¹⁶ and the most recent ban came into force on April 19, 2002.¹¹⁷ In all, eight major U.K. laws have addressed banning mammalian protein;¹¹⁸ however, the latest set of regulations, SI 843, is controlling.¹¹⁹

SI 843 is the current regulation enacting a mammalian protein ban in the United Kingdom.¹²⁰ The regulation prohibits the feeding of mammalian protein to

112. The article chooses these entities because they represent a cross-section of large government and other organizations addressing mammalian protein in cattle feed. The ones discussed, however, are not the only entities with bans concerning cattle feed. In its January 2002 report, the U.S. General Accounting Office noted that forty-one countries had some sort of ban. GAO, *supra* note 20, at 35.

113. WHO, *supra* note 38; *see also* APHIS, *supra* note 11.

114. The BSE Inquiry, created on December 22, 1997, was a British government committee commissioned by the British Parliament to review, evaluate, and report on the emergence of BSE and vCJD in the United Kingdom as well as the government's response to the diseases. THE BSE INQUIRY, *supra* note 40, at vol. 8.

115. WHO, *supra* note 38.

116. WHO, *supra* note 38. The United Kingdom was particularly active in passing statutes addressing BSE. WHO, *supra* note 38; *see also* CHRONOLOGY OF EVENTS, *supra* note 48.

117. TSE Regulations (2002), SI 2002/843.

118. *See* DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

119. TSE Regulations, (2002), SI 2002/843.

120. Schedule 9, Part I, Paragraph 1 of SI 843 repealed those portions of SI 2001/2376 (the previous statutory instrument) dealing with mammalian protein. *Id.* at Sched. 9, Pt. I, Paragraph 1, (repealing the

ruminants,¹²¹ the sale or supply of any mammalian meat or bone meal for use in feeding stuffs for livestock,¹²² the feeding of processed animal protein to farmed animals,¹²³ the supply or sale of processed animal protein for the feeding of farmed animals,¹²⁴ and the feeding of specified risk material to animals.¹²⁵ The regulation also mandates extensive recordkeeping for any consignment or receipt of mammalian meat and bone meal or processed animal protein.¹²⁶

Seven major regulations preceded SI 843, and an overview of these regulations illustrates the development of the current mammalian protein ban. SI 1039 (June 14, 1988) made it illegal to sell, supply, or use certain contaminated feed for ruminants.¹²⁷ SI 2299 (December 30, 1988) extended SI 1039 and additionally prohibited the use of milk from a diseased or suspected cow, except

Process Animal Protein Regulations (2001) SI 2001/2376, regs. 4, 5, 6, 7, 8, 9, 12, 13, 14, 15, & 16 and scheds 1,2,3.

121. SI 2002/843 at Pt. III, §11. The resolution states: "no person shall - (a) knowingly sell or supply for feeding to ruminant animals; or (b) feed to a ruminant animal, any feedingstuff in which he knows or has reason to suspect that any mammalian protein has been incorporated." *Id.* Ruminant animal is defined as a "bovine animal, a sheep or a goat." *Id.* at Pt. I, §3.

122. *Id.* at Pt. III, § 12. The statute states: "no person shall (a) sell or supply for incorporation into any feedingstuff for livestock any mammalian meat and bone meal; (b) use any mammalian meat and bone meal in the production of any feedingstock for livestock; (c) sell or supply for feeding to livestock any feedingstuff in which any mammalian meat and bone meal has been incorporated; or (d) feed to livestock any feedingstuff in which any mammalian meat and bone meal has been incorporated." *Id.* Mammalian meat and bone meal is defined as "(a) mammalian protein (including greaves), other than processed animal protein, derived from the whole or part of any dead mammal by (i) the process of rendering; or (ii) in the case of a product or material originating outside England, by an equivalent process; or (b) any material derived from mammalian protein, and for this purpose "protein" means any proteinaceous material which is derived from a carcass but does not include milk or any milk product." *Id.* at Pt. I, § 3.

123. *Id.* at Pt. III, § 14. The statute states: "no person shall feed any processed animal protein to a farmed animal." *Id.* Processed animal protein is defined as "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, and includes mixtures, feedingstuffs, feed additives and premixtures, containing these products; but does not include mammalian protein and bone meal." *Id.*, at Pt. I, § 3.

124. *Id.* at Pt. III, § 15. The statute states: "no person shall sell or supply any processed animal protein intended for the feeding of any farmed animal." *Id.*

125. *Id.* at Pt. IV, § 49. The statute states: "no person shall sell or supply any specified risk material for use in the preparation of any feedingstuff; or (b) use any specified risk material in the preparation of any feedingstuff. . . . [N]o person shall feed to any animal (a) any specified risk material; (b) any feedingstuff which he knows or has reason to suspect contains any specified risk material; or (c) a whole carcass or any part of a sheep, goat or bovine animal from which specified risk material has not been removed in accordance with these Regulations." *Id.* Specified risk material is defined as "(a) any part of - (i) a bovine animal, other than a carcass of a bovine animal containing vertebral column which has been imported in accordance with the Specified Risk Material Order 1997; (ii) a sheep or a goat, remaining attached to specified risk material after dissection of the carcass of the animal; (b) any animal material which comes into contact with specified risk material after it has been removed from the carcass." *Id.* at Pt. I, § 3.

126. *Id.* at Pt. III, § 26.

127. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

for the feeding of the cow's own calf.¹²⁸ SI 1989/2061 (November 13, 1989) banned the use of certain specified bovine offals (SBOs) for human consumption.¹²⁹ SI 2246 (November 6, 1991) combined previous BSE legislation and included regulations prohibiting the use of meat and bone meal from specified bovine offals ("SBOs") as fertilizer.¹³⁰ SI 2007 (August 1, 1996) amended SI 2246 by prohibiting the possession of mammalian protein in locales where livestock feeding stuff is kept and provided provisions for the cleaning, disinfecting and disposal of equipment which came into contact with mammalian proteins.¹³¹ SI 3183 (January 24, 1997) called for new procedures in disposing animals exposed to BSE.¹³² SI 2376 (July 3, 2001) extended the mammalian protein ban by prohibiting the sale of, supply, or feeding of animals with feed containing mammalian protein.¹³³ The inspection portion of SI 2376 gives inspectors the authority to examine facilities in order to enforce the statute and is still current law in the United Kingdom.¹³⁴

The efficacy of the United Kingdom's actions is a subject of debate. On the one hand, the regulations appear to be very effective. The number of BSE cases plummeted after their implementation, and they are offered as a possible reason for this decrease.¹³⁵ On the other hand, the government actions have also been criticized.¹³⁶ The BSE Inquiry made an even-handed review of government actions and concluded: "They were sensible measures, but they were not always timely nor adequately implemented and enforced."¹³⁷

The Inquiry concluded that the ruminant feed ban (SI 1039, June 14, 1988) and animal SBO ban (SI 2246, November 6, 1991) were flawed.¹³⁸ With regards to the ruminant feed ban, regulatory agencies did not appreciate the possibility of cross-contamination between feed for different animals, and they incorrectly assumed that a large quantity of BSE-tainted protein was necessary to spread

128. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

129. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48. Specified bovine offals are those tissues most likely to contain BSE and to transmit the disease. Crawford, *supra* note 38, at 12. They include tissues of the brain and spinal cord. Crawford, *supra* note 38, at 12.

130. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

131. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

132. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

133. SI 2001/2376, at §§ 4, 9, 10, 11.

134. SI 2001/2376, at §19(1). The statute states: "[a]n inspector shall have the power to carry out all checks and examinations necessary for the enforcement of these Regulations." *Id.* SI 2001/2376 §19(2) delineates the powers of examination.

135. See Crawford, *supra* note 38, at 12; Harpold et al., *supra* note 95, at 16-17.

136. THE BSE INQUIRY, *supra* note 40, at vol. 1.

137. THE BSE INQUIRY, *supra* note 40, at vol. 1.

138. THE BSE INQUIRY, *supra* note 40, at vol. 1 ch. 14.

BSE.¹³⁹ The Inquiry states: “Had rigorous thought been given to the matter, this would have involved seeking the views of the experts, who would have advised that a small quantity might suffice to infest.”¹⁴⁰ Similarly, the Inquiry found that the animal SBO ban was created without sufficient forethought: “It was prepared in haste and without consultation. It was also prepared without the rigorous thought that should have been given to the need to introduce Regulations that were enforceable and the manner in which the Regulations have achieved this.”¹⁴¹ Consequently, cattle raisers and others disregarded the SBO ban both purposefully and accidentally.¹⁴² Moreover, inspectors, as well as monitoring and enforcement officials at the Veterinary Field Service, did not inspect for violations nor did they enforce the ban with requisite diligence.¹⁴³

2. Other Actions by the United Kingdom

The British Government took additional actions to attack BSE. Since the epidemic principally began on its shores, the British had to act with a mixture of aggressiveness and deliberateness. First, after the discovery of the disease in November 1986, the government attempted to find scientific solutions to prevent and treat the disease.¹⁴⁴ Two scientific committees led the research front: the Southwood Working Party (created on April 21, 1988) and the SEAC (created on April 3, 1990).¹⁴⁵ Second, the government prohibited exports of British meat.¹⁴⁶ Other nations buttressed this ban by prohibiting the importation of British beef.¹⁴⁷ Third, Great Britain called for the destruction and recall of beef and animal feed

139. In fact, only a small amount is necessary to infest. See THE BSE INQUIRY, *supra* note 40, at vol. I ch. 14.

140. THE BSE INQUIRY, *supra* note 40, at vol. I ch. 14.

141. THE BSE INQUIRY, *supra* note 40, at vol. I ch. 14.

142. THE BSE INQUIRY, *supra* note 40, at vol. I ch. 14.

143. THE BSE INQUIRY, *supra* note 40, at vol. I ch. 14. The Inquiry attacked the officials themselves but also noted that Parliament’s statutes did not specify a monitoring function nor did they provide access to slaughterhouses. THE BSE INQUIRY, *supra* note 43, at vol. I ch. 14.

144. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

145. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

146. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48. The Department of Environment, Food, and Rural Affairs (“DEFRA”) is the government agency responsible for agriculture, food, and responses to the BSE epidemic. See U.K. DEP’T FOR ENV’T, FOOD AND RURAL AFFAIRS (DEFRA) - HOMEPAGE, at <http://www.defra.gov.uk> (last visited June 19, 2004). It was formed from the Ministry of Agriculture, Food, and Fisheries (“MAFF”). *Id.*

147. See APHIS, *supra* note 11. Countries banning the importation of British beef included Italy, Luxembourg, Greece, Austria, Finland, Germany, New Zealand, Singapore, South Africa, Spain, Jordan, Belgium, France, Netherlands, Portugal, and Sweden. CNN, LIST OF COUNTRIES BANNING BRITISH BEEF GROWS LONGER, Mar. 22, 1996, available at http://www-cgi.cnn.com/WORLD/9603/mad_cow/22/ (last visited June 19, 2004).

while providing varying levels of compensation to farmers and producers.¹⁴⁸ As of October 2000, Great Britain had destroyed 4.7 million cattle.¹⁴⁹

The newness and uncertainty of both BSE and vCJD posed challenges for the British government and its method of communicating with the public. Until SEAC's announcement on March 20, 1996, the British government told its populace that British meat was safe.¹⁵⁰ For example, in 1994, John Gummer, a minister in the British government, fed hamburger to his four year old child on national television in order to convince the population that British meat was safe.¹⁵¹ After SEAC's announcement in 1996 and the realization that people could get sick from BSE, consumers panicked and also blamed the government for its seeming misinformation and handling of the situation.¹⁵²

The BSE Inquiry discussed the British government's management of information concerning the diseases, stating that the British government did not completely inform the public of all of the government's information.¹⁵³ Moreover, the government told the public that it was safe to eat beef, but it did not mention that the safety of the beef was predicated on the use of proper precautionary steps in the beef's production.¹⁵⁴ The government's misinformation had two effects. First, when a link between BSE and vCJD was announced on March 20, 1996, the public felt betrayed by the government.¹⁵⁵ More disturbing, if members of the public had known all of the relevant information, they may not have eaten meat that was possibly infected with BSE.

An analysis of the British government's mishandling of information during the BSE epidemic provides strategies and lessons on the proper method of disseminating information to the public. Many of these theories suggest that conveying as much knowledge as possible to the populace is imperative.¹⁵⁶ It is

148. DEFRA CHRONOLOGY OF EVENTS, *supra* note 48.

149. THE BSE INQUIRY, *supra* note 40, at vol. 1 ch. 1.

150. Tim Lang, *BSE and CJD: Recent Developments*, in THE MAD COW CRISIS: HEALTH AND THE PUBLIC GOOD, *supra* note 38, at 80.

151. Paul Anand, *Chronic Uncertainty and BSE Communications: Lessons from (and Limits of) Decision Theory*, in THE MAD COW CRISIS AND THE PUBLIC GOOD, *supra* note 38, at 60.

152. See Lang, *supra* note 150, at 68, 69, 73, 80-81; see also Catherine Goethals et al., *The Politics of BSE: Negotiating the Public's Health*, in THE MAD COW CRISIS AND THE PUBLIC GOOD, *supra* note 38, at 99 (stating that the government did not mention the link between BSE and vCJD). See generally Scott C. Ratzan, *Introduction*, in THE MAD COW CRISIS AND THE PUBLIC GOOD, *supra* note 38, at 1-2 (discussing the British government misinformation and lack of information management).

153. THE BSE INQUIRY, *supra* note 40, at vol. 1, Summary & Chapter 1.

154. THE BSE INQUIRY, *supra* note 40, at vol. 1, Executive Summary.

155. THE BSE INQUIRY, *supra* note 40, at vol. 1, Executive Summary.

156. See Michael A. Chamberlain, *Avoiding, Averting, and Managing Crisis: A Checklist for the Future*, in THE MAD COW CRISIS AND THE PUBLIC GOOD, *supra* note 38, at 169-70 (analyzing government strategies using both the media and telecommunications, such as television, radio, and computers/internet, to better inform the public, limit the possibilities of the spread of disease, and decrease the chances of public panic); Scott C. Ratzan, *Strategies for Attaining Public Health in THE*

only with adequate information that people can make educated decisions and feel confident that they are not being deceived. Indeed, it is argued that an increased deference to consumer knowledge and power might have lessened the British public's feelings of betrayal.¹⁵⁷

B. The United States

The United States approaches the BSE problem from a different perspective than the United Kingdom. In contrast to the United Kingdom, the United States has had only one case of Mad Cow Disease, and, since it came from an imported cow and has not been discovered in any domestic cattle, it appears to be an isolated incident.¹⁵⁸ Consequently, the U.S.'s policy toward BSE is one of prevention and keeping the disease outside its borders.¹⁵⁹ While the U.S.'s approach is different than the U.K.'s, the United States still has been aggressive in its methods of addressing the disease. According to the most recent study, the United States has been successful in its goals of prevention.¹⁶⁰ Various factors, however, lead to and qualify this rate of success, and criticisms of U.S. actions could foreshadow incidences of the disease in the United States.

This Comment's treatment of U.S. actions is more detailed than its description of other countries' and organizations' measures. An in-depth analysis of the U.S.'s actions is appropriate because the lack of BSE in the United States creates an atmosphere in which deliberation and lawmaking can occur without the political and humanitarian pressures of a country's sickened cattle or human population. This section will focus on the provisions, administration, and efficacy of the U.S.'s mammalian feed ban, other actions by the U.S. government, and voluntary measures by private actors.

MAD COW CRISIS AND THE PUBLIC GOOD, *supra* note 38, at 182 (describing other methods of communicating about health issues). Among other techniques for health communication, Ratzan discusses the acronym COAST - Communication, Options, Alternatives, Standards, Trust - which defines goals of communicating information, listening to different perspectives, and advancing issues on the topic in issue. Ratzan, *supra*, at 188.

157. Lang, *supra* note 150 at 73.

158. APHIS, *supra* note 11; Wald & Lichtblau, *supra* note 1.

159. APHIS, *supra* note 11.

160. COHEN ET AL., *supra* note 111, at vii. The USDA commissioned the Harvard Center for Risk Analysis to draft and publish *Evaluation of the Potential for Bovine Spongiform Encephalopathy*, studying BSE in the United States, the effectiveness of United States measures to combat the disease, and possible new ways of addressing the disease. *See id.*

1. *Mammalian Protein Ban*

The United States has had a mammalian protein ban since 1997.¹⁶¹ It is regarded as one of the central mechanisms for preventing the occurrence of BSE in the United States.¹⁶² This section will detail the provisions of the ban as well as related documents drafted both before and after the ban. It will then explain the administration of the ban including oversight and funding issues. Finally, this section will discuss the efficacy of the ban by referencing FDA statistics and other government reports concerning the feed ban.

a. Provisions and History of the Ban

The FDA has authority over animal feed under the Food, Drug, and Cosmetic Act.¹⁶³ The FDA's final regulation on mammalian protein became effective on August 4, 1997.¹⁶⁴ The text of the regulation has not changed since that time.¹⁶⁵ In the years before and after the final regulation, the FDA proposed rules and solicited comments in order to refine its recommendations and make them as accurate and effective as possible.

In 1994, the FDA issued a proposed rule on the prohibition of substances from ruminant feed.¹⁶⁶ It noted that specified offal from adult sheep and goats in ruminant protein was not safe because it might be a cause of BSE.¹⁶⁷ Since "[i]t is believed that rendered feed ingredients contaminated with sheep scrapie and BSE agents served as the common source of infection,"¹⁶⁸ the FDA called for a ban on the "use of any feed ingredient containing specified offal from sheep and goats over 12 months of age in ruminant feed."¹⁶⁹

161. Substances Prohibited from Use in Animal Food or Feed, 21 C.F.R. § 589.2000 (1997). The cow with Mad Cow Disease in Washington state was probably born before the ban. Becker, *supra* note 3.

162. See COHEN ET AL., *supra* note 111 at vii.

163. 21 C.F.R. § 589.2000(b) (2003). Since mammalian feed can make the feed "adulterated," the FDA can act via the authority given in the Food, Drug, and Cosmetic Act. *Id.*

164. *Id.*

165. Compare 21 C.F.R. § 589.2000 (1997) with 21 C.F.R. § 589.2000 (2003).

166. Substances Prohibited From Use in Animal Food or Feed; Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie, 59 Fed. Reg. 44584 (proposed Aug. 29, 1994) (to be codified at 21 C.F.R. pt. 589).

167. Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed, 59 Fed. Reg. at 44587.

168. Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed, 59 Fed. Reg. at 44585.

169. Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed, 59 Fed. Reg. at 44587. According to the act, "specified offal is defined as any tissue from the brain, spinal cord, spleen, thymus, tonsil, lymph nodes, or intestines (duodenum to anus, inclusive) of sheep or goats, or any processed product that is reasonably expected to contain specified offal." *Id.* at 44587-88.

In 1996, the FDA put forward an advance notice of proposed rulemaking (“ANPRM”) to receive further comments on the 1994 Proposed Rule, to explain the need for a ban, and to reiterate its proposed rule.¹⁷⁰ The FDA gave two reasons for its aforementioned ban: “epidemiological evidence” linking BSE and animal protein, and the theory that exposure to BSE may explain outbreaks of vCJD.¹⁷¹ The ANPRM sought feedback on the mammalian protein ban, labeling requirements, and other issues.¹⁷²

In 1997, the FDA put forth another submission for comments before the promulgation of the final regulation.¹⁷³ In contrast to the previous proposed rule, the 1997 proposed rule expanded the range of regulated substances by prohibiting animal feed with any mammalian protein,¹⁷⁴ not merely offal from sheep and goats over twelve months of age.¹⁷⁵ The proposed rule also provided more scientific evidence on TSEs and BSE.¹⁷⁶ Since vCJD was formally discovered in 1996,¹⁷⁷ the 1997 proposed rule also discussed vCJD and the possible links between the vCJD and BSE.¹⁷⁸

The 1997 proposed rule analyzed the costs and benefits of the ban and the regulations from standpoints other than the scientific ramifications of BSE.¹⁷⁹ First, the ban could protect economic interests in the United States.¹⁸⁰ While the proposed rule contemplated a cost of the ban ranging annually from \$21.4 to \$48.2 million (depending on the eventual type of ban enacted),¹⁸¹ the amount spent on prevention would be significantly less than the cost of a BSE epidemic in the United States. If a BSE epidemic occurred in the United States and consumers

170. Substances Prohibited from Use in Animal Food or Feed; Proteins Derived from Ruminants Prohibited in Ruminant Feed; Advanced Notice of Proposed Rulemaking, 61 Fed. Reg. 24253 (May 14, 1996).

171. *Id.*

172. *Id.* at 24254. These other issues included scientific evidence on TSEs and why they occur, the possible establishment of coordinating agencies for ruminant feed, the amount of ruminant feed in the United States, and possible effects of the ban. *Id.* at 24254-55.

173. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 552 (proposed Jan. 3, 1997) (to be codified at 21 C.F.R. pt. 589).

174. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 570.

175. Substances Prohibited From Use in Animal Food or Feed; Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie, 59 Fed. Reg. 44584, 44587 (proposed Aug. 29, 1994) (to be codified at 21 C.F.R. pt. 589).

176. Compare Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. at 556-61 with Substances Prohibited From Use in Animal Food or Feed; Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie; Proposed Rule, 59 Fed. Reg. at 44584-86 (providing the 1994’s Proposed Rule’s scientific commentary on TSEs and BSE).

177. APHIS, *supra* note 11.

178. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 561.

179. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 556.

180. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 556.

181. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 556.

acted similarly to those in the United Kingdom, the United States could potentially lose \$9 billion in domestic beef consumption.¹⁸² Furthermore, the cost of destroying BSE-infected livestock could be \$3.7 billion.¹⁸³ Second, the FDA assessed the environmental aspect of the proposed rule.¹⁸⁴ The FDA concluded that the proposed rule would not have significant environmental consequences.¹⁸⁵ Rather, the FDA determined that much greater negative environmental consequences would occur if the FDA did not take action and the BSE epidemic occurred in the United States.¹⁸⁶

After three years of this notes-and-comments process, the FDA promulgated its final regulation, effective August 4, 1997.¹⁸⁷ It provides rules for ruminant feed and punishment for their violation.¹⁸⁸ The final regulation prohibits: "The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues . . ." ¹⁸⁹ While prohibiting the use of ruminant feed in the feeding of mammals, the regulation allows the production of ruminant feed but subjects it to strict regulations.¹⁹⁰ "Renderers that manufacture products that contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following measures to ensure that [prohibited]

182. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 575. The incidence of one case of Mad Cow Disease in the United States had significant economic consequences. See sources cited *supra* note 3. The 1997 proposed rule predicts the financial effects of a full-fledged epidemic.

183. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 575.

184. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 572.

185. Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 572.

186. See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 572. ("the greatest negative environmental effect would occur in the case of the "no action" alternative. This is because the likely spread of the BSE agent through animal feed before the first BSE case is diagnosed would result in disposal of large numbers of animals by means other than rendering. Similar large impacts would occur with the sheep and goat, and TSE animal, options").

187. 62 Fed. Reg. 30936-37. The regulation is listed at 21 C.F.R. § 589.2000: "Substances Prohibited from Use in Animal Food or Feed."

188. 21 C.F.R. §589.2000 (1997).

189. *Id.* at §589.2000(b). The regulation contains the following definitions to clarify its provisions: "Protein derived from mammalian tissues means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein."

Id. at §589.2000(a)(1).

"Ruminant includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes." *Id.* at §589.2000(a)(7).

190. A total ban does not exist on ruminant feed or feed with mammalian protein because it can be used for pig and poultry feed with insignificant chances of causing or spreading BSE. UNDERSTANDING THE BSE THREAT, *supra* note 63 at 2, 18. The rendering process itself can be beneficial because it provides for environmentally safe disposal of animal wastes and leads to products such as lubricants, soap, lipstick, candles, ink, pharmaceuticals, and cement. *Id.* at 7.

materials . . . are not used in the feed of ruminants.”¹⁹¹ These provisions include labeling the material¹⁹² and keeping records of the production process.¹⁹³ The regulations also apply to protein blenders, feed manufacturers, and distributors.¹⁹⁴ The regulations provided exceptions for those entities listed if they used the manufacturing methods to deactivate the TSE agent and testing methods to locate it or bought feed from renderers who followed these regulations.¹⁹⁵

The FDA regulations have remained essentially unchanged since 1997 and are still current law.¹⁹⁶ On October 5, 2001, the FDA began another notes-and-comment process to analyze the 1997 regulation and its effectiveness as well as to consider options for amending it.¹⁹⁷ One of the principal reasons for this process was the increased information on BSE and vCJD.¹⁹⁸ The hearing welcomed comments and posed seventeen topics in areas such as: broadening the ban, enforcement, efficacy of the ban, importation of food, and “labeling of protein-containing feed.”¹⁹⁹

On November 6, 2002, the FDA issued another ANPRM concerning a ban on mammalian protein.²⁰⁰ The FDA, relying on the *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*,²⁰¹ stated that the risk of BSE in the United States was small due to the previous FDA ban and other control measures.²⁰² The FDA wanted to further decrease this risk.²⁰³ It posed questions

191. 21 C.F.R. § 589.2000(c) (1997). Renderer is defined as:

any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes person who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

Id. at § 589.2000(a)(2).

192. *Id.* at § 589.2000(c)(i). Labeling must state: “Do not feed to cattle or other ruminants.” *Id.*

193. *Id.* at § 589.2000(c)(ii).

194. *Id.* at § 589.2000(d). Blender is defined as: “any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.” *Id.* at (a)(3). Feed manufacturer is defined as that group which “includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.” *Id.* at (a)(4). Distributors are defined as “person[s] who distribute or transport feeds or feed ingredients intended for animals.” *Id.* at (a)(6).

195. *Id.* at § 589.2000(c)(2)(i-ii) & (d)(2)(i-ii).

196. 21 C.F.R. § 589.2000 (2003).

197. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Public Hearing; Request for Comments, 66 Fed. Reg. 50929, 50929 (Oct. 5, 2001).

198. Animal Proteins Prohibited in Ruminant Feed, 66 Fed. Reg. at 50929

199. Animal Proteins Prohibited in Ruminant Feed, 66 Fed. Reg. at 50930.

200. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Advanced Notice of Proposed Rulemaking, 67 Fed. Reg. 67572 (Nov. 6, 2002).

201. COHEN ET AL., *supra* note 111.

202. Animal Proteins Prohibited in Ruminant Feed, 67 Fed. Reg. at 67572.

203. Animal Proteins Prohibited in Ruminant Feed, 67 Fed. Reg. at 67572.

in seven areas including possible exclusion of the brain and spinal cord in rendered animal products, the use of poultry litter in cattle feed, and the prevention of cross-contamination at feed processing facilities.²⁰⁴

b. Administration of the Ban

Compliance inspections for the feed ban began in January 1998.²⁰⁵ Administered by the FDA, these inspections occur at facilities that produce animal feed.²⁰⁶ Eighty percent of the inspections are conducted by state officials, and twenty percent are done by federal officials.²⁰⁷ In each instance, inspectors spend anywhere from one day to several days inspecting the feed production facility.²⁰⁸ They review a company's batch facilities (where feed is produced), invoices, and records to determine if violations are occurring or have occurred in the past.²⁰⁹ Inspectors fill out a form entitled "Report of Inspection for Compliance with 21 CFR 589.2000," detailing the results of the inspection.²¹⁰ The FDA's goal is to inspect plants once a year, but when this rate is not possible, they concentrate on those plants that have been in violation before or those that produce prohibited protein.²¹¹ Money for FDA oversight and inspections comes from the FDA budget.²¹² Feed companies do not pay a fee to the government for inspections.²¹³

204. Animal Proteins Prohibited in Ruminant Feed, 67 Fed. Reg. at 67572-73.

205. Pritchett, *supra* note 66.

206. Pritchett, *supra* note 66.

207. Pritchett, *supra* note 66.

208. Pritchett, *supra* note 66.

209. Pritchett, *supra* note 66.

210. Pritchett, *supra* note 66. The form asks whether mammalian protein is produced at the facility and, if it is, if there is proper labeling of mammalian protein; whether a system tracking the destination of products with mammalian protein exists; and if a system of cleaning is in place such that co-mingling does not occur in machines and storage areas. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., REPORT OF INSPECTION FOR COMPLIANCE WITH 21 C.F.R. § 589.2000, VERSION 4.2 (2003), at http://www.fda.gov/cvm/forms/BSE_V42.pdf (last visited June 19, 2004).

211. Pritchett, *supra* note 66.

212. Bataller, *supra* note 64. State governments fund some of the state inspectors. *Id.* An exact dollar figure for the program is not available. *Id.*

213. Bataller, *supra* note 64. While feed companies do not pay a fee to the government, they must pay for certain services in order to comply with inspections. Services include record-keeping, attorney fees for the interpretation of the regulations, consulting fees, etc. These extra costs are likely factored into the price of their products and thus passed on to consumers. *Id.*

c. Efficacy of the Ban

The efficacy of the feed ban is debatable. On the one hand, the feed ban has been effective. The only incidence of BSE has been from an imported cow,²¹⁴ and some models predict that BSE will never become established in the United States.²¹⁵ On the other hand, the feed ban has been criticized and viewed as a potential avenue for BSE introduction.²¹⁶ The FDA's own figures, reports from the General Accounting Office ("GAO"), and *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States* lead to the above conclusions.

FDA figures indicate that the feed ban has not yet achieved 100% compliance.²¹⁷ As of March 11, 2002, the FDA had inspected 10,458 firms, of which 2,153 handled prohibited materials.²¹⁸ The results are as follows: "77 (4%) had products that were not labeled as required, 34 (2%) did not have adequate systems to prevent co-mingling, 35 (2%) did not adequately follow record keeping regulations, [and] 113 (5%) were found to be out of compliance."²¹⁹ Upon re-inspection, 32 (1%) were still not in compliance with the rule.²²⁰ While improper labeling and record keeping may not directly result in BSE contamination (of

214. U.S. DEP'T OF AGRIC., *supra* note 3. Furthermore, the age of the cow indicates that it was probably born prior to the U.S. ban concerning ruminant protein in cattle feed. Adler, *supra* note 3. However, the lack of BSE cases in the United States does not, by itself, indicate that the feed ban has been effective and the cause of the U.S.'s relative safety from BSE. Rather, the lack of scrapie in the United States and bans on foreign meat products may be more likely reasons for the U.S.'s current BSE situation. APHIS, *supra* note 11; Lemonick, *supra* note 38 at 58. Furthermore, other aspects of BSE and United States' actions indicate that a BSE epidemic is still possible. First, since the incubation period of BSE is two to eight years, BSE may have already occurred without it being identified. APHIS, *supra* note 11. Second, lapses in import restrictions (such as "at least 72 shipments, including mammal-based bone meal, dried meat scraps, animal waste, and blood" imported from countries with BSE as well as imports from non-European countries that don't have BSE but may in the future) may lead to cases of BSE. Stecklow, *supra* note 19 at A6. See also Animal Disease Risk Assessment, Prevention, and Control Act; Public Hearing; Request for Comments, 66 Fed. Reg. 41195, 41196 (Aug. 7, 2001) (detailing the possible risks of BSE outbreaks in the United States due to imports). Third, other factors could lead to BSE incidence including incomplete inspections at ranches for diseased cattle, the presence of SBOs in meat as a result of flawed meat extraction processes, and possible danger in feeding chicken and pigs feed with ruminant feed. Ellen Ruppel Shell, *Could Mad-Cow Disease Happen Here?* THE ATLANTIC ONLINE, Sept. 1998, at <http://www.theatlanticonline.com/issues/98sep/madcow.htm> (last visited June 19, 2004).

215. COHEN ET AL., *supra* note 111, at vii. These models, however, make certain assumptions such as the spread of BSE will remain unchanged for twenty years following its introduction. *Id.*

216. COHEN ET AL., *supra* note 111, at viii-x.

217. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., CVM UPDATE, RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES (Apr. 15, 2002), at <http://www.fda.gov/cvm/index/updates/bseap02.htm> (last visited June 19, 2004).

218. *Id.* These firms included renderers, FDA licensed feed mills, feed mills not licensed by the FDA, and other firms such as ruminant feeders, on farm mixers, protein blenders, and distributors. *Id.*

219. *Id.*

220. *Id.*

course, it could if someone used the incorrect feed), possible co-mingling or noncompliance could result in outbreaks of BSE. The one percent rate after re-inspection is even more worrisome because of both the dangers these persistent violators pose and the FDA's continued allowance of their operation.

Government-sponsored inquiries have concluded that the feed ban is ineffective and its inadequacies could lead to incidents of BSE in the United States.²²¹ The GAO cites several flaws in the feed ban.²²² First, the FDA's database does not have updated results of feed ban compliance and fails to identify many plants operating in the U.S.²²³ Second, the FDA does not promptly or adequately enforce the feed ban.²²⁴ The FDA does not have an enforcement mechanism in place that would include criteria for actions taken or a time-frame for completion and re-inspection.²²⁵ Since May 1999, the FDA has reported hundreds of firms out of compliance, but the only enforcement action between the implementation of the feed ban inspection regulation in August 1997 and the date of the GAO study in April 2001 was to issue two warning letters in 1999.²²⁶ Third, feed plants which were out-of-compliance continued to operate and were not re-inspected in a timely fashion.²²⁷ The GAO recommended that the FDA develop an inspection strategy, implement guidelines on time frames for re-inspection, and improve its database.²²⁸

The *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States* addressed the feed ban as well.²²⁹ The report leads to the conclusion that improvement of the feed ban is necessary because "[t]he new cases of BSE would come primarily from lack of compliance with the regulations enacted to

221. See Stecklow, *supra* note 19, at 106 (providing information reinforcing that the FDA ban is flawed and that inspection of feed producing facilities is inadequate).

222. GAO, *supra* note 20, at 22-24.

223. GAO, *supra* note 20, at 22-24.

224. GAO, *supra* note 20, at 23-24.

225. GAO, *supra* note 20, at 24.

226. GAO, *supra* note 20, at 23.

227. GAO, *supra* note 20, at 23.

228. GAO, *supra* note 20, at 37-38. The GAO also recommended that the public be informed that "certain beef cuts and beef products may contain central nervous tissue." GAO, *supra* note 20, at 38. The USDA responded that this requirement was unnecessary because meat products did not contain these tissues. U.S. DEP'T OF AGRIC., FACT SHEET: USDA RESPONSE TO GAO RECOMMENDATIONS ON BSE PREVENTION, available at <http://www.usda.gov/news/releases/2002/02/fs0071.htm> (last visited June 19, 2004). Such signs were inappropriate because the presence of certain tissues did not necessarily mean BSE was present. "Labeling and warning statements should be reserved for known hazards." *Id.*

229. COHEN ET AL., *supra* note 112, at vii-viii, x.

protect animal feed."²³⁰ The study noted incomplete compliance with the feed ban, such as mislabeling and misfeeding, which could pose dangers in the future..²³¹

2. Other Actions by the United States

The FDA is not the only U.S. government agency working to combat BSE and vCJD. Rather, several other agencies have had roles in the fight against the diseases. They have all approached different aspects of BSE and vCJD surveillance.

In 1952, the Animal, Plant, and Health Inspection Service ("APHIS") started a scrapie control program and implemented an import restriction on sheep and goats.²³² This ban, which remains in place today, is one reason why there is a low level of scrapie incidence in the United States.²³³ Since it is believed that scrapie-infected sheep protein in cattle feed leads to BSE, the lack of scrapie-infected sheep (and, therefore, scrapie-infected sheep protein in U.S. animal feed), may be a reason why BSE has not developed in a cow born in the United States.²³⁴

U.S. agencies have developed import restrictions in an attempt to ensure that BSE-infected cattle and ruminants do not enter the United States.²³⁵ On July 21, 1989, APHIS banned the importation of all ruminants and certain cattle products from the United Kingdom.²³⁶ On December 6, 1991, APHIS restricted the importation of ruminant meat and edible products and prohibited most products of ruminant origin from countries known to have BSE.²³⁷ On December 12, 1997, APHIS banned the importation of live ruminants and most ruminant products from most of Europe until additional risk information became available.²³⁸ Lastly, on

230. COHEN ET AL., *supra* note 112., at vii.

231. COHEN ET AL., *supra* note 112, at ix. The Harvard Center for Risk Analysis summarized its conclusions with the feed ban; "Specific pathways or practices that would contribute the most to the spread of BSE if it were introduced into the U.S. relate to compliance with the FDA feed ban and include misfeeding on the farm . . . and the mislabeling of feed and feed products prohibited for consumption by cattle." COHEN ET AL., *supra* note 112, at ix.

232. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA, SCRAPIE PROGRAM (2002), at http://www.aphis.usda.gov/lpa/pubs/fsheet_fa_q_notice/fs_ahscrapiepgm.html (last visited June 19, 2004).

233. See Substances Prohibited From Use in Animal Food or Feed; Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie; 59 Fed. Reg. 44584, 44586 (proposed Aug. 29, 1994) (codified as amended at 21 C.F.R. pt. 589); see also Lemonick, *supra* note 38, at 58-59.

234. Lemonick, *supra* note 38 at 58-59. The argument concerning sheep protein in animal feed applies to both animal feed produced before the mammalian protein ban as well as animal feed not conforming to the ban.

235. APHIS, *supra* note 11.

236. APHIS, *supra* note 11.

237. APHIS, *supra* note 11.

238. APHIS, *supra* note 11. Countries in the ban included: Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Federal Republic of Yugoslavia, Finland, Germany,

December 7, 2000, the USDA prohibited the importation of all rendered animal protein products from Europe, regardless of species.²³⁹

Certain U.S. government agencies also conduct active surveillance.²⁴⁰ First, APHIS and the USDA educate veterinarians and cattle industry personnel (cattle raisers, renderers, etc.) on the clinical signs and pathology of BSE.²⁴¹ APHIS has sixty laboratories that examine cattle brains from suspected cattle.²⁴² In addition, the USDA has trained 250 state and federal field veterinarians on BSE recognition.²⁴³ Private veterinarians refer cases to appropriate government agencies as well.²⁴⁴ Second, APHIS monitors any cattle that could be imported into the United States.²⁴⁵ Third, the Food Safety Inspection Service ("FSIS") inspects all cattle prior to slaughter.²⁴⁶

The FSIS inspection is necessary for meat products to receive the USDA inspection legend which appears on meat.²⁴⁷ Inspectors are always present at these facilities.²⁴⁸ The federal government pays for the inspectors' first eight hours of work per day, and companies themselves pay for each additional hour.²⁴⁹ FSIS inspectors look for signs of central nervous system disorders (including BSE),²⁵⁰ and cattle displaying these disorders are condemned.²⁵¹ The FSIS inspectors also

Greece, Hungary, Italy, the former Yugoslavian republic of Macedonia, Norway, Poland, Romania, Slovak Republic, Slovenia, Spain, and Sweden. APHIS, *supra* note 11.

239. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA, USDA ACTIONS TO PREVENT BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) (2001), at <http://www.aphis.usda.gov/lpa/issues/bse/bsechron.html> (last visited June 19, 2004). The USDA took this action because the EU announced a possible cross-contamination between feed of non-ruminant origin and the BSE agent. The restriction was far-reaching since it applied to products originating in, processed in, rendered in, or associated with Europe. *Id.*

240. APHIS, *supra* note 11.

241. APHIS, *supra* note 11.

242. APHIS, *supra* note 11.

243. APHIS, *supra* note 11. Training includes, *inter alia*, the giving of fact sheets, sessions with veterinarians, and displays of videotape of diseased cattle and the signs of BSE. APHIS, *supra* note 11.

244. APHIS, *supra* note 11. BSE is a reportable disease by accredited veterinarians. APHIS, *supra* note 11.

245. APHIS, *supra* note 11.

246. APHIS, *supra* note 11.

247. Telephone Interview with Thomas Gallagher, Food Technologist, USDA Technical Services Center (Feb. 21, 2002).

248. *Id.*

249. *Id.*

250. *Id.* Since these inspections are antemortem, all cattle with BSE may *not* be identified for three reasons. First, the cattle might not display symptoms of BSE at the time of inspection. Second, BSE might only be in the incubation stage in which symptoms are not yet manifested. Third, the inspectors might misjudge the cattle. *Id.*

251. *Id.* The brains of these cattle are often sent for analysis to the USDA's National Veterinary Services Laboratories. *Id.*

look for certain standards of cleanliness and sanitation in slaughterhouses and meatpacking facilities.²⁵²

While a BSE epidemic has not occurred in the United States, government agencies are aggressive in their treatment of animals that could possibly have the disease or other TSEs. The government has traced all cattle imported into the United States from Great Britain and the Republic of Ireland between 1981 and 1989.²⁵³ Only three imported cows were alive as of November 2001, and they were quarantined in April 1996.²⁵⁴ In an even more aggressive move, the USDA euthanized flocks of sheep in Vermont that tested positive for TSE.²⁵⁵ Amid a flurry of media attention, the owners of the sheep contested USDA action, but a U.S. District Court ordered their destruction.²⁵⁶

Government agencies are also involved in studying the science of BSE and vCJD and planning contingencies for any change in disease outbreak or location.²⁵⁷ Agencies involved in the science effort and which share information amongst themselves include the USDA, APHIS, FSIS, FDA, the Centers for Disease Control and Prevention, and the National Institutes of Health.²⁵⁸ In 1990, APHIS developed a plan for a worse-case scenario in which BSE appears in the United States.²⁵⁹ In 1996, a joint APHIS-FSIS committee updated this plan.²⁶⁰ Other government agencies have seen the plan so that they can coordinate their own preparations.²⁶¹ When a case of Mad Cow Disease was discovered in Washington on December 23, 2003, the response plan was initiated.²⁶²

In the three weeks following the announcement of Mad Cow Disease in Washington, the USDA adopted further measures to protect against incidences of Mad Cow Disease in the United States. The safeguards were announced on December 30, 2003,²⁶³ and included the following provisions: (i) prohibiting

252. *Id.*

253. APHIS, *supra* note 11.

254. APHIS, *supra* note 11.

255. Heather Berit Freeman, *Trade Epidemic: The Impact of the Mad Cow Crisis on EU-U.S. Relations*, 25 B.C. INT'L & COMP. L. REV. 343, 356 (2002). The sheep numbered approximately 360. *Id.* They were imported from Belgium and the Netherlands and had been placed in federal and state quarantines. *Id.* See also Carolyn A. Schwarz, *Impact of Livestock Animal Disease Outbreaks on International Trade: A Study Focusing on the Current Foot-and Mouth Disease and Mad Cow Disease Crises*, 8 ILSA J. INT'L & COMP. L. 255, 262-63 (2001).

256. Freeman, *supra* note 255 at 356.

257. APHIS, *supra* note 11.

258. APHIS, *supra* note 11.

259. APHIS, *supra* note 11.

260. APHIS, *supra* note 11.

261. APHIS, *supra* note 11.

262. News Release, USDA, Veneman Announces Additional Protection Measures to Guard Against BSE, Release No. 0449.03, available at <http://www.usda.gov/news/releases/2003/12/0449.htm> (last visited June 19, 2004) [hereinafter USDA News Release].

263. *Id.*

downer cattle from the human food chain;²⁶⁴ (ii) expanding the list of specified risk materials;²⁶⁵ (iii) widening the definition of material prohibited in advanced meat recovery;²⁶⁶ (iv) banning the use of air-injection stunning;²⁶⁷ (v) prohibiting the use of mechanically separated meat in human food;²⁶⁸ and, (vi) ruling that BSE cattle will not be marked as “inspected and passed” until the agency receives confirmation of a negative test for BSE.²⁶⁹

The FDA also enacted measures in response to the discovery of Mad Cow Disease. On January 26, 2004, it announced two rules. The first rule banned certain bovine materials from human food, dietary supplements, and cosmetics.²⁷⁰ The second rule prohibited feeding and manufacturing processes that were previously permitted.²⁷¹

264. *Id.*

265. *Id.* The definition of expanded risk materials now includes “skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age and the small intestine of cattle of all ages. . . .” *Id.* The rule requires the removal and disposal of these materials so they don’t enter the human food supply. *Id.*

266. *Id.* While spinal cord tissue has always been prohibited, the new safeguards expanded the definition to include dorsal root ganglia which are “clusters of nerve cells connected to the spinal cord along the vertebrae column, in addition to spinal cord tissue.” *Id.*

267. Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, 69 Fed. Reg. 1885 (Jan. 12, 2004) (to be codified at 9 C.F.R. pts. 310, 313). Air injection stunning is a process in which technicians stun cows in the head prior to slaughter. Adler, *supra* note 3, at 44. The ban was created in response to fear that BSE-infected brain tissue could travel through the blood to muscles which are eaten. Adler, *supra* note 3, at 44.

268. USDA News Release, *supra* note 262.

269. USDA News Release, *supra* note 262. The USDA is probably referring to two tests. The first is the ante-mortem inspection of cattle by FSIS inspectors to look for signs of disease, such as central nervous system impairment. USDA News Release, *supra* note 262. The second is the post-mortem examination of cattle which have displayed signs of the disease or were pulled for post-mortem inspection. USDA News Release, *supra* note 262. Of the 35 million cattle slaughtered last year in the United States, only 20,536 cattle received a post-mortem examination for Mad Cow Disease. Marian Burros & Donald G. McNeil, Jr., *U.S. Inspections for Disease Lag Behind Those Abroad*, N.Y. TIMES, Dec. 24, 2003, at A19.

270. LESTER M. CRAWFORD, DEPUTY COMMISSIONER, U.S. FOOD & DRUG ADMIN., *Statement Before the Committee on Agriculture, Nutrition, and Forestry, United States Senate* (Jan. 27, 2004), available at <http://www.fda.gov/ola/2004/bse0127.html> (last visited June 19, 2004). Prohibited materials include material from “downer” cattle, material from “dead” cattle, specified risk materials (the FDA uses the new expansive definition of Sims defined by the USDA on December 30), and mechanically separated meat. Mechanically separated meat obtained via an Advanced Meat Recovery System is still permissible. Press Release, U.S. Dep’t of Health & Human Servs., Expanded ‘Mad Cow’ Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), available at <http://www.hhs.gov/news/press/2004pres/20040126.html> (last visited June 19, 2004).

271. U.S. FOOD & DRUG ADMIN., *supra* note 270; Press Release, *supra* note 270. This second rule is four-fold: It prohibits feeding mammalian blood and blood products to ruminants, prevents the use of “poultry litter” as feed for ruminants (Poultry litter is “bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised.” The concern is that poultry feed may be collected with “poultry litter” and fed to ruminants. It was feared that poultry litter may contain ruminants, and this concern is the source of the ban.), bans the use of plate waste as ruminant feed

The FDA is also concerned about transmission of vCJD via human blood transfusion.²⁷² Although vCJD has not unequivocally been shown to be transmitted via human blood,²⁷³ the agency has developed guidelines for human blood transfusion.²⁷⁴ Giving blood is prohibited if one has resided in the following locations for the following lengths of time: United Kingdom for three months or more, between 1980 and 1996; France for five or more years, between 1980 and the present; and in Europe for five or more years, between 1980 and the present.²⁷⁵

The U. S. Congress has also been involved in the prevention of Mad Cow Disease. A 2002 bill required that all beef carry a label indicating its country of origin, beginning on September 30, 2004.²⁷⁶ On January 22, 2004, Congress passed a spending bill which included a provision to delay the enactment of country-of-origin labels for two years, until 2006.²⁷⁷ Several Senators, including Senate Democratic leader Tom Daschle, attacked the two year extension on the food labeling provision and noted that forty-three countries required country-of-origin labeling.²⁷⁸

(“Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations and rendered into meat and bone meal for animal feed.”), and requires that machinery be designated for either ruminant or non-ruminant feed. Press Release, *supra* note 270.

272. Center for Biologics, Evaluation, and Research, *supra* note 13.

273. Center for Biologics, Evaluation, and Research, *supra* note 13. In late December, a case of variant Creutzfeldt-Jakob Disease was discovered in Britain in a person that had received a blood transfusion from a previously infected person. Alicia Ault, *Blood Transfusion Suspected in New Mad Cow Case in Britain*, N.Y. TIMES, Jan. 28, 2004, at A20. This discovery raised concerns that vCJD could be contracted via blood transfusion. (No definitive scientific ruling was made on the issue.) *Id.* The discovery led to the FDA’s decision to ban the use of mammalian blood and blood products for ruminants (*see supra* note 272). *Id.*

274. Center for Biologics, Evaluation, and Research, *supra* note 13.

275. Center for Biologics, Evaluation, and Research, *supra* note 13. The two other prohibited groups are those who received a blood transfusion in the United Kingdom between 1980 and the present and military personnel and dependents who spent six months or more at military bases in northern and southern Europe in the periods 1980-1990 and 1980-1996, respectively. Center for Biologics, Evaluation, and Research, *supra* note 13.

276. Farm Security and Rural Investment Act of 2002, H.R. 2646, 107th Cong. § 10816 (2002). *See also* Sheryl Gay Stolberg, *Mad Cow Case Heightens Debate on Food Labeling*, N.Y. TIMES, Jan. 8, 2004, at A16. The requirement also included pork, fish, fruits, and vegetables. *Id.*

277. Consolidated Appropriations Act of 2004, H.R. 2673, 108th Cong. § 743 (2004). *See also* Carl Hulse, *After Disputes, Congress Passes Spending Plan*, N.Y. Times, Jan. 23, 2004, at A1.

278. Stolberg, *supra* note 277.

3. Voluntary Actions by Private Actors

Given the dangers of BSE and other related concerns,²⁷⁹ private companies in the United States have taken actions in the fight against BSE.²⁸⁰ On January 17, 2001, a routine check at the Purina Mills plant in Gonzales, Texas, noted a contamination of ruminant material (not destined as cattle feed) with cattle feed.²⁸¹ The company recalled all of the feed and notified FDA officials who determined that the feed was probably safe.²⁸² Purina Mills, however, voluntarily purchased 1,222 animals (which had possibly consumed the contaminated feed) so that their meat would not enter the human food supply.²⁸³

Private actors have also instituted voluntary feed bans on ruminant feed.²⁸⁴ In 1989, the National Renderers Association and the Animal Protein Producers Industry recommended that members stop selling rendered adult sheep or sheep offal as meat and bone meal in cattle feed.²⁸⁵ An FDA study, however, showed that the voluntary ban was not fully implemented.²⁸⁶ On March 29, 1996, the National Cattleman's Beef Association ("NCBA"), the National Milk Producers Federation, the American Sheep Association, the American Veterinary Medical Association, the American Association of Veterinary Medical Colleges ("AAVMC"), and the American Association of Bovine Practitioners conducted a voluntary ban of feeding ruminant-derived proteins to ruminant animals.²⁸⁷ The NCBA and AAVMC feed bans had vastly different survey results,²⁸⁸ and the FDA

279. These concerns could include public relations and marketability of their products. See generally Freeman, *supra* note 255 (evaluating the impact of the Mad Cow Crisis on relations between the European Union and the United States).

280. Freeman, *supra* note 255, at 355-56.

281. Freeman, *supra* note 255, at 355-56.

282. Freeman, *supra* note 255, at 355-56. The FDA noted that the amount of feed consumed by the animals was small and that, since the prohibited material was from the United States, the feed probably did not have traces of BSE. Freeman, *supra* note 255, at 356.

283. Freeman, *supra* note 255, at 356.

284. Substances Prohibited From Use in Animal Food or Feed; Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie, 59 Fed. Reg. 44584, 44586 (proposed Aug. 29, 1994) (codified as amended at 21 C.F.R. pt. 589).

285. Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie, 59 Fed. Reg. at 44586.

286. Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie, 59 Fed. Reg. at 44587.

287. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 552, 564 (proposed Jan. 3, 1997) (to be codified at 21 C.F.R. pt. 589).

288. Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. at 564. The NCBA did not conduct a survey on the effectiveness of the voluntary ban but maintained ninety percent compliance. An anonymous comment to the FDA's Advanced Notice of Proposed Rulemaking (the document cited) argued that the compliance rate was less than five percent. *Id.*

did not conduct a survey.²⁸⁹ Therefore, it is impossible to determine the efficacy of these voluntary bans.

C. European Union

For its part, the European Union ("EU")²⁹⁰ concluded that a link existed between ruminant protein and BSE and, therefore, adopted a feed ban of its own.²⁹¹ The EU has enacted three principal statutes concerning the banning of ruminants.²⁹² On June 27, 1994, the EU passed a statute barring the "feeding of protein derived from mammalian tissues to ruminant species."²⁹³ The statute applied to both ruminant and non-ruminant mammals unless a country could differentiate between the two.²⁹⁴ On December 4, 2000, the feed ban was changed to state: "Member States shall prohibit the feeding of processed animal proteins to

289. *Id.*

290. The European Union is a multigovernmental body composed of twenty-five nations in Europe: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, the Netherlands, and the United Kingdom. EUROPEAN UNION, EUROPA - THE EU AT A GLANCE, at http://europa.eu.int/abc/index_en.htm (last visited June 19, 2004). It functions as a democratic organization and passes legislation that affects member countries. *Id.* The European Union's web site describes the EU as a "unique international organization" whose Member States have developed common institutions to which they delegate some of their sovereignty for certain matters of joint interest to the Union in order to permit decisions to be made democratically at the European level.

291. Commission Decision 94/381/EC, Introduction & art. 1, 1994 O.J. (L 172) 1-2.

292. EUROPEAN UNION, THE USE OF ANIMAL PROTEINS IN THE FEED OF FARMED ANIMALS, HISTORY OF COMMUNITY LEGISLATION ON THE FEED BAN, at http://europa.eu.int/comm/food/fs/bse/bse47_en.pdf (last updated Oct. 10, 2002). For a discussion of some EU actions on BSE and EU reaction to British actions and statutes regarding BSE, see Salmeh K. Fodor, *How Does the European Union Solve Crises—With Solutions or By Avoidance? A Study of the "Mad Cow Disease" Crisis*, 27 GA. J. INT'L & COMP. L. 249 (1998).

293. Commission Decision 94/381/EC, art. 1, 1994 O.J. (L 172) 2. The statute refers to the scientific reasoning for the ban: "Whereas the origin of BSE in cattle is considered to be from ruminant protein which contained the scrapie agent, and, later on, the BSE agent . . . Whereas ruminants are known to be susceptible to the BSE and scrapie agents, by the oral route; Whereas the Commission has carried out a detailed examination of the situation with the Scientific Veterinary Committee [in Great Britain] which concluded that protein derived from ruminant tissues is the only significant potential source of spongiform encephalopathy agents available to susceptible species; whereas, therefore, its exclusion from feed for these species would minimize the possibility of infection." *Id.* at 1.

294. *Id.* at 2. The statute states: "However, Member States which enforce a system that makes it possible to distinguish between animal protein from ruminant and non-ruminant species shall be authorized . . . to permit the feeding of protein from species other than ruminants to ruminants." *Id.* In a previous portion of the statute, the Commission explained the breadth of the statutes as applying to all ruminants: "Whereas there are difficulties in differentiating processed protein derived from ruminants and that from other mammalian species; whereas, for implementation reasons, it is therefore necessary to prohibit the feeding of protein derived from mammalian species to ruminants and to apply the same measure throughout the community." *Id.*

farmed animals which are kept, fattened, or bred for the production of food.”²⁹⁵ The most recent legislation, Commission Decision 2002/248/EC, effective March 27, 2002, extended the existing feed ban to include the prohibition on feeding any animal protein to ruminants.²⁹⁶

D. World Health Organization

The World Health Organization (“WHO”)²⁹⁷ has also researched the BSE epidemic and investigated incidences of vCJD. Since 1991, it has held eleven conferences on human and animal TSEs.²⁹⁸ The WHO currently recommends that: “[a]ll countries must prohibit the use of ruminant tissues in ruminant feed and must exclude tissues that are likely to contain the BSE agent from any animal or human food chain.”²⁹⁹ The WHO reached this conclusion after several conferences. In the “Report of a WHO Consultation on Medicinal and Other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies” (March 26, 1997), the WHO recommended that meat and bone meal from countries with BSE

295. Commission Decision 2000/766/EC, art. 2, 2000 O.J. (L 306) 2. “Processed animal proteins” are defined as “meat-and-bone meal, meat meal, bone meal, blood meal, dried plasma and other blood products, hydrolyzed proteins, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatine and any other similar products including mixtures, feedingstuffs, feed additives and premixtures, containing these products.” *Id.*

296. Commission Decision 2002/248/EC, art. 1, 2002 O.J. (L 84). Article 1 states “Article 2 of Decision 2000/766/EC is amended as follows: Paragraph 1 is replaced by the following: ‘1. Member States shall prohibit the feeding of: (a) proteins derived from animals to ruminants; (b) processed animal proteins to farmed animals which are kept, fattened or bred for the production of food.’” *Id.* at 1. This article does not address the efficacy of the EU feed ban. It is outside of its scope, and analysis of the United Kingdom’s and United States’ feed bans is sufficient to explain the possible deficiencies in feed bans.

297. Established on April 7, 1948, the World Health Organization is a specialized agency of the United Nations focusing on global health. WORLD HEALTH ORGANIZATION, OVERVIEW OF WHO, at <http://www.who.int/about/overview/en/> (last visited June 19, 2004) [hereinafter OVERVIEW OF WHO]. For U.N. authority granting the formation of U.N. agencies, see U.N. Charter art. 55-60, available at <http://www.un.org/aboutun/charter/chapter9.htm> (last visited June 19, 2004). It is composed of 192 member states and is governed by a Health Assembly composed of representatives from the member states. OVERVIEW OF WHO, *supra*. Its goal is “the highest possible level of [global] health . . . a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” *Id.* Article 2 of the WHO Constitution lists the WHO’s functions in achieving its mission. WORLD HEALTH ORGANIZATION, WHO CONSTITUTION BASIC DOCUMENTS CHAPTER II – FUNCTIONS, art. 2(a), 2(b), 2(c), 2(d), 2(i), & 2(q), available at http://www.wpro.who.int/public/policy/cons_chapII.asp (last visited June 19, 2004) [hereinafter WHO CONSTITUTION CHAPTER II - FUNCTIONS]. These functions include scientific research; coordination with governments and other agencies; improving nutrition, sanitation, and housing aspects; and providing information on health matters. *Id.*

298. WHO, *supra* note 38.

299. WHO, *supra* note 38.

should be avoided in ruminant feed.³⁰⁰ Further, the WHO suggested BSE risk assessments and surveying a country's rendering processes and possibilities of BSE outbreaks.³⁰¹ In "WHO Consultations on Public Health and Animal Transmissible Spongiform Encephalopathies: Epidemiology, Risk and Research Requirements" (December 1-3, 1999), the WHO continued to recommend risk assessments³⁰² and prohibitions against any animal showing signs of TSEs from entering the food chain (animal or human).³⁰³ In the "Technical Consultation on BSE: Public Health, Animal Health and Trade" (June 11-14, 2001), the WHO again recommended risk assessments,³⁰⁴ not feeding meat-and-bone meal of ruminant origin to ruminants,³⁰⁵ improved international monitoring of feed bans,³⁰⁶ measures to prevent cross-contamination of feeds (especially ruminant and non-ruminant feeds),³⁰⁷ and a ban on specified ruminant materials.³⁰⁸ Lastly, in October 2002, the WHO published "Understanding the BSE Threat" which is a comprehensive explanation of BSE and vCJD, their proposed origins, and recommendations to curb the diseases.³⁰⁹ The WHO called for active surveillance,³¹⁰ not feeding meat-and-bone meal from ruminants back to ruminants,³¹¹ not mixing ruminant and non-ruminant feed (which might contain

300. WORLD HEALTH ORGANIZATION, REPORT OF A WHO CONSULTATION ON MEDICINAL AND OTHER PRODUCTS IN RELATION TO HUMAN AND ANIMAL TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES CHAPTER 2 (1997), available at <http://www.who.int/emc-documents/tse/docs/whoemczoo973.html> (last visited June 19, 2004).

301. *Id.*

302. WORLD HEALTH ORGANIZATION, WHO CONSULTATIONS ON PUBLIC HEALTH AND ANIMAL TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES: EPIDEMIOLOGY, RISK AND RESEARCH REQUIREMENTS, at 1, 36 (1999), available at <http://www.who.int/csr/resources/publications/bse/en/whodscsgraph20002.pdf> (last visited June 19, 2004).

303. *Id.* at 37.

304. WORLD HEALTH ORGANIZATION, JOINT WHO/FAO/OIE TECHNICAL CONSULTATION ON BSE: PUBLIC HEALTH, ANIMAL HEALTH, AND TRADE, at 1, 4 available at <http://www.who.int/emc-documents/tse/docs/Whodscsgraph2001.8p.pdf> (last visited June 19, 2004).

305. *Id.* at 9. The WHO stated: "To ensure compliance, it may also be necessary to ban all mammalian protein-based feed from ruminant feeds or even from all farm-animal feeds." *Id.* at 10.

306. *Id.* Suggestions included certification programs and screening tests. *Id.*

307. *Id.*

308. *Id.*

309. UNDERSTANDING THE BSE THREAT, *supra* note 63. The publication speaks to the cause of BSE in cattle:

BSE is clearly linked to the practice of recycling bovine carcasses to recover so-called 'meat and bone meal protein,' and then feeding this protein back to other cattle. If cattle are not being fed protein derived from the carcasses of ruminants (cattle, sheep, and goats), there is virtually no risk of BSE Transmission of BSE occurs when cattle consume meat and bone meal feed contaminated with the causative agent.

UNDERSTANDING THE BSE THREAT, *supra* note 69, at 2, 6.

310. UNDERSTANDING THE BSE THREAT, *supra* note 63, at 16.

311. UNDERSTANDING THE BSE THREAT, *supra* note 63, at 14.

meat-and-bone meal from ruminants),³¹² prohibiting the use of specified risk materials,³¹³ and maintaining careful procedures at slaughterhouses such that feed types are not mixed via machinery.³¹⁴

The WHO has three methods to implement health policy. First, it can make recommendations with regard to international health matters.³¹⁵ Second, it can propose convention and agreements (collectively, “conventions”).³¹⁶ WHO conventions, however, are not binding legal authority without implementation via domestic law. The Health Assembly must adopt these conventions by a two-thirds vote.³¹⁷ Finally, the WHO can adopt regulations,³¹⁸ and these regulations come into force unless member states notify the Health Assembly of rejection or reservations.³¹⁹ Between 1948 and 1988, the WHO only utilized its regulation powers twice.³²⁰

Ultimately, the WHO does not appear to be an entity that can significantly impact the problems of BSE and vCJD. First, recommendations are voluntary and, therefore, they do not carry the authority to cause significant change.³²¹ Second, WHO conventions probably are not powerful instruments because they are dependent on domestic ratification and their infrequent use in the past does not

312. UNDERSTANDING THE BSE THREAT, *supra* note 63, at 14.

313. UNDERSTANDING THE BSE THREAT, *supra* note 63, at 15. Specified risk materials includes tissues from the head and spinal column. UNDERSTANDING THE BSE THREAT, *supra* note 69, at 14. They are considered high risk for BSE because they account for a large amount of infectivity. UNDERSTANDING THE BSE THREAT, *supra* note 63.

314. UNDERSTANDING THE BSE THREAT, *supra* note 63, at 15.

315. WHO CONSTITUTION CHAPTER II - FUNCTIONS, *supra* note 297, at art. 2(k).

316. WHO CONSTITUTION CHAPTER II - FUNCTIONS, *supra* note 297, at art. 2(k).

317. WORLD HEALTH ORGANIZATION, WHO CONSTITUTION BASIC DOCUMENTS CHAPTER V - THE WORLD HEALTH ASSEMBLY, art. 19, available at http://www.wpro.who.int/public/policy/cons_chapv.asp (last visited June 19, 2004) [hereinafter WHO CONSTITUTION CHAPTER V]. After adoption, WHO Member States must, within eighteen months, take their own domestic legislative action to give the conventions the force of law. *Id.* at art. 19 & 20. Member States, however, are free to ratify or dismiss the conventions. *See id.* at art. 20. Between 1948 and 1998, the WHO never used its power to promulgate conventions or agreements. David P. Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 VAND. J. TRANSNAT'L LAW 1079, 1089 (1988).

318. WHO CONSTITUTION CHAPTER V, *supra* note 317, at art. 21. Regulations can be in five areas:

(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) advertising and labeling of biological, pharmaceutical and similar products moving in international commerce.

WHO CONSTITUTION CHAPTER V, *supra* note 317, at art. 21.

319. WHO CONSTITUTION CHAPTER V, *supra* note 317, at Art. 22. *See also* Fidler, *supra* note 317, at 1087-88.

320. Fidler, *supra* note 317, at 1089.

321. It is possible, however, that the WHO's recommendations may have had an impact on countries that were developing their own domestic laws regarding BSE.

portend future use. Third, WHO regulations have problems similar to the WHO's conventions. Countries can reject regulations or opt out of provisions through reservations, and the infrequent use of regulations in the past probably indicates their limited use in the future.

E. The General Agreement on Tariffs and Trade and the World Trade Organization

The General Agreement on Tariffs and Trade and the World Trade Organization (collectively, "GATT")³²² does not have specific provisions on BSE. The regulation dealing most closely with BSE and its ramifications is the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement").³²³ The SPS Agreement, sometimes referred to as the "precautionary principle,"³²⁴ allows countries to establish measures to protect themselves from products they consider to be unsafe.³²⁵ The SPS Agreement requires that a country must have a basis before adopting such measures.³²⁶ Total scientific confirmation, however, is not necessary.³²⁷

322. GATT (the General Agreement on Tariffs and Trade) was adopted in Havana in 1948. DAVID J. BEDERMAN, *INTERNATIONAL LEGAL FRAMEWORKS* 143 (2001). Original negotiations took place in Bretton Woods, New Hampshire, in 1944, which resulted in the creation of the International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (World Bank). *Id.* Politically unacceptable to most countries, GATT was an interim trade agreement. The modern framework for international trade regulation is the World Trade Organization ("WTO"), and it was created in 1994. *Id.* Since it is similar to GATT, the WTO is sometimes referred to as "GATT/WTO." *Id.* The principal provisions of the WTO are "low tariffs . . . substantive trade equality and dispute settlement mechanisms." *Id.* at 143-44. These rules were made at rounds of negotiations such as the Geneva Round, Kennedy Round, Tokyo Round, and Uruguay Round. *Id.* at 144.

323. The most recent GATT negotiation, the Uruguay Round, resulted in the creation of the SPS Agreement. Marsha A. Echols, *Sanitary and Phytosanitary Measures*, in *THE WORLD TRADE ORGANIZATION: THE MULTILATERAL TRADE FORMULA FOR THE 21ST CENTURY AND U.S. IMPLEMENTING LEGISLATION* 191 (Terence P. Stewart ed., 1996) [hereinafter *Sanitary and Phytosanitary Measures*]. The Uruguay Round took eight years to be completed, 1986-1994. *See id.* at 234 n. 1; Terence P. Stewart, *Introduction*, in *THE WORLD TRADE ORGANIZATION: THE MULTILATERAL TRADE FORMULA FOR THE 21ST CENTURY AND U.S. IMPLEMENTING LEGISLATION* 1 (Terence P. Stewart ed., 1996).

324. Freeman, *supra* note 255, at 361. The Precautionary Principle states that countries may take precautionary measures to protect their populace from disease even if total scientific confirmation does not exist. Freeman, *supra* note 255, at 361-62. It is reflected in Article 5.7 of the SPS Agreement. Freeman, *supra* note 255, at 361-62.

325. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 192, 198.

326. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 192, 198. Both scientific and economic factors are considered. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 192, 198. Scientific factors include: "available scientific evidence . . . relevant inspection, sampling, and testing methods; prevalence of specific diseases or pests; relevant ecological or environmental conditions . . ." *Sanitary and Phytosanitary Measures*, *supra* note 323, at 199. Economic factors include "the potential damage in terms of the loss of production or sales that would result from the pest or disease; control or

The SPS Agreement's relation to Mad Cow Disease is threefold. First, on July 21, 2001, the "Sanitary, Phytosanitary Measures Committee" met and discussed BSE and its application to the SPS Agreement.³²⁸ The EU discussed its own new classification system (which identifies countries according to risk), and countries considering themselves to be BSE-free (such as the United States and Canada, who were BSE-free at the time) opposed the system.³²⁹ Peru, Chile, and the United States also raised objections to the EU's strict regulations concerning fishmeal as a feed for ruminants.³³⁰ Second, while the United States did not cite to the precautionary principle, its ban on European beef can be seen as an application of the precautionary principle because there was no evidence that BSE had spread to the United States.³³¹ Third, the precautionary principle was involved in a 1985 EU ban of meat produced with growth-promoting hormones (including certain U.S. meat).³³² After hearings in front of committees, World Trade Organization (WTO) arbitrators ruled that the ban was not a legitimate exercise of the precautionary principle and must be removed within fifteen months.³³³

GATT's ability to impact the BSE situation is probably minimal. Its only existing regulation, the SPS Agreement, is not an international lawmaking mechanism. Rather, it is merely a paradigm through which countries could make domestic change. The SPS agreement, therefore, could not be a worldwide solution. Furthermore, amending GATT to include agreements on BSE seems unlikely after an analysis of GATT's history. GATT passed the SPS Agreement

eradication costs; and the relative cost effectiveness of alternative approaches to limiting risks." *Sanitary and Phytosanitary Measures*, *supra* note 323, at 199. The science requirement helps ensure that countries with protectionist measures are confronted with a legitimate health risk and are not adopting protectionist strategies to improve their own economies. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 192. A country must conduct a scientific risk assessment to determine if there is a threat to its populace. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 198. If the risk is significant or high, the country may take steps to protect its population provided these steps are not excessive compared to the threat. *Sanitary and Phytosanitary Measures*, *supra* note 323, at 198. See also Freeman, *supra* note 255, at 360 (describing the SPS Agreement).

327. Freeman, *supra* note 255, at 360-62.

328. WORLD TRADE ORGANIZATION, SANITARY, PHYTOSANITARY MEASURES COMMITTEE 10-11 JULY 2001: COMMITTEE DISCUSSES FOOT AND MOUTH DISEASE, BSE, AND EQUIVALENCE (2001), available at http://www.wto.org/english/news_e/news01_e/010711_spsctte_e.htm (last visited June 19, 2004).

329. *Id.*

330. *Id.*

331. Linda O'Neil Coleman, *The European Union: An Appropriate Model for a Precautionary Approach?*, 25 SEATTLE U. L. REV. 609, 627 (2002). U.S. courts do not cite to the precautionary principle as a rule of international law. *Id.* at 629.

332. Freeman, *supra* note 255, at 359-63. The controversy surrounding BSE and growth-promoting hormones is outside the scope of this Comment. For information on this subject, see Freeman, *supra* note 255, at 359-65; Echols, *supra* note 232, at 195-96; PHILIPPE RUTLEY ET AL., DUE PROCESS IN WTO DISPUTE SETTLEMENT 42-47 (2001).

333. Freeman, *supra* note 255, at 364. For a more detailed analysis of the exact provisions of the SPS agreement growth-promoting hormones, see RUTLEY ET AL., *supra* note 332, at 42-47.

after eight years of deliberation, and an amendment on GATT concerning BSE would probably take as long if not longer to adopt.³³⁴

III. A NEW APPROACH TO THE CREATION OF BSE-SAFE CATTLE FEED

The world is still at risk for BSE and vCJD. First, current feed bans and governmental measures are often ineffective or improperly administered and enforced.³³⁵ In each case, the most likely cause of BSE, the presence of mammalian protein in cattle feed, is not completely prevented. Second, a large amount of meat around the world is unregulated³³⁶ and thus not covered by any protective measures. In order to address this situation, this part will propose the creation of a certification system for BSE-safe cattle feed which does not contain mammalian protein.³³⁷ It will then advance and examine governmental and private models for implementing the program of feed certification.

A. Proposal

In order to alleviate the problems with the current feed bans, this article proposes that a certification be placed on all meat products, indicating that the meat was not produced with feed containing mammalian protein.³³⁸ This certification must encompass three levels of inspection: at feed plants, at farms where cattle are raised, and at slaughterhouses and meatpacking facilities. Inspectors with knowledge of BSE and its causes would administer the

334. Scholars have argued that "amending the [sic] GATT is almost impossible." JOHN H. JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* 303 (1989).

335. Even in the United States, which has yet to have a domestic-born case of BSE, respected government agencies and research institutions warn of the possibilities of BSE. See APHIS, *supra* note 11.

336. Since only forty-one countries have feed bans, a majority of the world does not. GAO, *supra* note 20, at 35. The meat that is produced in those locales without feed bans, therefore, is unregulated. GAO, *supra* note 20, at 35.

337. The World Health Organization states that the feeding of animals with feed not containing mammalian protein is critical to the containment of BSE: "If cattle are not being fed protein derived from the carcasses of ruminants (cattle, sheep, and goats), there is virtually no risk of BSE." UNDERSTANDING THE BSE THREAT, *supra* note 63, at 2.

338. The certification proposal is different from, and more comprehensive than, country-of-origin labeling on meat products. Country-of-origin labeling merely denotes from what country the meat originated, but it does not state how the meat was produced in that country. While certain countries maintain higher standards regarding meat production and safety procedures, country-of-origin labeling does not indicate that meat was produced without mammalian protein. Country-of-origin labeling, therefore, does not reflect the safety of the meat nor does it provide effective information for consumers to use when selecting meat products. See Stolberg, *supra* note 276.

certification program. Since BSE can develop anywhere in the world, any meat produced throughout the globe could potentially be tainted with the disease. Ideally, the certification program should be international in scope so that all meat is produced with the highest standards of safety and care.

First, mammalian protein must not be present in any feed destined for cattle. Inspectors at feed producing facilities should examine the production of feed, the sanitation of equipment, separation of feed which does and does not contain mammalian protein, and formulas to ensure that the feed is not contaminated with mammalian protein. They should also document that feed producers only sell feed without mammalian protein to cattle raisers.³³⁹ Inspectors must be present at all times in feed plants because the current inspection system does not provide for the level of vigilance that is necessary to ensure that the feed is safe for cattle.³⁴⁰ If the feed passes inspection, the meat will satisfy the first certification requirement.

Second, farmers should be prohibited from feeding their cattle any feed containing mammalian protein. Farmers should be required to document that they fed their cattle with feed which did not contain mammalian protein.³⁴¹ Unlike inspection at the feed plants, inspectors will not be constantly present at every cattle raising facility. Thousands of meat producers, both big and small, exist worldwide, and it would be impossible to staff such a level of inspection. Necessarily, the farmers' affirmations must suffice, but inspectors should make spot-checks (unannounced inspections occurring approximately once a year) at cattle raising facilities to ensure compliance. If the cattle raising facilities pass inspection, the meat will satisfy the second certification requirement.

Third, when cattle arrive at the slaughterhouses and meatpacking facilities, inspectors should examine records from feed producing and cattle raising facilities to verify that the cattle satisfy certification requirements. Inspectors must always be present, and they must reconcile the paperwork. If the cattle satisfy all of the aforementioned certification requirements, inspectors will certify the meat, and a certification, such as a stamp, will be placed on the packaging of the meat product.³⁴²

The proprietors of food markets and restaurants may apply for a certificate to denote that they sell certified meat. Inspectors will review the store's records and

339. Feed producers should be required to maintain a database of feed purchasers. Inspectors will examine this database.

340. The system referenced is the United States' method of inspecting feed plants (via the FDA) which occurs, at most, a few times per year. See *supra* text accompanying notes 206-14.

341. This system presupposes that feed will be labeled, and farmers will know what feed to give to their animals.

342. Uncertified meat can still be sold under the proposed certification system. Its sale, however, will be dependent on consumers' desires for uncertified meat. It is possible that laws could be enacted to allow for only the sale of certified meat, but these laws are outside the scope of this article.

determine if certification is appropriate.³⁴³ If the records indicate that the owners sell certified meat, the proprietors will receive a certification symbol to put on their storefronts or menus describing how the meat was raised.

This certification program will ensure the sale and production of meat that is raised without feed containing mammalian protein. The certification program, therefore, will produce two results. First, certified meat will be safer than noncertified meat. Since the meat will be produced with feed which does not contain mammalian protein, the cattle will have a lower probability of acquiring BSE. Second, the populace will have peace of mind knowing that they can buy meat which is as safe as possible.

B. Methods of Implementation

Two possible methods of implementing the certification system exist. First, a governmental system could be administered by the government. Second, a private system could be voluntarily entered into by companies and would resemble the current system of certifying food as kosher. This section will discuss each of these systems and analyze their advantages and disadvantages.

1. Governmental System

In a governmental system, the government would conduct inspections and administer compliance. It would hire inspectors for feed plants, slaughterhouses, and spot-checks at cattle producing facilities, markets, and restaurants. For funding purposes, the government could pay for the program, require payment from each of the producers at each level of certification, or have a mixed payment system with funding from both the government and private sector.

Since the ideal certification system would be international, the governmental system should be international as well. The governmental system could be created by multilateral treaties, an amendment to GATT, WHO conventions or regulations, or United Nations resolutions. The pacts could also create a governmental body, international in nature, to oversee and mandate certification. If an international agreement on certification is impossible to create, individual countries could pass domestic legislation. At the least, therefore, those countries with laws in effect would benefit from the protection and sale of safe meat.

The governmental system would model the present system of USDA certification for American meat products.³⁴⁴ Inspectors in the USDA program are

343. Inspectors will also perform spot-checks to determine the veracity of the proprietors' claims.

344. USDA certification does *not* include complete inspection for BSE. Rather, it signifies that cows receive an ante-mortem examination for signs of neurological disease (which may not detect BSE)

government employees,³⁴⁵ and they investigate companies to ensure that meat producers satisfy government regulations concerning meat.³⁴⁶ The inspectors determine whether meat products receive certification.³⁴⁷ The program is primarily government funded, but companies pay inspectors for any overtime.³⁴⁸ USDA certification must appear on all meat products.³⁴⁹ A government model for certification concerning cattle feed similar to the USDA program, therefore, could be equally as effective and widespread as the current system of USDA certification.

A governmental system has advantages. First, because public safety activities are usually considered within the sphere of government oversight, the certification process could be considered an extension of the government's normal functions and readily accepted by the populace and producers. Second, most governments have an infrastructure in place to perform inspection and health safety activities. This new certification, therefore, may be easy to apply. Third, many governments already have certain feed and inspection procedures in place.³⁵⁰ Even though they may be flawed, they have provided a certain level of safety. Expanding these programs' scale may be logistically easy and a benefit to public health.

The governmental system has disadvantages as well. First, it could be difficult to enact. International actions such as multilateral treaties, amending GATT, WHO conventions, or United Nations resolutions are often difficult to enact. Even passage of domestic laws could be problematic given the debate, contentiousness, and time delays often involved in countries' domestic governmental actions. Second, a governmental system may not function effectively. Past experience with attempts by the United Kingdom and United States to provide safe feed indicate that the programs often are inadequate and do not completely provide for the public health.

2. Private System

In a private system, an independent entity would administer the certification program. The private system would not replace governmental laws and oversight concerning feed, but it would supplement existing regulations and enhance

by the FSIS and that slaughterhouses satisfy requirements such as sanitation. *See supra* notes 247-52 and accompanying text for a description of why FSIS inspections may not detect all cases of BSE.

345. APHIS, *supra* note 11.

346. Gallagher, *supra* note 247.

347. Gallagher, *supra* note 247.

348. Gallagher, *supra* note 247.

349. Gallagher, *supra* note 247.

350. *See supra* Part II.

protection for cattle and consumers. Because the private system would not replace governmental laws and oversight concerning cattle feed, society would not be losing health protection but gaining an extra level of oversight and increased consumer protection.

The private sector's independent entity would conduct certification at all three levels, and it would reconcile all documentation and determine if certification would be appropriate. Each level in the certification process (the feed producers, the cattle raisers, the meatpackers, and the restaurateurs and market owners) would pay the independent entity for certification procedures. In the end, the proprietors of food markets and restaurants (the final entities in the certification chain) would pass this cost onto the consumer.

Private administration of government functions and programs ("privatization") is becoming increasingly popular and has taken place in many industries.³⁵¹ The resulting increased productivity and overall improvement in services,³⁵² in part, has justified the usurpation of the traditional government role of providing public services.³⁵³ Private entities often are able to provide services with greater efficiency and quality,³⁵⁴ and these capabilities are attractive to government and citizens.³⁵⁵ Privatization can lead to great profits, and companies, therefore, are drawn to these industries.³⁵⁶

The transition to privatization often has taken place in areas that have a health component to them and traditionally have been viewed as governmental functions.³⁵⁷ For example, private companies entered the field of water management,³⁵⁸ and in these ventures, decreases in operating costs have ranged from twenty-two to forty percent.³⁵⁹ Private companies are also increasingly involved in waste management.³⁶⁰ Waste Management, one of the nation's largest private waste disposal companies, served 12 million households in 1995 and was growing.³⁶¹ Finally, privatization occurs in the health care field.³⁶² Private entities

351. Robert H. Wessel, *Privatization in the United States*, BUSINESS ECONOMICS, Oct. 1995, at 45.

352. *Id.*

353. *Id.*

354. *Id.*

355. *See id.*

356. *Id.*

357. *Id.* at 46, 48.

358. *Id.* at 46. *See* Robert Vitale, *Privatizing Water Systems: A Primer*, 24 FORDHAM INT'L L.J. 1382, 1382-86 (2001) (providing reasons to privatize water systems such as increased quality and easier administrative functioning). Vitale also points out that governments are willing to provide tax incentives for privatized water companies in the attempt of coercing private systems to take over government-run water systems. *Id.* at 1393.

359. Wessel, *supra* note 351, at 46.

360. Wessel, *supra* note 351, at 46.

361. Wessel, *supra* note 351, at 46.

362. Wessel, *supra* note 351, at 48.

take over and run formerly government hospitals in the hope of increased efficiency, quality, and profitability.³⁶³ For example, Columbia/HCA Healthcare Corporation, the United States' largest healthcare service provider, has acquired and continues to operate government hospitals.³⁶⁴

One of the more difficult hurdles to the private system of meat certification may be convincing those in the meat industry to subscribe to the system. Theoretical applications of free market principles³⁶⁵ and historical examples of consumer industries, however, demonstrate that the private system of certification could be readily applied throughout the meat industry. Theoretically, meat sellers may have to certify their meat in order to satisfy consumer demand. Because of certified meat's increased safety and the peace of mind which results from the safest possible meat, consumers may purchase certified meat in greater proportions than uncertified meat. Even if certified meat were more expensive, consumers may be willing to spend the extra money for certified meat because of the beef's aforementioned advantages. With increased sales of certified meat, the proportion of uncertified meat sold may decrease. Attempting to make a profit, therefore, meat producers would have to produce certified meat in order to make money.

The relationship between certifying meat and making a profit in the meat industry may not stop at a country's borders but may become international. The market for meat is comprised of both domestic and imported meat, and the two types of beef would need to be certified if the market dictated a requirement for certification. If the only type of domestic meat purchased was certified meat, imported meat would have to be certified in order to compete in that market. Likewise, if consumers purchased imported meat because it was certified, domestic meat would have to undergo certification in order to compete with imported meat.³⁶⁶

Current examples in the marketplace demonstrate the power of consumer choice. Certified Angus Beef ("CAB") is beef with cut and production processes resulting in distinctive "flavor, juiciness, and tenderness."³⁶⁷ CAB is usually more

363. Wessel, *supra* note 351, at 48.

364. Wessel, *supra* note 351, at 48.

365. In a free market economy, the rate and volume of consumption of products is determined by consumer demand. For more information on the free market, see generally ADAM SMITH, WEALTH OF NATIONS (1776) and works by Nobel Prize winning economist Milton Friedman.

366. Meat producers might have other reasons for producing certified meat other than merely satisfying consumer demand. First, meat producers might realize that creating safe meat in the present would be more cost effective than dealing with the future consequences of a BSE outbreak in their products. This reasoning is similar to the FDA's reasoning for creating feed bans. Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 552, 575 (proposed Jan. 3, 1997) (to be codified at 21 C.F.R. pt. 589). Further, companies may wish to avoid possible liability issues that could result from selling products which could be unsafe.

367. CERTIFIED ANGUS BEEF, BEEF GRADES, at <http://www.certifiedangusbeef.com/cab/product/grades.html> (last visited June 19, 2004).

expensive than other grades of meat.³⁶⁸ Meat sellers sell this type of beef, however, because they know that consumers are attracted by its qualities and the knowledge that its sale can lead to profits.³⁶⁹

Voluntary certification programs have previously been successful in the food industry. An example is the certification and labeling of food products as kosher.³⁷⁰ Kosher certification is privately driven and not a result of government mandated law.³⁷¹ Independent bodies of rabbis certify whether or not a product is kosher.³⁷² Approximately four hundred kosher certifiers operate around the world.³⁷³ Companies pay these entities to certify their products.³⁷⁴ It is impossible to give an average cost for certification because many variables can affect the price including the frequency of inspection, the time required for inspection, and the distance that the inspector must travel.³⁷⁵ Kosher products are up to three times

368. Brett Erickson, *Adding Value Through Value Added*, CERTIFIED ANGUS BEEF CORNER OF QUALITY #7, available at www.certifiedangusbeef.com/cab/sd/corner/corner07_print.html (last visited June 19, 2004).

369. CERTIFIED ANGUS BEEF, BUSINESS INQUIRIES, at <http://www.certifiedangusbeef.com/cab/biz/success.html> (last visited June 19, 2004). The power of consumer choice for certified meat (meat produced without mammalian protein) probably would be greater than the demand for Certified Angus Beef. Certified Angus Beef customers primarily buy the product because of taste and quality, but purchasers of certified meat would buy the meat for its increased safety. Safety may be a greater incentive to consumers than other concerns such as taste. *Id.*

370. Another voluntary certification process for food is organic food. Benjamin N. Gutman, *Ethical Eating: Applying the Kosher Food Regulatory Regime to Organic Food*, 108 YALE L.J. 2351, 2370-71 (1999). Practitioners of organic agriculture and livestock raise their products without chemicals or inhumane practices to animals, such as tiny cages. *Id.* at 2357, 2359. In contrast to kosher food, there is more state and federal regulation on the definition of "organic food." *Id.* at 2370-71.

371. *Id.* at 2353, 2376. While kosher labeling is not a result of government law, at least twenty-two states have laws prohibiting the defrauding of customers by certifying a product as kosher when it is not. *Id.* at 2369.

372. Stephen F. Rosenthal, *Food for Thought: Kosher Fraud Laws and the Religion Clauses of the First Amendment*, 65 GEO. WASH. L. REV. 951, 953-4 (1997). For a product to be kosher, it must satisfy aspects of both Jewish law and rabbinic decree such as method of slaughter and preparation as well as restrictions on types of food that cannot be eaten such as pig and shellfish. Gutman, *supra* note 370, at 2363-64.

373. ORTHODOX UNION, OU KOSHER Q & A BY RABBI YAAKOV LUBAN, at <http://www.ou.org/kosher/kosherqa/supervis.htm> (last modified Apr. 29, 2004).

374. Interview with Rabbi Reuven B. Stein, Director of Supervision, Atlanta Kashruth Commission, in Atlanta, GA (Feb. 24, 2003). In 2002, 9,850 food plants in the U.S. produced 75,000 kosher certified packaged products. KOSHER TODAY, THE KOSHER FOOD MARKET IN THE U.S.A.: U.S. FOOD PLANTS PRODUCING KOSHER PRODUCTS, at <http://www.koshertoday.com/resourcecenter/charts/usfoodplants.htm> (last visited Apr. 29, 2004); KOSHER TODAY, THE KOSHER FOOD MARKET IN THE U.S.A.: NUMBER OF KOSHER CERTIFIED PACKAGED PRODUCTS, <http://www.koshertoday.com/resourcecenter/charts/numberkoshercertproducts.htm> (last visited Apr. 29, 2004) [hereinafter NUMBER OF KOSHER CERTIFIED PACKAGED PRODUCTS].

375. ORTHODOX UNION, *supra* note 373. The Atlanta Kashruth Commission, a certifying body based out of Atlanta, charges \$4,000 a year to large companies, such as Coca-Cola or Nabisco, for certifying their products. Stein, *supra* note 374. These certifications do not occur at all nationwide facilities but just those in the Atlanta area. Interview with Rabbi Reuven B. Stein, *supra* note 374.

more expensive than their nonkosher counterparts,³⁷⁶ but the public spends the extra money in order to obtain products they desire. Of the \$165 billion of U.S. sales of certified kosher food in 2002,³⁷⁷ \$6.15 billion of sales were from consumers specifically looking for kosher products.³⁷⁸ Even though a company must pay to certify its products as kosher,³⁷⁹ the company pays for certification to acquire revenues from kosher-buying consumers and to maximize company profits.³⁸⁰ The market for kosher food and the operation of its certification program are examples of how the functioning of the marketplace can lead to the performance of voluntary certification. The operation, prevalence, and success of the market for kosher food is an analogue for how BSE certification can exist and why it could be successful. Since the market for meat³⁸¹ is much larger than the market for kosher food, certified meat could be even more economically successful than kosher food.

A private model for feed certification has advantages. First, the private model could result in an increase in BSE-safe cattle feed because it may not be plagued by certification lapses that could occur in a governmental system. The accuracy of kosher certification demonstrates that the private model can result in correct certification. Second, the consumer acceptance of and desire for certified items could become so great that the private certification system could become

376. Rosenthal, *supra* note 372, at 954.

377. KOSHER TODAY, THE KOSHER FOOD MARKET IN THE U.S.A.: U.S. SALES OF FOOD THAT ARE CERTIFIED KOSHER, at <http://www.koshertoday.com/resourcecenter/charts/retailsales.htm> (last visited Apr. 2, 2004) [hereinafter US SALES OF FOOD THAT ARE CERTIFIED KOSHER].

378. KOSHER TODAY, THE KOSHER FOOD MARKET IN THE U.S.A.: SCOPE AND SIZE OF 2002 MARKET WHO ARE LOOKING FOR KOSHER PRODUCTS, at <http://www.koshertoday.com/resourcecenter/charts/scopeandsize.htm> (last visited May 31, 2004). When determining the size of the kosher market and the increases in revenue to companies by virtue of certifying their products as kosher, it is necessary to differentiate between those who buy products specifically because the items are kosher and those persons who buy products which happen to be kosher. Hence, the statistics cited in the text state the total amount of sales and the sales specifically from those searching for kosher products. The market of consumers searching for kosher food is as follows: \$3 billion (44%) from Jews, \$1.8 billion (27%) from those who believe kosher products are better, \$1.25 billion (19%) from Muslims, and \$700 million (10%) from vegetarians/lactose intolerant. *Id.*

379. Aside from the cost of certification, companies probably would also have to pay other costs to make their products kosher such as providing for levels of cleanliness and sanitation, recordkeeping, etc. Interview with Rabbi Reuven B. Stein, *supra* note 374.

380. Between 1988 and November 2002, the market for kosher food has grown considerably. U.S. SALES OF FOOD THAT ARE CERTIFIED KOSHER, *supra* note 377; KOSHER TODAY, THE KOSHER FOOD MARKET IN THE U.S.A.: U.S. FOOD PLANTS PRODUCING KOSHER PRODUCTS, at <http://www.koshertoday.com/resourcecenter/charts/usfoodplants.htm> (last visited Apr. 29, 2004). See also NUMBER OF KOSHER CERTIFIED PACKAGED PRODUCTS, *supra* note 374. During that time period, the amount of sales have increased from \$30 billion to \$150 billion, the number of plants producing kosher products increased from 5,800 to 9,850, and the number of kosher certified packaged products increased from 19,000 to 75,000. NUMBER OF KOSHER CERTIFIED PACKAGED PRODUCTS, *supra* note 374.

381. In the United States alone, beef is a \$56 billion industry per year. GAO, *supra* note 20.

widespread. The growth of the kosher market demonstrates the power of consumer choice in the creation of certified products. Third, the private model may not be subject to the diplomatic and bureaucratic delays often inherent in governmental systems and ratification procedures.

The private model, however, has drawbacks as well. First, although governmental laws would still exist, the private sector would be intruding on the sphere of ensuring public health, a traditional governmental function. Governments usually provide health services, and if the private model is not successful, its creation might set a dangerous precedent for the establishment of private ventures which are less safe. Second, it might be difficult to begin the private process of certification. Producers might not be able to foresee an economic incentive in paying for private certification and thus might not begin the system.³⁸² Third, since the certification process would be voluntary, uncertified meat could still be produced which could be unsafe. Consumers may, out of preference or economic necessity, buy unsafe meat, and these buyers could possibly be subjected to BSE-tainted meat and vCJD.³⁸³

IV. CONCLUSION

Outbreaks of BSE started in 1986 and continue to the present day. Because of the disease, people have died, cattle have been destroyed, and economies have suffered. Scientists discovered that the presence of mammalian protein in cattle feed can lead to BSE and ultimately vCJD, and governments and organizations throughout the world have attempted to address the problems posed by contaminated cattle feed. Such efforts have been flawed and achieved only limited amounts of success.

A new system of compliance should be created, and a certificate should be placed on meat products indicating that meat was produced with feed which did not contain mammalian protein. This new system would include inspection at all levels of meat production and sale: cattle raising facilities, feed plants, meatpacking plants and slaughterhouses, and food markets and restaurants. A governmental or private system would be responsible for implementing this

382. Four reasons account for this possible phenomenon. First, the United States has yet to have an incidence of BSE in a domestic-born cow, so producers might not consider BSE as a potential problem in the United States. Second, incidences of BSE are decreasing, so producers might think the Mad Cow scare is over. Third, producers might not understand that the economic effects of the December 2003 Mad Cow episode in the United States would be greatly exacerbated if BSE were found in the American domestic beef population. Fourth, producers might not grasp the economic incentives of certified meat.

383. Even though unsafe meat would still be produced, the benefits of consumer choice would outweigh this negative consequence. Consumers would have the option of buying safe meat, unsafe meat, or substitutes for meat. A choice in providing for one's health is significantly better than the current system of having a flawed inspection system possibly resulting in unsafe meat and an uninformed populace.

certification system. Both the governmental and private systems have advantages and disadvantages.

The proposal of a certification program regarding the production of BSE-safe cattle feed is the first step in the process of containing BSE and vCJD. More effort must be focused on the certification program in order to make the proposal into a reality. First, either agreements for the meat industry or governmental statutes and regulations detailing the certification system must be drafted. Second, more research must be conducted into the nature, transmission, and epidemiology of BSE and vCJD. Third, lobbying efforts must commence in order to begin the certification program as quickly as possible.