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The Law and Transmissible Spongiform Encephalopathies: The Case for Precautionary Measures

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ARTICLES

**THE LAW AND TRANSMISSIBLE
SPONGIFORM ENCEPHALOPATHIES:
THE CASE FOR
PRECAUTIONARY MEASURES**

Susanne Aberbach-Marolda*

I. Introduction	2
II. Pesticides: A Contributing Factor to the European <i>BSE</i> Crisis	11
III. Legal Options: Available but Under Utilized	14
IV. Sweden, A Case Study on how Working Within the Existing Framework can Lead to Positive Results .	17
V. What Can be Done to Halt the Spread of <i>BSE</i> on an International Level?.....	25

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VI. The United States' Response to the <i>BSE</i> Crisis . . .	30
VII. While There are no Reported cases of <i>BSE</i> in the United States, Various forms of Transmissible Spongiform Encephalopathies (<i>TSEs</i>) have been Documented	47
VIII. Conclusion	50

I. INTRODUCTION

In October 1983 a veterinarian in Malmesbury, Wiltshire, England, was contacted to treat five cows that were agitated, losing weight, and falling down while walking.¹ They were eventually slaughtered.²

By January 1985, several cows from the same farm exhibited similar symptoms.³ This time when the cows were slaughtered, a post mortem exam revealed neurological abnormalities, including "tremors, mania and hind leg ataxia."⁴ These abnormalities were similar to those found in sheep suffering from *Scrapie*, a "fatal progressive neurological disorder."⁵ In sheep, the abnormalities manifest in the form of hind leg ataxia, tremors, twitches, irregular gait, and aggressive behavior.⁶ It was not until 1987, however, when yet another cow from the same farm exhibiting similar symptoms was autopsied, that Mad Cow Disease or *Bovine Spongiform Encephalopathy* ("*BSE*") was finally confirmed in the brains of the cattle in England.⁷ This would become the first clue that a threat to the world's food supply was emerging.

Since 1995, 136 Europeans, mostly from the United Kingdom⁸ have died from *Creutzfeldt-Jakob Disease* ("*CJD*"), the human form of Mad Cow Disease after they consumed infected

¹ See MINISTRY OF AGRICULTURE, FISHERIES AND FOOD (United Kingdom), 3 THE BSE INQUIRY ¶ 1.42 (2000) [hereinafter THE BSE INQUIRY].

² See *id.*

³ See *id.* ¶ 1.43.

⁴ *Id.*

⁵ DEPARTMENT FOR ENVIRONMENT, FOOD & RURAL AFFAIRS (United Kingdom), SCRAPIE, at <http://www.defra.gov.uk/animalh/bse/bse-science/level-4-scrapie.html> (last reviewed Feb. 6, 2001).

⁶ See *id.*

⁷ See THE BSE INQUIRY, *supra* note 1, ¶ 1.43.

⁸ See Jodi Wilgoren, *Hearts Heavy, Hunters Stalk Ailing Deer*, N.Y. TIMES, Sept. 14, 2002, at A1.

beef.⁹ Estimates made over the past several years have predicted that the number of deaths from the human form of Mad Cow Disease could climb as high as 136,000 or be less than 7,000 by 2080.¹⁰ The revised estimates are based on the use of a statistical model using all the data available on the new variant form of *Creutzfeldt-Jakob Disease* (“*vCJD*”).¹¹ While the legal framework was already in place to curtail the epidemic that first ravaged the United Kingdom and then spread around the globe, most of the world has stood idly by during the past fifteen years since the virus was first identified as the causative agent. With food, the very staple which we need to survive, we are left to wonder whether our food supply is really safe and what can be done to contain the epidemic that has touched every corner of the globe.

It has been more than fifteen years since *BSE* was first identified and scientists linked the practice of grounding up same species animal parts and feeding it back to healthy animals as the primary cause of *BSE* in cattle.¹² This practice of feeding ruminants back to ruminants, coupled with the improper use of pesticides, has resulted in a global crisis, the exact magnitude of which is still not determined. With the causative agents of the problem identified, there is still no coherent plan of attack either internationally or within the borders of the United States despite the existence of laws, treaties and policy decisions that would allow for action. Instead, countries have been left to decide for themselves how to handle the ethical issues involved with animal cannibalism and the trade issues associated with products that may generate from *BSE* infected cattle. Only one country, Sweden, acted swiftly when the crisis was first identified. Sweden has taken the ethical high road and changed the way it allows animals to be treated. Sweden has instituted policy decisions, such as prohibiting the practice

⁹ See Paul Elias, *Hunter's Death Raises Disease Worries*, ASSOCIATED PRESS NEWS WIRE (Sept. 7, 2002), available at <http://groups.yahoo.com/group/asthmacured/message/612>.

¹⁰ See *Study Says 136,000 May Die From Mad Cow Disease*, REUTERS (1999).

¹¹ See *id.* For further discussion on the new variant form of *CJD*, see *infra* note 52 and accompanying text.

¹² See Michael Greger, *Mad Cow Disease "Much More Serious Than AIDS,"* ENVIROLINK, at <http://www.people.virginia.edu/~rjh9u/madcow.html> (last visited Feb. 5, 2003).

of animal cannibalism, that today allow its citizens to purchase food with confidence that it is not infected with *BSE*. Until the United States and the rest of the global community follow Sweden's example, can we be assured that the food we are eating is free of disease and safe to consume?

BSE is part of a closely related family of brain wasting diseases called *Transmissible Spongiform Encephalopathies* ("*TSEs*"). Until now *TSEs*, which create sponge-like holes in the brains of its victims, were not believed to be able to cross the species barrier. In sheep it is called *Scrapie*, in cattle it is called *BSE*, in people it is called *CJD*, and in deer and elk it is *Chronic Wasting Disease*. All forms of *TSEs* are believed to "occur when healthy proteins called prions become twisted and clump together."¹³ The resulting "mutant prions"¹⁴ by themselves are not "lethal" but become destructive "only when their shape is altered."¹⁵ This alternation can occur either through an already infectious protein or through a genetic mutation.¹⁶ It is believed that this is "probably caught by eating infected beef"¹⁷ Prions themselves appear to be virtually indestructible. Unlike conventional viruses, they are "resistant to heat, ultraviolet and ionizing radiation and to chemical disinfectants."¹⁸ High temperatures such as those experienced during a cooking process cannot eradicate the mutant prions. Even soaking them in formaldehyde for ten years did not destroy the mutant prions.¹⁹ Epidemiological studies conducted on the consump-

¹³ Helen Pearson, *Antibodies Cripple Prions, Therapy Looks Best to Tackle Brain Disease*, NATURE.COM (Mar. 6, 2003), at <http://www.nature.com/nsu/030303/030303-7.html>.

¹⁴ Tom Clarke, *Prions Bend the Rules*, NATURE.COM (Mar. 8, 2001), at <http://www.nature.com/nsu/010308/010308-13.html>.

¹⁵ News Release, University of California San Francisco, Data Establishes Link between "Mad Cow" Disease, Human Brain Disorder (Dec. 20, 1999), available at <http://media.ucsf.edu/ucsf/newsitem.nsf/20cb52fe59c7e8c288256a54001ac1b/BA5F7FE0B357A6968825684A0060577A?OpenDocument>.

¹⁶ See *id.*

¹⁷ Pearson, *supra* note 13.

¹⁸ WORLD HEALTH ORGANIZATION, REPORT OF A WHO CONSULTATION ON PUBLIC HEALTH ISSUES RELATED TO HUMAN AND ANIMAL TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ¶ 2.1(1) (Apr. 2-3 1996), available at <http://www.who.int/emc/diseases/bse/bsecjd.html#a2>.

¹⁹ See Dr. Joseph Mercola, *Can It Happen Here? The Puzzle of Mad Cow Disease*, MERCOLA.COM, at http://www.mercola.com/beef/mad_cow_here.htm (last visited Feb. 5, 2003).

tion of sheep infected with *Scrapie*, however, found no link between *Scrapie* and the spontaneously occurring sporadic form of *CJD*.²⁰ Therefore, scientists believed it to be harmless to humans and thus not considered a health threat. During the past decade, however, scientific evidence has shown that not only can the mutant prion not be destroyed but also it in fact can jump from species to species when a diseased animal is consumed.²¹

When cattle in the United Kingdom began exhibiting *Scrapie*-like neurological symptoms, the scientific community for the first time began to think that the disease might not be species limited. This was also the first indication that questionable farming practices such as same species cannibalism, coupled with improper pesticide use, might be to blame for the disease that was ravaging not just sheep but cattle throughout the United Kingdom. This threat was not only limited, however, to the food supply but also had the potential of undermining the economic survival of many countries that rely on animal based products such as meat, milk, tallow, medicines, and gelatin for their economic survival.

Now, sixteen years later, politicians and scientists are still searching for ways to arrest this global threat brought on by economically feasible farming practices of animal cannibalism and pesticide use. However, with the damage to the food supply already committed, and with national and international laws that are unenforceable or ineffective to curtail the damage, what can the citizens of the United States or the rest of the world expect the next time they take a bite of a hamburger, eat a bowl of gelatin, or need an insulin injection, all produced from the remains of cattle?

To appreciate the current threat, it is important to understand how the food chain became contaminated. *Scrapie* has been around for centuries. First reported in England in the 1700s, there have been outbreaks reported in all parts of the

²⁰ See Raymond P. Roos, M.D., *Controlling New Prion Diseases*, 344 NEW ENG. J. MED. 1548 (2001), <http://www.organicconsumers.org/madcow/controlling51901.cfm>.

²¹ See "Mad Cow" Disease is Here!, HEALTHALERT, at <http://www.cqs.com/madcow.htm> (last visited Feb. 5. 2003). See also Greger, *supra* note 12.

globe including the United States.²² In the United States, the first outbreak was reported in 1947, when sheep imported from England were infected with the disease.²³ Since it could not cross the species barrier, it was not considered a health threat to people.

During the mid 1980s, veterinarians throughout the United Kingdom began to notice a pattern developing among cattle herds located in different parts of the country. In December 1984, a veterinarian in Sussex, England, was called to treat a cow that had an arched back and was losing weight.²⁴ On subsequent visits, the veterinarian noticed a head tremor and lack of coordination.²⁵ The cow died on February 11, 1985.²⁶ Within the next two months, five more cows from the same farm died all exhibiting similar symptoms.²⁷ Brain samples were taken and analyzed. By the summer, the farmer had two more cows exhibiting the same symptoms. Brain and spinal cord samples taken from these cows were given a tentative diagnosis of *Bovine Scrapie*,²⁸ a TSE type disease usually found in sheep that until now was not believed to be able to jump across the species barrier.

Still there were more cases and clues that a new disease was emerging. In April 1985, a farmer at the Plurenden Manor Farm in Kent, England, noticed that his Holstein cow was acting peculiar.²⁹ The cow, like the others, was aggressive and lacked coordination. During the year more cows in the herd became infected and the symptoms worsened. They were unable to stand without assistance. When the cows died, their brains, like the cows from the Pitcham farm were sent to the Central Veterinary Laboratory in England for diagnosis.³⁰ It was not until 1987 when the pathology files were reviewed that these

²² See generally Dan Murphy, *Live from the Food Safety Summit: BSE Likelihood Low; Consumer Concern High*, MEATINGPLACE.COM (Apr. 18, 2001), at http://meatingplace.com/meatingplace/Archives/oop/qnohit_g.asp?ID=7283.

²³ See *id.*

²⁴ See THE BSE INQUIRY, *supra* note 1, ¶ 1.9.

²⁵ See *id.*

²⁶ See *id.*

²⁷ See *id.* ¶ 1.10.

²⁸ See *id.* ¶¶ 1.7, 1.12.

²⁹ See *id.* ¶ 1.32.

³⁰ See generally THE BSE INQUIRY, *supra* note 1, ¶¶ 1.35-1.36.

cases were classified as *BSE*.³¹ Between 1986 and 2002, 180,000 *BSE* cases were confirmed in the United Kingdom alone.³²

Compounding the problem were changes made in the rendering process during the early 1980s. During the rendering process, all consumable parts are removed and the remaining carcass is submerged into large vats of boiling water to allow for decomposing.³³ This process produces an "aqueous slurry of protein under a layer of fat (tallow)."³⁴ After the fat is removed, the remaining "slurry" is turned into protein pellets that are sold to farmers and those responsible for the care of laboratory and zoo animals in countries around the world.³⁵ The changes made included the removal of a solvent that was used during the extracting process along with the use of steam heat.³⁶ Some scientists believe that changes made to this process have allowed the prion to survive up to thirty years.³⁷ Scientists such as Paul Brown of the National Institutes of Health in Washington, D.C.³⁸ now believe that changes made to this process have allowed the prion to survive.³⁹

As new cases of *BSE* were emerging across the country, the United Kingdom continued to export the protein pellets as animal feed.⁴⁰ The pellets were made from cows deemed to be unfit for human consumption. Upon being slaughtered, the cat-

³¹ See *id.* ¶ 1.7.

³² See REGIONAL OFFICE FOR EUROPE, WORLD HEALTH ORGANIZATION, BOVINE SPONGIFORM ENCEPHALOPATHY (BSE), http://www.euro.who.int/foodsafety/other-issues/20020402_2 (last visited Feb. 5, 2003).

³³ See Paul Brown et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns*, 7 EMERGING INFECTIOUS DISEASES 6, 6 (2001), available at <http://www.cdc.gov/ncidod/eid/vol7no1/pdfs/brown.pdf>.

³⁴ *Id.*

³⁵ See *id.*

³⁶ See NATIONAL CATTLEMEN'S BEEF ASSOCIATION, *Bovine Spongiform Encephalopathy*, in CJD, BSE, NV/CJD INFORMATION RESOURCE (Mar. 2003), available at http://www.bseinfo.org/dsp/dsp_locationContent.cfm?locationId=1261.

³⁷ See Greger, *supra* note 12.

³⁸ Dr. Paul Brown is Senior Research Scientist in the Laboratory of Central Nervous System Studies at the National Institutes of Health. He is also a consultant to the European CJD surveillance program and chair of the Transmissible Spongiform Encephalopathy advisory committee of the US FDA (TSEAC).

³⁹ See Brown, *supra* note 33, at 6.

⁴⁰ See *The Madness Spreads*, NEWSIDENTIST.COM (Feb. 10, 2001), at <http://www.newscientist.com/hottopics/bse/bse.jsp?id=22770100>.

tle carcasses were then dissected into usable parts and the remainder was turned into protein pellets and sold as feed to be given to healthy cows and other animals.⁴¹ The exportation of the potentially contaminated feed was done despite the fact that Britain had banned its use in its own cattle and sheep in 1988.⁴² The feed remained legal for export to "supplement pig and poultry food right up to 1996, when the European Union banned all exports of the product."⁴³ Between 1988 and 1996 "potentially contaminated meat and bone meal was exported"⁴⁴ from the United Kingdom to seventy countries worldwide.⁴⁵ It is estimated that Asian countries purchased "nearly a million tons"⁴⁶ of the protein pellets. The United States also purchased 21 tons in 1989.⁴⁷ The problem was also compounded by the exportation of 3.2 million live British cattle to 36 countries around the globe during the same six-year period.⁴⁸ The result has been an outbreak of *BSE* across Europe and in Canada, where some of the infected cattle were exported. Since 1989, 3,286 cases of *BSE*⁴⁹ have been confirmed in not only imported cattle but in cattle native to Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Spain, and Switzerland;⁵⁰ countries that have all reported importing the tainted animal feed. In addition, cases have also been confirmed in Italy, Canada, the Falkland Islands, Germany, and Oman,⁵¹ all of which imported cattle or feed from the

⁴¹ See Greger, *supra* note 12.

⁴² See *BSE-Contaminated Feed Said to Reach 70 Countries*, UNITED PRESS INTERNATIONAL (Feb. 4, 2001), available at http://www.healthresearchbooks.com/articles/mad_cow15.htm.

⁴³ *Id.*

⁴⁴ *Mad Cow Disease: 70 Nations May Have Imported Contaminated Feed*, UN WIRE (Feb. 6, 2001), at <http://www.unfoundation.org/unwire/archives/UNWIRE010206.asp#4>.

⁴⁵ See *id.*

⁴⁶ Bette Hileman, *The 'Mad' Disease has Many Forms*, 79 CHEMICAL AND ENGINEERING NEWS 24, 30 (2001), available at <http://pubs.acs.org/cen/coverstory/7915/7915gov3.html>.

⁴⁷ See *id.*

⁴⁸ See *id.*

⁴⁹ See WORLD HEALTH ORGANIZATION, BOVINE SPONGIFORM ENCEPHALOPATHY FACT SHEET NO. 113, available at <http://www.who.int/mediacentre/factsheets/fs113/en/> (last revised Nov. 2002).

⁵⁰ See *id.*

⁵¹ See *id.*

United Kingdom before exportation was banned in 1989.⁵² In Japan, two new cases were reported in 2003, bringing the total to seven cows infected.⁵³ Six of the seven cows are believed to have ingested milk when they were calves in 1996 made from “material imported from Western Europe”⁵⁴

While veterinary scientists were grappling with the *BSE* outbreak in cattle herds, medical doctors in the United Kingdom were reporting the emergence of a new form of *CJD*, an extremely rare and fatal neurological disorder that is part of the *TSE* family. This new version was identified when it began striking young people. Doctors then discovered a “distinctive clinical syndrome” that appeared to be associated with plaque formation and psychiatric symptoms at very young ages.⁵⁵ While recognized by the medical community for decades, this human form of *BSE* was now striking younger victims much in the same way that the cows were being struck across the United Kingdom. With a median age of twenty-eight,⁵⁶ it was young people, those under the age of thirty at the time of death, that were most likely to be stricken with the *vCJD*.⁵⁷ More than fifty of the people who have died from *vCJD* have been teenagers and young adults.⁵⁸ Usually found in people over age fifty-five⁵⁹ at a rate of one in a million,⁶⁰ doctors in the United Kingdom were reporting cases of *CJD* in people in their teens, twenties, and thirties. In 1996, ten cases were reported in the United Kingdom and it was determined that the most likely

⁵² See WORLD HEALTH ORGANIZATION, VARIANT CREUTZFELDT-JAKOB DISEASE FACT SHEET NO. 180, available at <http://who.int/mediacentre/factsheets/fs180/en/> (last revised Nov. 2002).

⁵³ See James Brooke, *Asia: Japan: More Mad Cow Cases*, N.Y. TIMES, Jan. 24, 2003, at A6.

⁵⁴ *Id.*

⁵⁵ See Brown, *supra* note 33, at 9.

⁵⁶ See Elias, *supra* note 9.

⁵⁷ See WORLD HEALTH ORGANIZATION, TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (2002), available at <http://www.euro.who.int/foodsafety/otherissues/20020724>.

⁵⁸ See *Data Link Mad Cow Disease, Human Brain Disorder*, UCSF'S ELECTRONIC DAILY DAYBREAK NEWS (Dec. 21, 1999), at http://www.ucsf.edu/daybreak/1999/12/21_madcow.htm.

⁵⁹ See Claire Ainsworth & Damian Carrington, *BSE Disaster: The History*, NEWSIDENTIST.COM (Oct. 25, 2000), at <http://www.newscientist.com/news/print.jsp?id=ns999991>.

⁶⁰ See FACT SHEET NO. 180, *supra* note 52.

cause was the consumption of *BSE* tainted meat.⁶¹ This new variant has been identified in 129 cases in the United Kingdom between March 1996 and November 2002 and has also been reported in France and Ireland⁶² as well as in a thirty-four-year old Chinese woman who lived in Great Britain between 1987 and 1992 and was a patient in a Hong Kong hospital.⁶³ Statistics provided by the World Health Organization indicate that since the mid 1990s, there have been 105 reported cases of *vCJD*, with a majority occurring in the United Kingdom. So far, 115 people in the United Kingdom have died of *vCJD* and an additional ten have been stricken.⁶⁴ In France, there were two confirmed deaths from *vCJD*⁶⁵ and in Canada, a Saskatchewan man became the first death attributable to the human form of Mad Cow Disease when he died in August 2002.⁶⁶ There have been no confirmed cases of *vCJD* caused by tainted meat in the United States;⁶⁷ however, a British woman living in Florida has exhibited symptoms of *vCJD*.⁶⁸ Complicating the issue, scientists have discovered that, in addition to the mutant prions being virtually indestructible, the incubation period in humans can be as long as thirty years.⁶⁹ In animals, the incubation period can be as long as five years. Since animals are often slaughtered before the age of three, detection of *BSE* is more difficult because they could be silently harboring the infected prion without showing visible symptoms and thus not tested at

⁶¹ See WORLD HEALTH ORGANIZATION, REPORT OF A WHO CONSULTATION ON MEDICINAL AND OTHER PRODUCTS IN RELATION TO HUMAN AND ANIMAL TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES OPENING REMARKS (1997), available at <http://www.who.int/emc-documents/tse/docs/whoemczoo973.html#a4>.

⁶² See FACT SHEET NO. 180, *supra* note 52.

⁶³ See Rose Tang, *Human Form of Mad Cow Confirmed in Hong Kong*, CNN.COM (June 15, 2001), at <http://europe.cnn.com/2001/WORLD/asiapcf/east/06/15/hongkong.madcow/>.

⁶⁴ See Emma Young, *First Confirmed Case of vCJD In North America*, NEWS-SCIENTIST.COM (Aug. 9, 2002), at <http://www.newscientist.com/hottopics/bse/bse.jsp?id99992656>.

⁶⁵ See 'Mad-Cow Disease' Where do we go From Here?, CONSUMERREPORTS.ORG (May 2001), at http://www.consumerreports.org/main/detailv2.jsp?CONTENT%3C%3Ecnt_id=3387&FOLDER%3C%3Efolder_id=3327&bmUID=1044504806765.

⁶⁶ See More "Mad Cow" Deaths Likely, TORONTO STAR, Aug. 10, 2002, <http://www.organicconsumers.org/madcow/cjddeaths81002.cfm>.

⁶⁷ See *Woman Has Human Form of Mad Cow Disease*, N.Y. TIMES, Oct. 18, 2002, at A21.

⁶⁸ See *id.*

⁶⁹ See Greger, *supra* note 12.

the time of slaughter.⁷⁰ As a result, *BSE* infected meat could be introduced into the food chain without being detected.

II. PESTICIDES: A CONTRIBUTING FACTOR TO THE EUROPEAN *BSE* CRISIS

While the worldwide medical community has generally accepted the tainted bone meal theory as the main cause of the *BSE* outbreak,⁷¹ a new theory involving pesticide contamination has been gaining some momentum. Mark Purdey, an organic dairy farmer who, as an independent scientist,⁷² has been studying the etiology of *TSEs* worldwide, claims that Phosmet, a chemical composed of disulfoton: O, -Diethyl s-[2-(ethylthio)ethyl], Phosphorodithioate 0.625% and inert ingredients totaling 99.375%,⁷³ is also at fault. Phosmet was used by English farmers to kill warble flies.⁷⁴ This chemical is a systemic pesticide which penetrates the skin by absorption, thus allowing the active ingredient to be released slowly over time.⁷⁵ Farmers in the 1980s were directed by the English government to pour it along the spinal cords of their cattle at four times the recommended dosage using an oil-based systemic formulation.⁷⁶

⁷⁰ See Murphy, *supra* note 22.

⁷¹ See generally Wendy L. Bonifazi, RN, *USDA Seeks Comment on Mad Cow Proposals*, THE NATURAL FOODS MERCHANDISER (Mar. 2002), at http://exchange.healthwell.com/nfm-online/nfm_backs/mar_02/news12.cfm.

⁷² See THE PURDEY ENVIRONMENTAL HOME PAGE, U.K. *BSE* INQUIRY PAGE, at www.purdeyenvironment.com/bseinqui.htm (last visited Feb. 5, 2003).

⁷³ See ENVIRONMENTAL PROTECTION AGENCY, PHOSTEMIC-D* LABEL [hereinafter PHOSTEMIC-D* LABEL] (on file with author).

⁷⁴ See generally Mark Purdey, *Does an Ultra Violet Photooxidation of the Manganese-loaded / Copper-depleted Prion Protein in the Retina Initiate the Pathogenesis of TSE?*, available at 57 MEDICAL HYPOTHESES 29 (2001), <http://www.purdeyenvironment.com/uvpaper.htm>.

⁷⁵ See generally *Cases of BSE and CJD May be due to Environmental Contamination with Manganese Compounds and Organophosphates*, THE NEW ZEALAND HEALTH INFORMATION NETWORK, available at http://www.nzhealth.net.nz/dis_ease/cjd.html (last visited Feb. 6, 2003).

⁷⁶ See generally Mark Purdey, *Does an Ultra Violet Photooxidation of the Manganese-loaded / Copper-depleted Prion Protein in the Retina Initiate the Pathogenesis of TSE?* 57 MEDICAL HYPOTHESES 29 (2001), available at <http://www.purdeyenvironment.com/uvpaper.htm>; Mark Purdey, *High-dose Exposure to Systemic Phosmet Insecticide Modifies the Phosphatidylinositol Anchor on the Prion Protein: The Origins of New Variant Transmissible Spongiform Encephalopathies?*, 50 MEDICAL HYPOTHESES 91 (1998), available at <http://www.purdeyenvironment.com/Med%20Hyp%202nd.htm>.

In four separate papers⁷⁷ published in *MEDICAL HYPOTHESES*, a peer reviewed English scientific journal, Purdey states that in addition to the rendered feed, cattle in the United Kingdom were also fed chicken manure taken from chickens that were given high doses of manganese designed to increase their egg output.⁷⁸ This, coupled with the Phosmet an organophosphate, which captures copper, acted as a barrier and deprived the cow's brains of the much-needed copper and overdosed it with magnesium.⁷⁹ The result, Purdey argues, is a distortion in the prions, which in turn causes *TSE*.⁸⁰ To prove his hypothesis, Purdey tested his theory on known *TSE* clusters in three separately distinct areas of the world: Iceland, where *Scrapie* infected sheep were studied; Colorado in the United States where elk and deer were afflicted with *Chronic Wasting Disease*; and Slovakia where there were known clusters of *CJD* victims.⁸¹ He found that in each of these locations the test subject living in the area had a deficiency in copper and an overexposure to manganese.⁸² In Colorado government programs that included blanket slaughter of herds known to be infected with *Chronic Wasting Disease* and then restocking four years later failed to eradicate the problem, Purdey suggests that this demonstrates the existence of a "persistent presence of a hitherto unrecog-

⁷⁷ Three of Purdey's papers are available on-line at <http://www.purdeyenvironment.com/>. They include: *Does an Ultra Violet Photooxidation of the Manganese-loaded / Copper-depleted Prion Protein in the Retina Initiate the Pathogenesis of TSE?*, 57 *MEDICAL HYPOTHESES* 29 (2001); *High-dose Exposure to Systemic Phosmet Insecticide Modifies the Phosphatidylinositol Anchor on the Prion Protein: The Origins of New Variant Transmissible Spongiform Encephalopathies?*, 50 *MEDICAL HYPOTHESES* 91 (1998); and *Ecosystems Supporting Clusters of Sporadic TSEs Demonstrate Excesses of the Radical-generating Divalent Cation Manganese and Deficiencies of Antioxidant Co Factors Cu, Se, Fe, Zn*, 54 *MEDICAL HYPOTHESES* 278 (2000).

⁷⁸ See George Monbiot, *Mad Cows, Bretons and Manganese*, *GUARDIAN UNLIMITED* (Nov. 23, 2000), www.guardian.co.uk/Archive/Article/0,4273,4095057,00.html.

⁷⁹ See *id.*

⁸⁰ See *id.*

⁸¹ See generally Mark Purdey, *Ecosystems Supporting Clusters of Sporadic TSEs Demonstrate Excesses of the Radical-generating Divalent Cation Manganese and Deficiencies of Antioxidant Co Factors Cu, Se, Fe, Zn*, 54 *MEDICAL HYPOTHESES* 278, 282 (2000), available at <http://www.purdeyenvironment.com/MEDHYP2000.htm>.

⁸² See *id.*

nized environmental causal factor common to these regions.”⁸³ When he further applied this theory to specific areas in the United Kingdom and France where there were documented clusters of *BSE* infected cows, the same set of environmental circumstances was found. In France, where twenty of the first twenty-eight cases of *BSE* were reported in Brittany, which was the first area where the government mandated the use of Phosmet, Purdey discovered that farmers there had used the chemical pesticide much in the same over abundance that their English counterparts had⁸⁴ in an effort to eradicate the warble fly.⁸⁵

In the United Kingdom, Purdey looked at specific clusters of *BSE* infections and came up with the same conclusions. In Kent and Queniborough, where there were two main clusters of *BSE* infected cattle, an abundance of manganese was found in the soil.⁸⁶ Traditionally this area is deficient in manganese. However, in Kent, local farmers had used “copious amounts” of a liquid form of the mineral as a spray.⁸⁷ When the soil was tested, it revealed excessive levels of manganese.⁸⁸ In addition, organophosphates were used on the hops and fruit fields in Kent. Meanwhile in Queniborough, chemicals were sprayed all over the village from a dye works plant, which used “shed loads of manganese.”⁸⁹ The plant was also responsible for dumping residue into the sewage system, which in turn was sprayed over the fields.⁹⁰ When manganese levels in animals rise when exposed to systemic organophosphates such as Phosmet, “the oxidizing effect of the Phosmet is able to oxidize the normal manganese 2 plus atoms [thus] transforming them into their

⁸³ Mark Purdey, *Ecosystems Supporting Clusters of Sporadic TSEs Demonstrate Excesses of the Radical-generating Divalent Cation Manganese and Deficiencies of Antioxidant Co Factors Cu, Se, Fe, Zn*, 54 *MEDICAL HYPOTHESES* 278, 282 (2000), available at <http://www.purdeyenvironment.com/MEDHYP2000.htm>.

⁸⁴ See Monbiot, *supra* note 78.

⁸⁵ See Bob Woffinden, *The Seeds of Madness*, *THE GUARDIAN WEEKEND* (Aug. 13, 1994), <http://www.purdeyenvironment.com/Woffinden0001.htm>.

⁸⁶ See generally Monbiot, *supra* note 78.

⁸⁷ See *id.*

⁸⁸ See Mark Purdey, *Does an Ultra Violet Photooxidation of the Manganese-loaded/Copper-depleted Prion Protein in the Retina Initiate the Pathogenesis of TSE?*, 57 *MEDICAL HYPOTHESES* 29, 34 (2001), available at <http://www.purdeyenvironment.com/uvpaper.htm>.

⁸⁹ Monbiot, *supra* note 78.

⁹⁰ See *id.*

highly lethal 3 plus form – a form which is able to initiate a whole chain reaction of free radical assault on the brain cells and *BSE*, *CJD* ensues.⁹¹

Despite the unraveling of a world health crisis, response both worldwide and in the United States has been slow. As early as 1988, the United States and other countries were aware of the dangers of animal cannibalism but failed to react. In 1988, the United Kingdom issued a ban on using the ruminant protein feed within its own borders;⁹² however, it did not stop the exportation of the tainted pellets. Countries around the world continued to import the tainted pellets. In 1991, exportation was halted to members of the European Union, but the tainted feed continued to be sold to third world countries until 1996.⁹³ The result has been more than 3,800 reported cases of *BSE* outside of the United Kingdom,⁹⁴ which has reported more than 182,000 cases since the mid 1980s.⁹⁵ Ireland alone has reported 1,199 cases since 1989,⁹⁶ and has reported 47 cases during the first two months of 2003.⁹⁷ Also reporting substantial numbers of cases are: France (754); Portugal (725); Switzerland (432); Spain (248); and Germany with 249 reported cases.⁹⁸

III. LEGAL OPTIONS: AVAILABLE BUT UNDER UTILIZED

In Europe, the mechanism exists to cut through the myriads of laws and regulations that govern each individual country and ban both the practice of animal cannibalism and the use of suspect pesticides that are being blamed for the worldwide *BSE*

⁹¹ E-mail from Mark Purdey, Scientist, to Susanne Aberbach-Marolda, student, Pace University School of Law (July 4, 2001) (on file with author).

⁹² See Brown, *supra* note 33, at 7.

⁹³ See Monbiot, *supra* note 78.

⁹⁴ See OFFICE INTERNATIONAL DES EPIZOOTIES, NUMBER OF REPORTED CASES OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) WORLDWIDE (EXCLUDING THE UNITED KINGDOM), available at http://www.oie.int/eng/info/en_esbmonde.htm (last updated Mar. 27, 2003).

⁹⁵ See OFFICE INTERNATIONAL DES EPIZOOTIES, NUMBER OF CASES OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) REPORTED IN THE UNITED KINGDOM, available at http://www.oie.int/eng/info/en_esbru.htm (last updated Nov. 21, 2002).

⁹⁶ See *id.*

⁹⁷ See *Four New Cases of BSE Reported This Week*, RTE INTERACTIVE NEWS (Feb. 28, 2003), at <http://www.rte.ie/news/2003/0228/BSE.html>.

⁹⁸ See *id.*

crisis. Under the "Precautionary Principle," as set forth in Principle 15 of the Rio Declaration on the Environment and Development,⁹⁹ the United Kingdom and the other member nations agreed that when it came to protecting the environment a precautionary approach "shall be widely applied by States according to their capabilities."¹⁰⁰ This approach was deemed to be warranted where there "are threats of serious or irreversible damage, [and] lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."¹⁰¹

Adopted by the European nations,¹⁰² this principle works on the premise of risk management. It expresses the concept that "a country should exercise caution in the face of scientific uncertainty and provides that preventive measures must be cost effective"¹⁰³ Since its adoption in 1992, the spirit of the principle has been included in a variety of multilateral environmental agreements and declarations "as well as scattered judicial opinions."¹⁰⁴ It has most recently been adopted by the European Commission, which issued a communication to its members on February 2, 2000, outlining the manner and scope on how the principle should be applied.¹⁰⁵ In its communiqué to members, it was stated that while the environment, including plant and animal life is extremely important, the Commission believes that its scope can be much broader and it views the principle as a tool that "provides a basis for action when science is unable to give a clear answer."¹⁰⁶ It authorizes its members to "establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appro-

⁹⁹ See Rio Declaration on Environment and Development, June 14, 1992, Principle 15, U.N. Doc. A/Conf.151/26 (1992), *reprinted in* 31 I.L.M. 874 (1992).

¹⁰⁰ *Id.* at 31 I.L.M. 874, 879.

¹⁰¹ *Id.*

¹⁰² See generally Stephen M. McCaffrey, *Biotechnology: Some Issues of General International Law*, 14 TRANSNAT'L LAW. 91, 97 (2000).

¹⁰³ *Id.*

¹⁰⁴ Christopher D. Stone, *Is There A Precautionary Principle?*, 31 ENV'L. L. REP. 10790 (Jul. 2001).

¹⁰⁵ See Press Release, The European Commission Health and Consumer Protection Directorate-General, Commission Adopts Communication on Precautionary Principle (Feb. 2, 2000), *available at* http://europa.eu.int/comm/dgs/health_consumer/library/press/press38_en.html [hereinafter The European Commission Press Release].

¹⁰⁶ *Id.*

priate.”¹⁰⁷ The Commission also urged members to use it “within a structured approach”¹⁰⁸ when conducting risk analysis, “which comprises three elements: risk assessment, risk management, and risk communication.”¹⁰⁹

The Commission, for example, has embraced the principle and used it when there was a concern about food safety. This was demonstrated when it banned the importation of U.S. hormone fed beef, fearing a safety threat to consumers.¹¹⁰ It also invoked the principle when it decided to regulate trade of genetically modified organisms. The Commission now requires labels notifying consumers of how that particular food was produced so they can make the decision for themselves if they want to consume genetically altered products.¹¹¹

In the United States, the State Department has taken the position that it will not adopt this principle. Instead, it has altered its original wording as laid out in Principle 15 and refers to it as a “precautionary approach.”¹¹² The United States government has also failed to follow the intent of the principle. For example, the United States Department of Agriculture (“USDA”) had issued a statement that its process for evaluating genetically engineered plants was still “evolving.”¹¹³ However, at the same time, it also approved the use of genetically altered vegetables,¹¹⁴ despite findings that the plants might not be safe. If the United States government had complied with the intent of the “Precautionary Principle,” it would have erred on the side of scientific uncertainty and banned the genetically altered vegetables until it was certain that they were safe for human consumption.

Using the “Precautionary Principle,” member nations clearly had the ability to stop the spread of *BSE* without fear of economic reprisals from other member nations when conducting

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ See Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters more than Money*, 76 N.Y.U. L. REV. 114, 183 (2001).

¹¹¹ See *id.* at 184.

¹¹² McCaffrey, *supra* note 102, at 97.

¹¹³ *Id.* at 98.

¹¹⁴ See *id.* (citing Carol Kaesuk Yoon, *Reassessing Ecological Risks of Genetically Altered Crops*, N.Y. TIMES, Nov. 3, 1999, at A1).

international trade, but so far have failed to do so. They even had the model to follow. The Swedish government since the early 1980s had already begun to realize the dangers of factory farming and overuse of pesticides and antibiotics. This realization led to the prohibition on the importation of animal feed made from recycled animal parts nearly a full ten years before other countries. In addition, it also began to regulate pesticide use. Yet, despite the necessary regulations and the model to do so, none of the other countries followed Sweden's example.

IV. SWEDEN, A CASE STUDY ON HOW WORKING WITHIN THE EXISTING FRAMEWORK CAN LEAD TO POSITIVE RESULTS

The economies and health practices around the world and in the United States are protected and monitored by multitudes of rules and regulations that are designed to protect all aspects of human concerns. They are also intended to guard against outbreaks, such as the *BSE* crisis, which is now being felt in every corner of the globe. But are those laws and regulations adequate on all levels to stem the spiraling *BSE* problem if applied in a creative fashion? And, could those existing laws and treaties be utilized to protect both the animal and vegetable based foods from another unintentional but horrific crisis of this magnitude?

When the ethical and sanitary considerations that led to the practice of allowing consumption of animal parts are viewed on a global level, there are no existing laws or treaties that specifically prohibit the practice. As the countries of the world have failed to institute a cohesive legal plan for dealing with the *BSE* crisis, many have also failed until recently to revamp their farming practices in an effort to prevent a catastrophe similar to what happened in Great Britain. Only one country, Sweden, took the initiative more than fifteen years ago and is now reaping the benefits of being able to truly claim to be *BSE* free. Sweden, because of ethical and health concerns, did not follow the laissez-faire pattern of the rest of the world, and thus issued a ban on the importation of the tainted animal feed. In addition, it went even further when it strengthened its animal welfare laws and banned the practice of animal cannibalism.

In Sweden, which takes the "Precautionary Principle" very seriously, the government used the principle to address envi-

ronmental concerns, but most specifically has applied this principle to areas concerning work and food.¹¹⁵ The result has been that other countries in the European Union are now looking at Sweden as the model for healthy food production. The Swedish government has adopted the premise that its citizens must be guaranteed safe food even if the scientific research is not one hundred percent certain. To achieve this objective, the government has decided "to err on the side of caution and apply the precautionary principle."¹¹⁶ "This means that they take steps to minimize or prevent the suspected risk."¹¹⁷ Actions taken have included banning meat containing growth hormones and the marketability of genetically modified products.¹¹⁸ "If there is insufficient evidence to prove that a GMO product does not represent a threat to the environment or to human or animal health, the product will not be approved."¹¹⁹ Each of the products is assessed on a case-by-case basis.¹²⁰

In Sweden, this philosophy is what prompted the government to take action when it became apparent that industrial farming practices were not producing the larger yield for less money as intended. Despite the rampant use of antibiotics, farm animals were sicker and the movement to bring about better treatment for those animals and the environment was born. Beginning in the 1970s when the Swedish parliament ordered that all plans for the construction on animal environments be done with the point of view to prohibit cruelty to animals¹²¹ and issued the 1974 Code of Recommendations For The Welfare Of Animals, citizens began to question the industrialized and mechanized methods of farming, which utilized chemicals and machines to maximize production and thus profits for the nation's farmers.¹²²

¹¹⁵ See MINISTRY OF AGRICULTURE, FOOD AND FISHERIES (Sweden), *SAFE, SUSTAINABLE ETHICAL – A HOLISTIC VIEW OF THE FOOD CHAIN* 6 (2000).

¹¹⁶ *Id.* at 5.

¹¹⁷ *Id.* at 6.

¹¹⁸ See *id.*

¹¹⁹ *Id.*

¹²⁰ See *id.*

¹²¹ See ANIMAL WELFARE INSTITUTE, *A Call for Ethical Consideration of Hundreds of Millions of Animals Abnormally Immobilized By Meat Industry, in FACTORY FARMING: THE EXPERIMENT THAT FAILED* 17, 17 (1987).

¹²² See generally Nicholas George, *Sweden's Caring Farmers are Rewarded with Public's Trust*, FIN. TIMES, Feb. 20, 2001.

During the 1960s and 1970s, Swedish farmers replaced the family farm with large-scale operations that promoted low building costs and minimum working hours.¹²³ They modeled their operations after industrialized factory farming techniques that were designed to maximize space by cramming as many animals as possible together and treating the process as an assembly line production to maximize output and profits. The result was sicker animals that were routinely being fed antibiotics. Statistics later showed that despite the use of anti-microbial feed additives, mortality rates were high and the animals were generally sicker.¹²⁴

Starting in 1981, the Federation of Swedish Farmers ("LRF") made a decision that antibiotics were not going to be used routinely, but instead only under the control of a veterinarian.¹²⁵ This was done to promote consumer confidence.¹²⁶ The movement away from factory farming and back to the family run farm with minimal use of drugs and pesticides gained momentum in the mid 1980s when ethical debates were running high and the medical community was warning about the overuse of antibiotics. Anti-microbial growth promoters were eventually banned in 1986.¹²⁷ With concern running high, several documentaries were produced, which showed the conditions in the farming industry.¹²⁸ "In the wake of the very tense debate we looked with new eyes upon food production,"¹²⁹ said Lars Hook, a member of the Swedish Farmers Association in a published interview.¹³⁰

It was also during this time that the first signs of the effects of the practice of same species animal cannibalism were beginning to show. The pet cat of an influential Swedish journalist became ill and began scratching his fur off. Its symptoms were similar to those found in sheep suffering from *Scrapie*.

¹²³ See MINISTRY OF AGRICULTURE, FOOD AND FISHERIES (Sweden), *Economic Effects on Swedish Farming*, in THE SWEDISH MODEL OF ANIMAL PRODUCTION 15, 15 (1998) [hereinafter *Economic Effects on Swedish Farming*].

¹²⁴ See *id.*

¹²⁵ See *id.*

¹²⁶ See *id.*

¹²⁷ See *id.*

¹²⁸ See Carol J. Williams, *Feline Puts Farmers in Catbird Seat*, L.A. TIMES, Mar. 16, 2001.

¹²⁹ *Ethical Practices may have Kept Sweden Clear*, FIN. TIMES, Nov. 30, 2000.

¹³⁰ See *id.*

When the pet food the cat was routinely fed was analyzed at the University of Uppsala, it was found to have contained "meat and bone meal additives" along with "filler from diseased livestock and even ground-up cat and dog carcasses . . ."¹³¹ The analysis also revealed that it was similar in composition to the contaminated animal feed coming from Europe.¹³² The discovery prompted the journalist, who was head of the consumer affairs section for Swedish radio, to prepare a documentary about the feed industry.¹³³

By 1986, the Swedish government, prompted by the outcry of its citizens, became one of the first countries in the world to ban the practice of animal cannibalism.¹³⁴ In 1985, the Swedish government adopted the "feedstuff law," which prohibited the practice of same species animal cannibalism, and it went into effect on January 1, 1986.¹³⁵ In 1987, the farmers voluntarily instituted a ban affecting animal bone and fish meal being fed to milk cows. In 1991, that voluntary ban became formalized and expanded in a trade agreement reached between Sweden's business organizations in the food and farm industries.¹³⁶ The agreement prohibited the use of bone and fish meal in feed given to cows and other ruminants.¹³⁷ The effect of this was to ban the practice of interspecies recycling, which allowed ground

¹³¹ Williams, *supra* note 128.

¹³² *See id.*

¹³³ *See id.*

¹³⁴ *See* George, *supra* note 122.

¹³⁵ *See* Animal Feed Act, SFS 1985:295. Section 3(a) states:

As animal feed one may not use

1. animals who ha[ve] died out of themselves,
2. animals who ha[ve] been put away, unless they have been slaughtered and afterwards examined by a veterinary surgeon,
3. parts of such animals that are mentioned in 1 or 2,
4. sickly changed parts of animals that have been slaughtered,
5. feedstuff or any other product that have been produced out of animals or parts of animals that are referred to in parts 1-4.

The first paragraph does not apply to fishes that are used as animal feed or feed that has been produced out of fishes or feed intended for reptiles or batrachians.

E-mail translating Sweden's Animal Feed Act from Rikard Backelin, Legal Advisor to the Swedish Ministry (2001), to Susanne Aberbach-Marolda, student, Pace University School of Law (Aug. 14, 2001, 03:37:34 AM EDT) (on file with author).

¹³⁶ *See* e-mail from Helena Sivard, English-speaking Spokesperson for the Swedish Agricultural Ministry to Susanne Aberbach-Marolda, student, Pace University School of Law (Aug. 8, 2001, 11:49:03 AM EDT) (on file with author).

¹³⁷ *See id.*

up animal parts to be used in feed given to a different species of animal. Further, in 1991, the feeding of all ruminants was also forbidden.¹³⁸ In 1988, the Swedish Board of Agriculture, which monitors animal health situations in other countries and is also responsible for the import and export decisions concerning Sweden's animals and animal based products, made a formal decision to ban the importation of live cattle, embryos, and semen from the United Kingdom.¹³⁹ In 2000, the Swedish parliament set the goal that twenty percent of the nation's farmed land should be organic by the year 2005.¹⁴⁰

In addition to the specific bans on animal cannibalism and other food additives such as anti-microbial additives,¹⁴¹ the Swedish government enacted The Animal Welfare Act¹⁴² and Animal Welfare Ordinance¹⁴³ in 1988, which are designed to protect the health and safety of the country's food supply. The acts also acknowledged that animals have an intrinsic value as well as a value to humans. The Animal Welfare Act specifically outlines acceptable standards for animal management such as the sizes of the stalls and the environment in which they live.¹⁴⁴ This was intended to "promote their health and permit natural behavior."¹⁴⁵ Some of the changes made were simple such as mandating that all of Sweden's 1.7 million heads of cattle¹⁴⁶ be allowed outside to graze. Separate bedding, feeding and voiding places for animals were now being required.¹⁴⁷ Other changes required more cost-intensive measures such as constructing new cages to replace the battery cages where poultry was housed.¹⁴⁸ Both the Act and Ordinance also required that tech-

¹³⁸ See *id.*

¹³⁹ See *Ethical Practices May Have Kept Sweden Clear*, *supra* note 129.

¹⁴⁰ See KRAV CERTIFICATION ORGANIZATION FOR ORGANIC PRODUCTION, KRAVE IN SMALL WORDS, KRAV IN ENGLISH (on file with author).

¹⁴¹ See *Economic Effects on Swedish Farming*, *supra* note 123, at 15.

¹⁴² See The Animal Welfare Act (Sweden), SFS 1988:534 (as last amended by SFS 1998:56, Feb. 19, 1998) [hereinafter The Animal Welfare Act].

¹⁴³ See The Animal Welfare Ordinance (Sweden), SFS 1988:539 (as last amended by SFS 1998:175, Apr. 16, 1998) [hereinafter The Animal Welfare Ordinance].

¹⁴⁴ See The Animal Welfare Act, *supra* note 142, § 3.

¹⁴⁵ *Id.* at § 4(I).

¹⁴⁶ See SWEDISH BOARD OF AGRICULTURE, *Animal Products*, in *FACTS ABOUT SWEDISH AGRICULTURE* 10, 10 (2000) [hereinafter *Animal Products*].

¹⁴⁷ See The Animal Welfare Ordinance, *supra* note 143, § 10.

¹⁴⁸ See *id.* § 9.

nology be "adapted to the animals, not in the reverse"¹⁴⁹ as was previously the practice. This was also the first time that the Swedish government included penalties of up to a year in jail if any of the provisions contained in the Animal Welfare Act were violated.¹⁵⁰ These violations could include failing to slaughter an animal as humanely as possible¹⁵¹ or failing to provide adequate medical care for a sick or injured animal.¹⁵² It is believed that the additional cost to the farmer for implementation of these ordinances is equalized by the healthfulness of the animals.¹⁵³ "The law affords protection to animals as individuals. Animals should be protected from unnecessary suffering and disease."¹⁵⁴

For animals used as a source of food or fur, or for research or competition, the law also states that they should be kept and cared for in an environment that is suitable for the animal, and in a way that promotes their health and allows them to behave in a natural way.¹⁵⁵

Animal welfare was not the only area that the citizens of Sweden wanted to improve. They also realized that the way the land is farmed and used was important to their health and welfare. While the use of pesticides and fertilizers over the past few decades has led to increased agriculture production, the problems associated with its use have also been great. Problems with nutrient leaching developed and farms had been abandoned.¹⁵⁶ As a result, the government developed an objective to promote a "rich and varied agricultural landscape and to minimize the environmental load caused by the sector."¹⁵⁷ Use of financial controls, passage of legislation, education, and training were some of the methods used by the Swedish govern-

¹⁴⁹ See Press Release, Swedish Ministry of Agriculture, New Animal Protection Laws (on file with the Swedish Embassy).

¹⁵⁰ See *id.*

¹⁵¹ See The Animal Welfare Act, *supra* note 142, § 13.

¹⁵² See *id.* § 9.

¹⁵³ See generally *Economic Effects on Swedish Farming*, *supra* note 123, at 15.

¹⁵⁴ MINISTRY OF AGRICULTURE, FOOD AND FISHERIES (Sweden), *Animal Legislation*, in HAPPY AND HEALTHY ANIMALS ETHICAL AND MORAL PERSPECTIVES ON KEEPING ANIMALS 1, 4 (2001) [hereinafter *Animal Legislation*].

¹⁵⁵ *Id.*

¹⁵⁶ See SWEDISH BOARD OF AGRICULTURE, *Environment*, in FACTS ABOUT SWEDISH AGRICULTURE 7, 7 (2000) [hereinafter *Environment*].

¹⁵⁷ *Id.*

ment to achieve these goals.¹⁵⁸ When it came to the use of pesticides, the effort was focused on “using products of less environmental hazard, both when handled and in the long run.”¹⁵⁹ It was also required that pesticides were to be applied only by people who had been educated in their use and proper spraying techniques.¹⁶⁰ In addition, the government passed a tax on the use of fertilizer nitrogen and pesticides in the hopes of achieving a reduction in use.¹⁶¹ The European Union also provided financial support to farmers who participated in preserving valuable land within the agricultural sector, farmed organically, and helped preserve environmentally sensitive areas.¹⁶²

It is this philosophy that today allows Swedes to walk into their local markets and buy food, clothes, and flowerpot soil with confidence that it has not been produced with pesticides. If it is not certified organic, then they know it was at least produced with the health and well being of the animal in mind. They can have an organic certified meal at any train station or enjoy one at the Parliament restaurant.¹⁶³ Even the milk sold at the local McDonalds is organic certified.¹⁶⁴ This was achieved through a cooperative effort of farmers, processors, trade, consumer and animal welfare advocates who formed an association called KRAV, which sets the standard for organic agriculture, certifies it, and monitors the production under the KRAV label.¹⁶⁵

However the change over to ethical and politically correct farming was not an easy sell initially for farmers who were used to maximizing profits through automation. “As a farmer, you really felt that you were being picked on, but after a while we realised [sic] we had to change,”¹⁶⁶ said Richard Cederholm, a third generation Swedish cattle and dairy farmer who operates

¹⁵⁸ *See id.*

¹⁵⁹ *Id.*

¹⁶⁰ *See id.*

¹⁶¹ *See Environment, supra* note 156, at 7.

¹⁶² *See id.*

¹⁶³ *See* KRAV CERTIFICATION ORGANIZATION FOR ORGANIC PRODUCTION, KRAV FACT SHEET (on file with author).

¹⁶⁴ *See id.*

¹⁶⁵ *See id.*

¹⁶⁶ George, *supra* note 122.

his farm just north of Stockholm.¹⁶⁷ The result has been the most stringent animal protection laws in the world, and a strict regulation of use of chemicals. "For most of us it was clear that if you say 'farmer' to people, they should not associate the word with pesticides, ground water problems and cruelty to animals,"¹⁶⁸ said Hans Jonsson, chairman of the Swedish Farmers Association.¹⁶⁹

It was also during this time that the Swedes decided that factory farming practices, which allowed farmers to maximize space by cramming as many animals as possible into small stalls, were also contrary to their ethical and moral wishes. Today, unlike many of their European counterparts, Swedish farmers are involved with the processing and marketing of their agricultural goods. This is achieved through their membership in cooperative societies and associations.¹⁷⁰ This ethical and moral approach to farming has ultimately resulted in both an environmentally friendly and ethically palatable farm community consisting of 80,000 farms without a single case of *BSE*.¹⁷¹ "We said we had to agree with the ban as consumer trust was more valuable,"¹⁷² said Lars Hook, a member of the Swedish Farmers Association during a published interview.¹⁷³ Because of their *BSE* free status, sales of Swedish beef were up three percent in 2001, while demand for English and German beef dropped by as much as eighty percent.¹⁷⁴ It is this exact philosophy that Margareta Winberg, the Swedish agricultural minister who is also president of the European Union Farm Council, is trying to espouse. "The *BSE* crisis has undermined consumer confidence in Europe – but it has also provided us with an opportunity to reform the Common Agriculture policy,"¹⁷⁵

¹⁶⁷ *See id.*

¹⁶⁸ *Id.*

¹⁶⁹ *See id.*

¹⁷⁰ *See* SWEDISH BOARD OF AGRICULTURE, *The Structure of Agriculture*, in *FACTS ABOUT SWEDISH AGRICULTURE* 4, 4 (2000) [hereinafter *The Structure of Agriculture*].

¹⁷¹ *See* Williams, *supra* note 128.

¹⁷² *Ethical Practices May Have Kept Sweden Clear*, *supra* note 129.

¹⁷³ *See id.*

¹⁷⁴ *See* Williams, *supra* note 128.

¹⁷⁵ Dan Bilefsky, *EU's Women Form Ministers Espouse 'Green' Agriculture*, *FIN. TIMES*, Mar. 7, 2001.

she said during an interview published in March of 2001.¹⁷⁶ “It will not be easy to change overnight something that was created in the 1950s – but now is not the time to wait and see; now is the time to do something before the situation gets even worse.”¹⁷⁷ The shift away from factory farming and the encouragement of a shift back to small-scale environmentally friendly farming are among her stated goals.¹⁷⁸ This shift will lead to a twenty percent reduction in the amount of chemicals, fertilizer and fuel, which is currently being used.¹⁷⁹ But even if she manages to convince the European farm community to make the switch back to environmentally friendly farming, the effects of the damage caused by decades of overzealous pesticide use and factory farming will take just as long to reverse. This is attributable in part to the long incubation period associated with *BSE*.

V. WHAT CAN BE DONE TO HALT THE SPREAD OF *BSE* ON AN INTERNATIONAL LEVEL?

While Sweden appears to have been able to escape the ravages of *BSE*, other countries such as France, Switzerland and Germany are now grappling with the eradication process. They have banned the import of animal feed made in the United Kingdom and have also taken steps to prohibit the use of animal parts in the animal feed produced within their own borders. For these countries, the future is still a big question mark as to how much of the population will ultimately develop *vCJD* and what percentage of the animal population is currently infected. As technology improves, increasing numbers of cattle are being diagnosed as *BSE* positive at younger ages. However, because there is a long incubation period for both animals and humans once they ingest *BSE* infected meat, the ultimate devastation could still be staggering.

There is still another group of countries that the countries' populations are at an even a higher risk of developing *BSE* because of the vast quantities of meat and bone meal imported

¹⁷⁶ See *id.*

¹⁷⁷ *Id.*

¹⁷⁸ See *id.*

¹⁷⁹ See Margareta Winberg, Minister of Agriculture, Food and Fisheries (Sweden), Speech at the European Parliament's Seminar on Quality Production: The Challenge of the Common Agriculture Policy (June 20, 2001).

during the 1980s, but are now only beginning to feel the effects. In June of 2001, the first case of *BSE* was reported in Eastern Europe after testing was done at a lab in Germany.¹⁸⁰ A six-year-old cow that lived on a farm seventy-five miles outside of Prague in the Czech Republic tested positive, prompting the Czech government to order the slaughter of an additional 139 animals that will also be tested.¹⁸¹ The discovery prompted the Czech government to budget \$3.9 million to begin testing all cattle thirty months of age or older.¹⁸² Others in Eastern Europe, Asia, and the Near East are considered at an even greater risk because of the sizable quantities of tainted feed, which they imported during the same time frame.

In response to this pending world crisis, the Food and Agriculture Organization of the United Nations ("FAO") issued a set of guidelines in 2001 urging members to take action to control the spread of *BSE*. Using a compilation of press reports, the FAO reports that most of the actions, which include banning importation of live cattle and meat products along with stricter sanitary controls, have been adopted by the member countries since it issued its guidelines in January of 2001.¹⁸³ While there are no international laws and few national laws prohibiting the practice of animal cannibalism or intra-species recycling, the European Union eventually reached an agreement that will prohibit the "recycling of fallen stock and condemned animal material in animal feed."¹⁸⁴ It also "introduces the prohibition of intra-species recycling (healthy pigs to pigs or healthy poultry to poultry)"¹⁸⁵ As the world's scientific and political leaders slowly begin to take corrective actions in an attempt to halt the progression and contain the damage that has been done to the world's cattle population, they have neglected to address the role that improper pesticide use may have played in the evolu-

¹⁸⁰ See Ian Elliott, *BSE, A Global Threat, Say Scientists*, FIN. TIMES, June 18, 2001.

¹⁸¹ See *id.*

¹⁸² See *id.*

¹⁸³ See Press Release, Food and Agriculture Organization of the United Nations, FAO: More than 30 Countries have Taken Action on BSE, But More Needs to be Done (June 21, 2001).

¹⁸⁴ Press Release, EU Food Law News, BSE - Common Position on Animal By-Products Regulation Agreed: MBM Ban Will be Prolonged (June 19, 2001), available at <http://www.foodlaw.rdg.ac.uk/news/eu-01-88.htm>.

¹⁸⁵ *Id.*

tion of *BSE* in cattle. Like the Phytosanitary laws that were already in place to address the animal cannibalism practice but not utilized, there are already legal mechanisms in place that are being applied.

When the regulations and use of pesticides are looked at on the international level, here too, the organophosphate insecticides such as Phosmet, which may have played a role in the development of *BSE* in England and other countries in Europe, are also not covered under international regulations.

During the final negotiations to adopt the Stockholm Convention on Persistent Organic Pollutants ("POPs"),¹⁸⁶ held in May of 2000, ninety governments signed a global treaty calling for the elimination of twelve of the most dangerous chemicals, including pesticides, industrial chemicals, and unintended by-products and contaminants.¹⁸⁷ The objective of the Convention and its participants was to "protect human health and the environment from persistent organic pollutants."¹⁸⁸ Phosmet and the other organophosphates in the same grouping are not among the initial twelve mentioned by the legally binding international treaty, of which the United States is a signatory.

Nonetheless, a provision contained in the treaty may allow for Phosmet and other organophosphates to be included in the future.¹⁸⁹ Contained in Annex D of the Convention, the members included provisions and criteria for adding additional POPs to the original twelve banned substances.¹⁹⁰ When evaluating additions, the Convention will look at its chemical structure, evidence of its half life in water, soil and sediment, evidence that the chemical poses a concern for health and human safety, and its long range environmental impact.¹⁹¹ It would appear based on these criteria that organophosphates

¹⁸⁶ See Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, U.N. Doc. UNEP/POPS/CONF/2 (2001), reprinted in 40 I.L.M. 432 (2001).

¹⁸⁷ The banned substances included: pesticides, Aldrin, Dieldrin, Endrin, DDT, Tozaphene, Mirex, Chlordane, Heptachlor as well as industrial chemical products, PCB's, Hexachlorobenzene and unintended produced by-products and contaminants: Dioxins and Furans. See Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, U.N. Doc. UNEP/POPS/CONF/2 (2001), reprinted in 40 I.L.M. 432, 551 (2001).

¹⁸⁸ *Id.* at 40 I.L.M. 432, 534.

¹⁸⁹ See *id.*

¹⁹⁰ See *id.* at 40 I.L.M. 432, 560.

¹⁹¹ See *id.*

such as Phosmet should be included. While it is too late to prevent the *BSE* crisis, it is not too late to halt its spread and limit future damage. While it is hypothesized that the improper use of Phosmet was at least partially responsible for the *BSE* crisis in the United Kingdom and in France, there is no way to ensure that dangerous chemical compounds will always be used in the proper dosage and application. The mistakes made by the British government when it ordered its farmers to apply Phosmet in an inappropriate way, leaves no doubt that Phosmet should be included under POPs as its ban would further the goal of the Convention, which is to protect human health and the environment.

Provisions for additional national legislation also lie within international law rules of the General Agreement on Tariffs and Trade ("GATT")¹⁹² originally signed in 1947 and amended in 1994. However, banning specific items from international trade is not an easy task. The burden of proof that there is good cause for the ban lies with the importing country. That country must justify its ban of the product under the exceptions listed in Article XX of the GATT.¹⁹³ Under the international trade exceptions listed in Article XX, which were adopted in 1952, countries have the right to ban specific imports provided that it is not "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries . . . or a disguised restriction on international trade."¹⁹⁴ Among the eight categories of exceptions is one that allows for a ban if it is "necessary to protect human, animal, or plant life or health" ¹⁹⁵ Included in the GATT is a separate agreement which more explicitly defines the exception for the health and preservation of plant and animal life. The Protocol on Phytosanitary Measures was adopted on April 15, 1994.¹⁹⁶ Under this provision, which is similar to the "Precautionary Principle," member

¹⁹² See General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b), 61 Stat A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 (1950).

¹⁹³ See McCaffrey, *supra* note 102, at 91, 99-100.

¹⁹⁴ General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b), 61 Stat A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, 262 (1950).

¹⁹⁵ *Id.*

¹⁹⁶ See Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, reprinted in 1994 WL 761483, at 90-120, available at <http://www.maf.govt.nz/biosecurity/sps/agreement/sps-agreement.pdf>.

countries can institute trade barriers even if scientific information is incomplete. Article 5, Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection, subsection 7 states:

In cases where relevant scientific evidence is insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain additional information necessary for a more objective assessment of risk and review the sanitary and phytosanitary accordingly within a reasonable period of time.¹⁹⁷

Using the procedures set out in Article 5, subsection 7, member nations could have used the data and scientific information available through a variety of sources to, at a minimum, to halt the practice of animal cannibalism and prohibit the sale and use of the tainted feed. As early as 1988, enough scientific evidence had been culled to prompt the English government to institute a ban throughout the United Kingdom on the use of ruminant protein feed within its own borders.¹⁹⁸ Despite the link being made between the feed and *BSE* appearing in cattle with enough scientific certainty to prompt the United Kingdom to ban its use within its own borders, it was still allowed to be exported and marketed around the world until 1996. If the connection was strong enough for the United Kingdom to take action, clearly other member countries could have used that same information and acted as well.

In addition to the internal actions taken by the United Kingdom, the member nations also had the ability to adopt sanitary or phytosanitary measures applied by other members. One of the member nations that applied these measures is Sweden. When one looks at the case study of Sweden over the past fifteen years, there is no reason why other member nations could not have followed Sweden's lead. For states that had not yet experienced a confirmed case of *BSE*, they could have applied the "Precautionary Principle" to avert the *BSE* crisis. If

¹⁹⁷ *Id.*

¹⁹⁸ See Brown, *supra* note 33, at 7.

they had, as the regulations clearly permit, perhaps the *BSE* crisis could have been at the very least contained, if not totally averted.

VI. THE UNITED STATES' RESPONSE TO THE BSE CRISIS

Unlike Sweden, the United States did not begin to take measures to protect its livestock and keep *BSE* out of the country until 1989, when the USDA issued an emergency order banning the importation of live ruminants such as cows and sheep.¹⁹⁹ The ban also included products made from ruminants from countries with known cases of *BSE*.²⁰⁰ In 1997, the USDA extended the ban to include animal-based imports from all European countries because of "inadequate animal-import restrictions or surveillance"²⁰¹ It was also in 1997 that the Food and Drug Administration ("FDA") implemented its "final rule," Title 21 Part 589.2000 of the Code of Federal Regulations, which prohibited "feeding mammalian protein to ruminant animals in most cases."²⁰² It was not until December 7, 2000, that the USDA took the final step to ban the importation of all rendered animal protein products.²⁰³ This was more than fifteen years after Sweden enacted its ban. Prior to the total ban, the United States government through the FDA issued regulations in 1997,²⁰⁴ regarding the practice of same species cannibalism within its own borders. This was almost a full ten years after the problem was identified in England and eleven years after Sweden issued its ban. The United States finally took action by passing these regulations in 1997. These regulations were issued a full ten years after animal cannibalism was first suspected as a cause for *BSE* in England and billions of pounds of United States cattle were "fed back to other cattle,"²⁰⁵ which

¹⁹⁹ See Press Release, USDA Press Office, Statement of Craig Reed, USDA Animal and Plant Health Inspection Service Administrator (Dec. 19, 2001) (on file with the USDA Press Office) [hereinafter Statement of Craig Reed].

²⁰⁰ See *id.*

²⁰¹ Roos, *supra* note 20.

²⁰² Press Release, FDA Center For Veterinary Medicine, Update on Ruminant Feed (BSE) Enforcement Activities (Jan. 10, 2001) (on file with author).

²⁰³ See Statement of Craig Reed, *supra* note 199.

²⁰⁴ See Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (2003).<http://>

²⁰⁵ SHELDON RAMPTON & JOHN STAUBER, MAD COW USA: COULD THE NIGHTMARE HAPPEN HERE? 215 (1997).

ultimately ended up on the dinner plates of Americans across the fifty states. But even then, the regulations passed did not address the problem completely. Under the rules promulgated on July 4, 1997,²⁰⁶ the feeding of ruminant animals such as sheep, cattle and goats back to other ruminants was banned. However, exceptions were made for the feeding of “blood products” and fat.²⁰⁷ In addition, non-ruminant animal protein such as feather meal, pig and fish protein, and chicken manure was also considered acceptable feed for cows.²⁰⁸ However, the regulations did not stop the turning of processed ruminant parts into feed for other animals, including chickens, fish and household pets, which in turn could be processed back into feed for the cattle, goats and sheep.²⁰⁹

It is on these regulations that the National Cattlemen’s Beef Association is relying to keep *BSE* out of the United States. The Association continually points out in its literature that there has not been a single confirmed case of *BSE* in this country, and if the rules are strictly followed, it is possible to prevent *BSE* from entering the United States.²¹⁰ The Association conducted a conference, which included members of the rendering industry, feed producers, meat processors and officials from Animal and Plant Health Inspection Service (“APHIS”), and the FDA. All of the participants discussed the need for “100-percent compliance with the U.S. ban on feeding ruminant protein from other ruminants.”²¹¹ Under the FDA rules, labels and invoices must be saved by anyone feeding ruminant animals containing recycled animals.²¹² Feed that does not have an invoice or label from the manufacturer or distributor does not comply with the law and the feed cannot be fed to cattle.²¹³ Canada and Mexico have similar regulations.²¹⁴ On

²⁰⁶ See Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (2003).

²⁰⁷ See Michael Pollan, *Power Steer*, N.Y. TIMES, March 31, 2002, § 6 (Magazine), at 44.

²⁰⁸ See *id.*

²⁰⁹ See generally RAMPTON & STAUBER, *supra* note 205, at 198.

²¹⁰ See NATIONAL CATTLEMEN’S BEEF ASSOCIATION, FMD & BSE WHAT EVERY PRODUCER NEEDS TO KNOW 6 (2001).

²¹¹ *Id.*

²¹² See *id.* at 7.

²¹³ See Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000(c)(1)(i) (2003).

February 3, 2001, the National Cattlemen's Association, along with members of the Canadian Cattlemen's Association and Conferacion Nacional Ganadera of Mexico signed a joint statement pledging to keep *BSE* out of North America.²¹⁵ The National Cattlemen's Beef Association is also taking additional safety measures by urging that feed producers have "written documentation from their feed suppliers that the premixes, supplements and complete feeds they buy are free of prohibited materials."²¹⁶ The Association also suggests that cattle feeders and producers should buy only from feed mills that they know do not handle "prohibited material."²¹⁷ While this is not required by the FDA, the Association believes that "this is a reasonable step to reduce the risk of prohibited materials being incorporated in premixes, supplements and complete feeds destined for cattle."²¹⁸

While the cattle industry may believe that the United States government regulations are stringent enough to protect the food supply, not everyone is convinced. Critics of the government's policy include the Consumers Union, which has issued statements based on its own independent research about the United States government's rules and regulations and the inadequacy for protecting the food supply. The Consumer Union reports that:

[t]he most effective way to be certain that the meat we are eating stays safe is to prohibit the feeding of animals that might be infected to animals people might eat. In our view, the FDA should stop practices that could spread TSEs in U.S. food animals. It could do that by banning the feeding of any mammal remains to food animals, as the British government has now done. And the sooner the better. Even after a comprehensive ban, it will take several years before all of the meat in the supermarket comes from animals that have never consumed animal protein.²¹⁹

A screening program for cows has been developed and administered by the APHIS of the USDA for cows that have exhib-

²¹⁴ See NATIONAL CATTLEMEN'S BEEF ASSOCIATION, *supra* note 210, at 6.

²¹⁵ *See id.*

²¹⁶ *Id.* at 7.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ Mercola, *supra* note 19.

ited signs of neurological difficulties before slaughter.²²⁰ Under this program, sixty-two percent of all tests administered by APHIS are studied by the National Veterinary Services Laboratory (“NVSL”).²²¹ The NVSL is responsible for examining random samples of animals presented for slaughter that show signs of neurological difficulties, downer cattle, and others where rabies and other domestic diseases have been eliminated.²²² Meanwhile, thirty-six percent are conducted by the state Veterinary Diagnostic Laboratories and these are primarily animals suspected of having either rabies or other domestic diseases.²²³ Between May 10, 1990, and July 18, 2001, the USDA reported that 13,916 cattle brains were tested.²²⁴ The brains tested came from the fifty states, along with specimens from Puerto Rico, the U.S. Virgin Islands and Canada.²²⁵ It reports that not a single case of *BSE* was found.²²⁶ It is this testing process that has drawn much of the criticism. During 2000, the government tested 2,300 cattle out of a population of thirty-five million slaughtered cattle.²²⁷ This number is expected to rise to five thousand per million.²²⁸ Consumers Union, along with various other organizations, has consistently called the testing procedures inadequate.²²⁹ In June 2001, Public Citizen and the Government Accountability Project (“GAP”) released a report that called the United States government’s testing program “haphazard.”²³⁰

²²⁰ See PETER LURIE, ET AL., PUBLIC CITIZEN’S HEALTH RESEARCH GROUP, USDA’S MAD COW DISEASE SURVEILLANCE PROGRAM: A COMPARISON OF STATE CATTLE-TESTING RATES (2001), available at http://dev.citizen.org/publications/print_release.cfm?ID=6783.

²²¹ See *id.*

²²² See *id.*

²²³ See *id.*

²²⁴ See ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEP’T OF AG., BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE [hereinafter BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE] (on file with author).

²²⁵ See *id.*

²²⁶ See *id.*

²²⁷ See Peter Lurie, et. al., *Study Finds Flaws in “Mad Cow” Detection Program* [hereinafter *Study Finds Flaws*], PUBLIC CITIZEN (July 19, 2001), at <http://www.citizen.org/pressroom/release.cfm?ID=670>.

²²⁸ See LURIE, *supra* note 220.

²²⁹ See generally *id.*

²³⁰ *Id.*

According to the GAP report, testing of cattle brains has increased from one hundred per year submitted to the NVSL between 1990 and 1992 to an estimated 2,300 expected in 2000, but there is no coherent method of selection and as a result, suspect cattle are being missed.²³¹ Compounding the problem is that the USDA has no definition of what constitutes a “downer” animal and, as a result, veterinarians in slaughterhouses must use subjective judgments when determining what animals may be suspect.²³² For smaller slaughterhouses, a veterinarian is not always present, and thus suspect animals can be missed.²³³ APHIS has 250 veterinarians who are specially trained to diagnose *BSE* symptoms.²³⁴ These veterinarians are regulated at both the federal and state level, and are specially trained to diagnose foreign animal diseases such as *BSE*. They are also responsible for inspecting the nation’s slaughterhouses. As of July 18, 2001, the USDA has inspected 13,916 “downer” cattle since 1993.²³⁵

Another area of concern is that the testing rates between the states with the highest cattle populations and the lowest can vary as much as two thousand percent.²³⁶ Using data collected from the USDA from 1997 to 2000, researchers and doctors from GAP found that in the State of Texas 4,034 brains per million cattle slaughtered were tested compared to seven per one million in Minnesota during the same three year period.²³⁷ The researchers also concluded that only three states — New York, Pennsylvania, and California are testing cattle at rates higher than the USDA proposed rate of 5,000 tested for every 35.6 million cattle slaughtered or a rate of 140 tests for every million cattle slaughtered.²³⁸ The results garnered by the Public Citizen report mirror findings of similar research conducted by two journalists and authors of the book *MAD COW USA*,²³⁹ which also found that the percentage of cattle tested is not the

²³¹ *See id.*

²³² *See id.*

²³³ *See generally id.*

²³⁴ *See* BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE, *supra* note 224.

²³⁵ *See id.*

²³⁶ *See* LURIE, *supra* note 220.

²³⁷ *See id.*

²³⁸ *See id.*

²³⁹ *See* RAMPTON & STAUBER, *supra* note 205.

only problem but questioned the selection method for brains to be tested. They point to a testing procedure where cattle in states, which produce a lot of dairy and beef, are not tested at all and there is a higher percentage tested in states in which beef and dairy are not the primary industry.²⁴⁰

By 1997, the USDA had tested 5,621 brains of cattle without finding a trace of *BSE*.²⁴¹ However, when a breakdown is conducted on a state-by-state basis as to where the cattle brains were taken from, it demonstrates just how flawed the testing procedures are. Of the 5,621 brains tested, 1,406, or twenty-five percent had come from Kentucky, a state not known for dairy or beef production.²⁴² Of the remaining seventy-five percent, only 226 came from Wisconsin, a state heavily involved in dairy production and where mink encephalopathy had been found.²⁴³ In Minnesota and Idaho, where mink encephalopathy has also been recorded, only twenty-two brains were tested in Minnesota and forty-seven in Idaho.²⁴⁴ In Florida, which is considered an important beef and dairy state, only one brain had been tested.²⁴⁵

In its May 17, 2001, issue, *THE NEW ENGLAND JOURNAL OF MEDICINE*²⁴⁶ reported that yearly there are approximately 150,000 U.S. "downer" cows that exhibited neurological abnormalities before being sent off to slaughter.²⁴⁷ Of those, only twelve thousand during the ten-year period since testing began have been examined.²⁴⁸ None have come back positive.²⁴⁹

Screening should be extended to include a much larger proportion of the more than 150,000 downer cattle in the United States each year, including cattle that die before they are slaughtered. Some asymptomatic animals older than four years of age should also be tested, since prions accumulate over time in the infected host and therefore are easier to detect in older animals.²⁵⁰

²⁴⁰ See *id.* at 210.

²⁴¹ See *id.*

²⁴² See *id.*

²⁴³ See *id.*

²⁴⁴ See *id.*

²⁴⁵ See RAMPTON & STAUBER, *supra* note 205, at 210.

²⁴⁶ See Roos, *supra* note 20.

²⁴⁷ See *id.*

²⁴⁸ See *id.*

²⁴⁹ See *id.*

²⁵⁰ *Id.*

Some of America's leading experts on *BSE* have called for the United States government to scrap its testing procedures altogether. Currently the method used by the United States government is the Western Blot Test,²⁵¹ which requires "removing a portion of the brain . . . staining it with dye and examining how the dye has interacted with the tissue . . ." ²⁵² Because it takes three to five years for mutant prions to begin multiplying after the host body has been infected, Will Hueston, D.V.M., a professor at the Virginia-Maryland School of Veterinary Medicine and an acknowledged expert on *BSE*, claims that the governments testing procedures are valueless.²⁵³ "Such cattle are almost universally marketed before the age of three years, so testing them for development of *BSE* would be a complete and total waste of time,"²⁵⁴ Hueston told 150 food industry managers and scientific personnel who had gathered in Washington, D.C., in April for a conference entitled: "Is America at Risk for *BSE*?"²⁵⁵

Part of the problem lies in the fact that "unlike conventional disease causing agents [such as] bacteria, viruses and parasites, *TSE* agent can not be routinely isolated or cultured."²⁵⁶ As a result, "there is no specific detectable cellular or serological reaction"²⁵⁷ when a living animal is tested.²⁵⁸ Thus, diagnosis of *BSE* relies on the changes observed in the central nervous system of dead animals.²⁵⁹ In Europe, however, three separate "rapid tests" have been approved for usage by the European Commission.²⁶⁰ They include the Biorad by CEA,

²⁵¹ See generally Jeffrey A. Nelson, *USDA Mad Cow Strategy: Don't Look, Don't Find*, VEGSOURCE.COM, at http://www.vegsource.com/articles/bse_usda.htm (last visited Feb. 18, 2002).

²⁵² *Id.*

²⁵³ See Murphy, *supra* note 22.

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ WORLD HEALTH ORGANIZATION, PROCEEDINGS JOINT WHO/FAO/OIE TECHNICAL CONSULTATION ON BSE: PUBLIC HEALTH, ANIMAL HEALTH AND TRADE (2001), available at <http://www.who.int/emc-documents/tse/docs/Whocdscsraph2001.8p.pdf>.

²⁵⁷ *Id.*

²⁵⁸ See *id.*

²⁵⁹ See *id.*

²⁶⁰ See THE EUROPEAN COMMISSION, FREQUENTLY ASKED QUESTIONS ABOUT BSE TESTS (2000), available at http://europa.eu.int/comm/food/fs/bse/bse21_en.html.

Prionic Check by Prionics AG, and the Enfer Test System by Enfer Technology Ltd.²⁶¹ Unlike the Western Blot, where cultures need to be grown, these rapid tests allow for brain and spinal cord samples to be taken upon slaughter to a laboratory and tested immediately for the presence of PrPres., a misshaped prion protein, which is considered a marker for *BSE*.²⁶² The tests have also been successful at detecting the *BSE* infection in animals that were considered to be asymptomatic at the time of slaughter and are being credited with discovering the disease in Germany, which had not previously had a *BSE* positive animal.²⁶³

Another aspect of the United States government's testing policy that militates against making it more effective are the economic consequences that the discovery of *BSE* would trigger. At best, if the small percentages and uneven testing patterns yielded a positive result, the damage to the United States economy, particularly the biomedical industry could be devastating and the economic impact would be felt immediately. Currently in the United States, of the 650 biomedical products made from cattle and used by humans, 380 are derived from proteins such as insulin.²⁶⁴ If *BSE* was ever found, these products could no longer be used and the export trade of cattle products would come to a halt.²⁶⁵ In addition to these impacts, there is the multi billion-dollar beef industry that would be hurt if people stopped eating meat.

Effects on the medical industry are already starting to be felt. Despite the lack of a single confirmed case of *BSE* in the United States, the federal government now enforces a blood donor policy, which prohibits anyone who has lived in the United Kingdom for a cumulative period of more than six months between the years 1980 through 1996 from giving blood.²⁶⁶ This policy was instituted in response to studies that suggest that prions can be present in lymphoid tissue of *vCJD* patients and the blood and bone marrow of animals known to be infected with *BSE*, and therefore could be communicated as *vCJD*

²⁶¹ See *id.*

²⁶² See *id.*

²⁶³ See *id.*

²⁶⁴ See RAMPTON & STAUBER, *supra* note 205, at 210.

²⁶⁵ See *id.*

²⁶⁶ See Brown, *supra* note 33, at 12.

through blood transfusions. The result of the policy has been a "chronically low blood supply"²⁶⁷ because more than five percent of all potential donors are turned away because of this policy.²⁶⁸ Several other countries, including Canada, Australia, New Zealand, Switzerland, Japan, and Germany have instituted policies similar to the United States regarding blood donations.²⁶⁹ But even here, the United States' policy does not go far enough. In its May 17, 2001, issue of the *NEW ENGLAND JOURNAL OF MEDICINE*,²⁷⁰ Dr. Raymond P. Roos of the University of Chicago, Pritzker School of Medicine called for the United States to extend its blood ban policy even further.

Extending this policy to people who have lived in other European countries is prudent, given the increase numbers of cases of *BSE*. Such exclusions should also be considered for donors of other tissues, especially dura mater and corneas collected after death. These tissues are easily contaminated with central nervous system tissue, which could cause iatrogenic Creutzfeldt-Jakob disease if the donor had unrecognized disease.²⁷¹

Biomedical products made from blood such as intravenous immune globulin would be the first affected and could be the cause of a wide spread infection.²⁷² In the United Kingdom, all plasma is being imported and all blood from UK donors is now filtered to eliminate leukocytes, which are "the most likely carriers of infectivity in blood . . ."²⁷³ This procedure was instituted after several people who had later developed *vCJD* had donated blood.²⁷⁴

Compounding the problems is the method of testing currently utilized in the United States. The United States uses the Western Blot Test to detect *BSE* in cattle. A portion of the brain must be removed, a culture is grown and dyed, and then

²⁶⁷ *Mad Cow Victim: US Blood Supply*, WHAT YOU NEED TO KNOW ABOUT, at <http://usgovinfo.about.com/library/weekly/aa020701a.htm?terms=mad+Cow+Victim%3A+US+Blood+Supply> (last visited Mar. 28, 2003).

²⁶⁸ See *id.*

²⁶⁹ See Brown, *supra* note 33, at 12.

²⁷⁰ See Roos, *supra* note 20.

²⁷¹ *Id.*

²⁷² See *id.*

²⁷³ Brown, *supra* note 33, at 12.

²⁷⁴ See generally *id.*

the results examined under a microscope.²⁷⁵ It is this method that was used widely throughout Europe in countries such as Germany that were declaring themselves *BSE* free. However, when these countries started to use a more sensitive testing method that could detect the prions much earlier, they too were testing positive for *BSE*.²⁷⁶ These tests are administered in the slaughterhouses before the carcass enters the food chain. In Switzerland, when the switch was made from Western Blot, four times as many *BSE* infected cows were discovered.²⁷⁷

In response to the testing discrepancies, the European Union formed a commission to study the testing methodology. The result was a joint effort which resulted in a rapid response test that sells for \$16 per cow, that quickly became in high demand.²⁷⁸

As a result of the policy decisions regarding the uneven way the United States administers its testing process for *BSE*, coupled with the gaps in the laws that still allow for inter-species recycling, the United States food supply is still at risk for *TSE* contamination. These gaps were recently demonstrated in two separate but highly publicized incidents, which demonstrated just how vulnerable our food supply is to potential contamination.

In July 2000, several sheep that were part of a 233-member flock of rare sheep were quarantined after testing positive for *TSE*.²⁷⁹ The sheep, which were imported from Belgium and the Netherlands in 1996, were removed from a private farm in Vermont March 2001. They were slaughtered and then studied.²⁸⁰ It is believed that the sheep contracted the *TSE* from "feed contaminated with bovine spongiform encephalopathy."²⁸¹ Because it was not known whether the sheep had *Scrapie*, which so far has not been known to be harmful to humans, or *BSE*, the United States government took extraordinary measures to re-

²⁷⁵ See Nelson, *supra* note 251.

²⁷⁶ See *id.*

²⁷⁷ See *id.*

²⁷⁸ See *id.*

²⁷⁹ See Press Release, United States Department of Agriculture, USDA Removes Quarantined Sheep from Vermont Farm (Mar. 21, 2001), available at <http://www.usda.gov/news/releases/2001/03/0051.htm>.

²⁸⁰ See *id.*

²⁸¹ *Id.*

move and destroy the sheep. The USDA sought federal court orders, and the flocks' owners claimed their records indicated that the prized rare sheep never consumed the tainted feed.²⁸² The owners appealed and the Second Circuit²⁸³ denied a stay thus allowing the sheep to be taken and destroyed.²⁸⁴

The concern expressed by United States' officials was that, if this were truly *BSE* in the sheep and not *Scrapie*, the disease would be much harder to contain because of the way it presents itself in different species.²⁸⁵ In cows, it is primarily limited to the spinal cord and brain while in sheep, the prions are found throughout the body.²⁸⁶ This finding was based on a 1996 study, which hypothesized that when dealing with sheep, it could be spread through routine contact among animals.²⁸⁷ This was unlike cows, where transmission was limited to consuming tainted feed.²⁸⁸ Because testing methods currently used in the United States are so slow, it will not be until the latter half 2003, that it will be known for sure whether the slaughtered sheep had *Scrapie* or *BSE*.²⁸⁹

Vulnerabilities to the health of the United States population and to the economy were further exposed in January 2001, when it was learned that twelve hundred head of cattle in Texas had consumed feed tainted with recycled cattle remains.²⁹⁰ This was a direct violation of United States law, which banned the practice in 1997.²⁹¹ The manufacturer of the feed, Purina Mills, reported to the FDA that each of the cattle consumed approximately one-quarter ounce of the tainted feed.²⁹² To eradicate the problem, Purina purchased all 1,222 head of cattle,

²⁸² See David Stipp, *Scared of Mad Cow Now?*, FORTUNE MAGAZINE, Apr. 19, 2001, <http://www.fortune.com/fortune/articles/0,15114,370316,00.html>.

²⁸³ See *Freeman v. United States Dep't of Agric.*, 2001 WL 409504 (2nd Cir. 2001).

²⁸⁴ See *id.*

²⁸⁵ See Stipp, *supra* note 282.

²⁸⁶ See *id.*

²⁸⁷ See *id.*

²⁸⁸ See generally *id.*

²⁸⁹ See generally *id.*

²⁹⁰ See Lynna Goch, *Fears of Mad Cow Disease Boost Sales of Product-Recall Policies*, 101 *BEST'S REV.* 83 (2001).

²⁹¹ See *id.*

²⁹² See *id.*

which consumed the tainted meat and “voluntarily removed them from the human food chain.”²⁹³

This was not the only instance of a possible threat to the United States population. In New York City, a popular polish fruit chew type candy was pulled from supermarket shelves when the Polish government issued a decree that prohibited the sale of its candies.²⁹⁴ The candy was made from a gelatin that could have come from cows infected with *BSE*.²⁹⁵

Of the approximately 9,500 feed manufacturers in the United States, fewer than 3,000 have been inspected²⁹⁶ to insure that the rules laid out by the United States government to prevent an outbreak of *BSE* are being followed. It is these types of incidents that have raised the concerns of animal activists groups such as the Food Animal Concerns Trust (“FACT”).²⁹⁷ The Chicago-based group is pushing for feed companies and meat processors to be more diligent in the way they process animal feed. They claim that co-mingling exists at plants, which produce feed for both ruminants and non-ruminants and that, “some feed companies are not properly cleaning their equipment.”²⁹⁸ They are also calling for better enforcement of rules that prohibit commingling of the feeds used for different types of farm animals.²⁹⁹ The group, which focuses on promoting more humane ways of raising livestock, also wants to see a prohibition against blood and blood products from entering the food chain because the role this body fluid plays in the transmission of *BSE* is still unclear.³⁰⁰

In addition to adopting the total ban on animal cannibalism advocated by Consumers Union and other animal welfare groups, the United States government through Section 101 of

²⁹³ News Release, Texas Cattle Feeders Association, *BSE and the U.S. Beef Industry A Situation Analysis* (Feb. 2, 2001), available at <http://www.tcfa.org/News%20Releases/analysis.html>.

²⁹⁴ See Goch, *supra* note 290.

²⁹⁵ See *id.*

²⁹⁶ See Deborah Silver, *Execs in Wait-and-See Mode on Mad Cow Issue*, 111 RESTAURANTS & INSTITUTIONS 136 (2001), available at http://www.findarticles.com/cf_0/m3191/11_111/74410805/p1/article.jhtml?term=%22Deborah+Silver%22.

²⁹⁷ See Willie Vogt, *Activist Group Issues Call For Tougher Fight Against Mad Cow*, FARM PROGRESS, Apr. 18, 2001.

²⁹⁸ *Id.*

²⁹⁹ See *id.*

³⁰⁰ See *id.*

the National Environmental Policy Act (“NEPA”), which was enacted in 1969, has the congressional mandate to “use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare.”³⁰¹ This mandate further states that it is the “policy of the Federal Government in cooperation with state and local governments and other concerned public and private organizations,”³⁰² to carry out this goal. Yet, the government has not yet used NEPA on *BSE* testing or the use of Phosmet despite warnings from its own scientists.³⁰³ Phosmet is suspected of playing a role in Great Britain’s *BSE* outbreak and has been experiencing problems in this country. Under Section 101(b) of the NEPA, the policy considerations under which the Act should be applied are laid out. It states that there is a:

continuing responsibility of the Federal Government to use all practical means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs and resources to the end that the nation may . . . attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences³⁰⁴

Clearly, based on the findings of EPA scientists on the health risks associated with Phosmet, the ability to act under Section 101 of the NEPA was present, but no action has yet been taken.

All federal agencies are required to implement the policies and procedures set forth in the NEPA. This mandate is laid out in Part 1500 of the Code of Federal Regulations.³⁰⁵ Under Sec-

³⁰¹ NEPA § 101(a), 42 U.S.C. 4331(a) (1995).

³⁰² *Id.*

³⁰³ See Memorandum from Sid Abel, Environmental Scientist et. al, Environmental Risk Branch IV/Environmental Fate and Effects Division of the EPA, to Linda Werrell, Chemical Review Manager, Special Review and Re-registration Division of the EPA (Apr. 24, 1998) (on file with Environmental Protection Agency).

³⁰⁴ NEPA § 101(b), 42 U.S.C. 4331(b) (1995).

³⁰⁵ See 40 C.F.R. § 1500.1 (2002), which lays out the purpose, policy, mandate, reducing paperwork, reducing delay and agency authority when administering NEPA:

(c) Ultimately, of course, it is not better documents but better decisions that count. NEPA’s purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action. The NEPA process is intended to help public officials make decisions that are based on understanding of the environmental consequences, and take actions that protect, restore,

tion 102(2)(C) of the NEPA, federal agencies are required to file an environmental impact statement when a new “recommendation or report on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. . . .”³⁰⁶ It also mandates that a detailed statement be prepared concerning the

- (i) environmental impact of the proposed action,
- (ii) and adverse environmental effects which cannot be avoided should the proposal be implemented,
- (iii) alternatives to the proposed action,
- (iv) the relationship between local and short-term uses of man’s environment and the maintenance and the enhancement of long term productivity, and
- (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.³⁰⁷

Under Section 102 and Title 40 CFR part 1500, the USDA should have been required to file the impact statements when it promulgated its rules concerning testing of cattle and issued its policies concerning animal cannibalism and inter-species recycling which is still allowed. Clearly these issues significantly affect the quality of the human environment and, at a minimum, the USDA should be required to file the impact statement to examine the effects its policies concerning these issues have on the population and the food supply as whole. Additionally, the EPA also should have been required to file an impact statement concerning its adverse findings with Phosmet.

According to Environmental Protection Agency (“EPA”) documents, Phosmet, which is used as a commercial fertilizer on fruits, vegetables, and on livestock to kill insects, has been classified as a possible human carcinogen as recently as 1994 and those that the toxicology data is still suggestive of carcinogenicity.³⁰⁸ Yet, the chemical remains are available for com-

and end enhance the environment. These regulations provide the direction to achieve this purpose. *Id.*

³⁰⁶ NEPA § 102(2)(C), 42 U.S.C. § 4332(2)(C) (1995).

³⁰⁷ NEPA § 102(2)(C), 42 U.S.C. § 4332 (2)(C)(i-v) (1995).

³⁰⁸ See Memorandum from Christina Swartz, Chemist, Reregistration Branch of the EPA, to Linda Werrell, Special Review and Reregistration Division, EPA 3 (Sept. 8, 1999) (on file with author) [hereinafter Memorandum from Christina Swartz].

mercial use. On the packaging label, there is a warning that states: "Precautionary Statements – Hazard to Humans and Domestic Animals."³⁰⁹ It also warns that, like many other chemicals, it can be fatal if swallowed or inhaled and the dust left behind from its application should not be inhaled. Other warnings include contact with the eyes and skin should be avoided. There are also warnings that it can be "rapidly absorbed through the skin"³¹⁰ and "do not get on skin, in eyes or on clothing."³¹¹ There are also environmental warnings, stating that the pesticide is "toxic to fish and wildlife" and should not be applied directly "to water or areas where surface water is present or to inter-tidal areas below the mean high water mark."³¹²

With Phosmet also being used as an insecticide, it is commonly being applied to many of the fruit and vegetable staples that we consume daily. Apples and peaches are among the most common usages for the pesticide as well as beans, nuts, peas, tomatoes, and lettuce.³¹³ As is the practice in the United Kingdom, Phosmet is also applied dermally to livestock.³¹⁴ Under the chemical label guidelines, there are specific ratios for dilution, depending upon which crop it is being applied to, and time frames for application until the time of harvest must also be strictly followed.³¹⁵ If not followed correctly or under adverse weather conditions, the label warns that crops can become damaged. Between 1988 and 1997, 402,000 acres were treated with approximately one million pounds of Phosmet, with most of the usage occurring in California, Louisiana, Washington, and Indiana.³¹⁶

Even with these warnings, EPA documents show that surveys and reportable incidents concerning Phosmet "show a widespread pattern of misuse."³¹⁷ Any misuse of the chemical

³⁰⁹ PHOSTEMIC-D* LABEL, *supra* note 73.

³¹⁰ *Id.*

³¹¹ *Id.*

³¹² *Id.*

³¹³ See Memorandum from Christina Swartz, *supra* note 308, at attachment 1.

³¹⁴ See *id.*

³¹⁵ See PHOSTEMIC-D* LABEL, *supra* note 73.

³¹⁶ See Memorandum from Christina Swartz, *supra* note 308, at attachment 1.

³¹⁷ Memorandum from Jerome Blondell, Ph.D, Health Statistician, Health Effects Division, EPA, to Christina Swartz, Chemist, Office of Prevention, Pesticides and Toxic Substances Division, EPA 14 (Dec. 7, 1998) (on file with author) [hereinafter Memorandum from Jerome Blondell].

is a violation of the Federal Insecticide Fungicide Rodent Control Act ("FIFRA") 136j, Section (a)(2)(G), which states that it is unlawful to "use any registered pesticide in a manner inconsistent with its labeling."³¹⁸ According to the EPA's records, there were 2,548 cases in the Poison Control Center database involving Phosmet misuse between the years 1984 and 1997.³¹⁹ Of those, 136 of the cases involved occupational exposure.³²⁰ Included in those reportable incidents was a subcategory involving 155 pet owners and 12 veterinarian groomers who reported being exposed between 1994 and 1995 when they were using a product containing Phosmet to control fleas.³²¹ Their exposure was due to misuse that included applying the chemical without gloves, not using the proper dilution, direct contact with the dog before the chemical dried, spills, and not using it in a properly ventilated area. Their primary symptoms included: respiratory problems; flu like symptoms; skin irritation; disorientation and headaches.³²²

In 1994, the EPA took administrative enforcement action against E.I. Dupont De Nemours and Co.,³²³ the manufacturer of Phosmet, when it discovered that 379 shipments of the chemical were mislabeled, and thus violated Sections 2(q)(1)(F) and (G) of FIFRA.³²⁴ The violation involved a failure to put a warning on the label that protective eyewear must be worn by "early-entry agricultural workers who enter agricultural fields within a short time after pesticide application."³²⁵ A label under

³¹⁸ FIRFA 7 U.S.C.A. § 136j.(a)(2)(G) (West 2003).

³¹⁹ See Memorandum from Jerome Blondell, *supra* note 317, at 4.

³²⁰ See *id.*

³²¹ See *id.* at 3.

³²² See *id.*

³²³ See *In re E.I. du Pont de Nemours and Co*, EPA App. Bd., FIRFA Appeal No. 98-2 (Apr. 3, 2000) [hereinafter FIRFA Appeal].

³²⁴ FIRFA 7 U.S.C. § 136(q)(1) states:

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136(a)(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136(a)(d) of this title, is adequate to protect the health and the environment

³²⁵ FIRFA Appeal, *supra* note 316, at 4.

FIFRA is considered misbranded if "its labeling does not contain necessary warnings or caution statements or directions for use, that comply with other requirements of FIFRA and are 'adequate to protect the health and the environment.'"³²⁶ Du Pont admitted to the mislabeled shipments; however, it appealed on the basis that the EPA had approved the label in November of 1993, and therefore they were not liable.³²⁷ The three judge panel ruled that if Du Pont's argument is accepted it would mean that "the EPA granted Du Pont the right to use any misbranded labeling, including false and misleading labeling, so as long as the products bearing the labeling were released for shipment prior to Jan. 1, 1994. That result is absurd and was not intended."³²⁸ The case was remanded for further proceedings and no decision has been published.³²⁹

Under the federal government's regulatory scheme, all pesticides are required to be registered with the EPA as called for under FIFRA. Under this Act, no chemical can be distributed or sold in any of the fifty states without first being tested and registered.³³⁰ It is then classified either for general use or restricted use³³¹ and should be clearly labeled as to any use restrictions.³³² Once approved, it is possible to cancel or change a chemical's classification if "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."³³³

Children, especially those under the age of six, appear to be at the most risk of developing problems from improper Phosmet use.³³⁴ It would seem that clearly the EPA has the means and motive to ban or highly regulate the use of Phosmet, but has instead chosen to ignore its own warnings.

When it comes to the application of the pesticides, the federal government does not regulate applicators or license them.

³²⁶ *Id.* at 8 (*quoting in part* FIRFA § 2(q)(1)(F)-(G), 7 U.S.C. § 136(q)(1)(F)-(G)).

³²⁷ *See id.* at 29.

³²⁸ *Id.* at 43 n.35.

³²⁹ In an unpublished decision, the Environmental Appeals Board issued an Order Denying Motion for Reconsideration of Decision and Remand Order. In re E.I. DuPont DeNemours & Co., EPA App. Bd., Docket No. FIFRA-95-H02.

³³⁰ *See* FIRFA 7 U.S.C.A. § 136a.(a) (West 2003).

³³¹ *See* FIRFA 7 U.S.C.A. § 136a.(d)(1) (West 2003).

³³² *See generally* FIRFA 7 U.S.C.A. § 136a.(d)(1)(A) (West 2003).

³³³ FIRFA 7 U.S.C.A. § 136a.(c)(5)(D)(West 2003).

³³⁴ *See* Memorandum from Christina Swartz, *supra* note 308, at 3.

Instead, it is up to the states to decide what standards to require for pesticide applicators. In New York, for example, any person who applies pesticides in either the commercial or residential setting or engages in the sale of a restricted use pesticide must first take a test and then be certified by the state.³³⁵

The process includes first making an application to the state, and then taking a test intended to demonstrate his knowledge and experience in dealing with proper use and application of pesticides.³³⁶ Once certified, the applicant is required to re-certify every five years by either participating in a training course, utilizing a workbook, or by taking an examination.³³⁷ In addition, current law also limits the sale of a restricted use pesticide to a "certified person" who holds a "valid identification card."³³⁸

Still, even with these restrictions and regulations, there is still the possibility for error. New York State law does not apply to private use of general use pesticide³³⁹ such as Phosmet when applied to a dog to prevent fleas or on the family farm to control aphids. If the state legislature were so inclined, it could strengthen its regulations by limiting the allowable uses for a chemical like Phosmet where there is a question concerning its safety, prohibiting its use on cattle, or taking an even larger step and ban its use completely.

VII. WHILE THERE ARE NO REPORTED CASES OF *BSE* IN THE UNITED STATES, VARIOUS FORMS OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (*TSEs*) HAVE BEEN DOCUMENTED

Official statistics released by the USDA indicate that the United States is still declaring itself a *BSE* free country because no cattle has ever tested positive for the brain wasting disease. Taken at face value, that statement is still correct. However, scientists around the country have been warning that the disease is already here in various forms affecting numerous animal species, some of which are ending up on the dinner plates of

³³⁵ See N.Y. ENVTL CONSERV. LAW § 33-0905(1) (McKinney 2003).

³³⁶ See *id.* § 33-0905(3)(a-b).

³³⁷ See *id.* § 33-0905(3)(b).

³³⁸ *Id.* § 33-0905(3)(c).

³³⁹ See *id.* § 33-0905(2)(b).

Americans. As a result, they claim that *vCJD* is already here and it is just a matter of time before the general population becomes more greatly at risk.

Scrapie has been found within the United States borders since the 1940s, but because it is believed not to cross species barriers or be a health threat to humans, its existence has largely been deemed not to be a health threat. However, for decades, animals such as pigs, minks, swine, deer and elk have been showing symptoms of a central nervous system disorder mimicking those found in cattle known to be inflicted with *BSE*,³⁴⁰ and the USDA has ignored those warning signs much to the detriment of the meat eating population. Pigs and chickens, like cattle, were routinely fed rendered animal protein as part of their regular diet. This practice had been going on for decades, even longer than the practice of feeding ruminants back to ruminants, which has been blamed for the crisis in the United Kingdom.³⁴¹

In 1979, Veterinarian Matsou Doi conducted a study for the USDA involving 106 pigs in an upstate New York packing plant that were exhibited symptoms similar to those found in sheep with *Scrapie* or transmissible mink encephalopathy, a form of *TSE* previously known to strike minks.³⁴² Many of the pigs first appeared as "downer" animals and were hyper-reactive to outside stimulation. A total of sixty of the brains were studied and degeneration of the nervous system was found that was consistent with sheep infected with *Scrapie* and the similar disease found in minks.³⁴³ Continuation of the study was scrapped fifteen months later for lack of funding. In 1996, Dr. Doi was watching footage of the *BSE* afflicted cows in England and began to believe that the pigs he had studied nearly twenty years earlier were inflicted with a similar form of the disease. He brought this to the attention of USDA officials, who did nothing.³⁴⁴

³⁴⁰ See generally RAMPTON & STAUBER, *supra* note 205, at 213-14.

³⁴¹ See *id.* at 213.

³⁴² See *id.*

³⁴³ See *id.* at 214.

³⁴⁴ See *id.*

Dr. Doi's study was not the only one to link pigs to possible *TSEs*. In 1985 a study³⁴⁵ was conducted which found that people who consumed pork based products such as hot dogs, roast pork, ham, scrappie, and pork chops had an increase risk of contracting *CJD* compared to a control group.³⁴⁶ In the other study conducted in 1973, it was learned that one third of the *CJD* patients who ate brains had a preference for hog brains compared to the control group.³⁴⁷ In a British study, a pig injected with material from a diseased cow developed *TSE*.³⁴⁸

In a related group of incidents, ranch-raised minks died of a *TSE* type disease after they were fed cattle remains that had been deemed unfit for humans.³⁴⁹ The ranches were located in Wisconsin and the mink were fed "downer cattle."³⁵⁰ In two studies conducted on *CJD* patients in this country, it was determined that many of them had consumed pig brains and were more likely to have consumed pork and lamb — animals that have been shown to have exhibited symptoms of *TSE*.³⁵¹

In mule, deer and elk, the disease is known as *Chronic Wasting Disease* and has been documented in herds in Colorado, Wyoming, and South Dakota.³⁵² It is believed to spread by animals eating placental afterbirth from sheep infected with *Scrapie*³⁵³ and from a research facility that had conducted studies on *Scrapie*. Two hunters in the area who were potentially exposed to *Chronic Wasting Disease* have died of *CJD*.³⁵⁴ The typical incidence of *CJD* is one in a million.³⁵⁵

Believing that the risk to the United States population and its food supply was genuine, the Consumers Union released a four-part policy plan, which it believed the USDA should insti-

³⁴⁵ This study was one of two small "case controlled epidemiological studies" conducted on US *CJD* sufferers. See Michael Hansen, Ph.D., *The Reasons Why FDA's Feed Rule Won't Protect us From BSE*, 17 GENETIC ENGINEERING NEWS 4 (1997), <http://www.consumersunion.org/food/genewsmny798.htm>.

³⁴⁶ See *id.*

³⁴⁷ See *id.*

³⁴⁸ See *id.*

³⁴⁹ See Mercola, *supra* note 19.

³⁵⁰ Deborah S. Rogers, *US Not Immune from Prion Diseases*, MINNEAPOLIS STAR TRIB., Apr. 2, 2001, <http://www.organicconsumers.org/madcow/US4201.cfm>.

³⁵¹ See Mercola, *supra* note 19.

³⁵² See Rogers, *supra* note 350.

³⁵³ See *id.*

³⁵⁴ See *id.*

³⁵⁵ See generally *id.*

tute to ensure that the food supply in this country remains safe.³⁵⁶ The plan was first sent to the USDA in the form of a letter and then Michael Hansen, a scientist with Consumers Union presented the plan during a public meeting of the Harvard BSE Risk Analysis Project on September 28, 1998.³⁵⁷ Among the recommendations were that the USDA change its current policy and look at the risk of *BSE* and all forms of *TSEs* such as those found in mink, sheep, and deer, which have been known to occurred in the United States. It also urged the USDA to take another look at the possible link between *TSE* and pigs,³⁵⁸ as identified by Dr. Doi. Its second recommendation called for the government to take a look at human studies linking *CJD* to the consumption of certain animal parts, including raw meat and brains.³⁵⁹ Thirdly, the plan called for the government to take a more in depth look at the role prions play in converting normal human prion proteins into abnormal forms.³⁶⁰ Lastly, the group called for the government to take another look at the presumption that since that the incidence of *CJD* in this country has not risen over the years, *TSEs* are not being transmitted through the food supply.³⁶¹

VIII. CONCLUSION

The total impact of the current *BSE* crisis will not be known for many decades to come. This is attributable to laws, policies, and treaties both locally, nationally, and internationally that still allow forms of animal cannibalism to be practiced and the use of dangerous environmentally damaging pesticides. It is also attributable to the inexact testing procedures of animals suspected of harboring the *BSE* virus and the long incubation period in humans that are speculated to last upwards of thirty years from the time of consumption.³⁶² With the damage already done, many countries including the United States are

³⁵⁶ See Michael Hansen, Ph.D., Comments to the FSIS/APHIS Meeting on the Harvard BSE Risk Analysis Project (Sept. 28, 1998), available at www.consumersunion.org/food/harvardcpi301.htm.

³⁵⁷ See *id.*

³⁵⁸ See *id.*

³⁵⁹ See *id.*

³⁶⁰ See *id.*

³⁶¹ See *id.*

³⁶² See Greger, *supra* note 12.

still unwilling to attack the problem head on despite having the legal tools already in place to do so.

In the United States today, the practice of feeding ground up animal parts back to animals is still being practiced in a limited fashion. The practice is banned when recycling ruminant animal to ruminant animal.³⁶³ However, it does not prohibit *Scrapie* infected sheep, deer and elk suffering from chronic wasting disease to be ground into food pellets and fed to pigs or chickens in the form of the protein pellets used to feed cattle.³⁶⁴ The same law, which prohibits feeding ruminants to ruminants and mandates that invoicing and labeling be saved, also carves out an exception when it comes to what pigs, chickens and household pets can be fed when it comes to the ingredients contained in pet food.³⁶⁵ The only requirement mandated by the law is that it be labeled “[d]o not feed to cattle and other ruminants.”³⁶⁶ This directly contradicts a report issued by the World Health Organization in 1996, which urges countries not to permit any part or product of any animal, which has shown signs of *TSE* to enter any human or animal food chain.³⁶⁷ The report also urges countries not to permit “tissues that are likely to contain the *BSE* agent to enter the food chain (human or animal).”³⁶⁸

³⁶³ See Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (2003).

³⁶⁴ See RAMPTON & STAUBER, *supra* note 205, at 217.

³⁶⁵ See Animal Proteins Prohibited in Ruminant Feed, 21 CFR § 589.2000(b) (2003).

³⁶⁶ RAMPTON & STAUBER, *supra* note 205, at 216. However, household pet food is specifically exempt from this labeling requirement. See *id.*

³⁶⁷ See WORLD HEALTH ORGANIZATION, REPORT OF A WHO CONSULTATION ON PUBLIC HEALTH ISSUES RELATED TO HUMAN AND ANIMAL TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, *supra* note 18, ¶ 2.2(1).

³⁶⁸ *Id.* ¶ 2.2(3). The recommendations contained in the report also include information relating to specific products:

[m]ilk and milk products, even in countries with a high incidence of BSE, are considered safe. There is evidence from other animal and human spongiform encephalopathies to suggest that milk does not transmit these diseases. Gelatin in the food chain is considered to be safe if produced by a manufacturing process utilizing production conditions which have been demonstrated to significantly inactivate any residual infectivity . . . that may have been present in source tissues. Tallow is likewise considered safe if effective rendering procedures are in place . . .

Id.

Clearly the United States government must close the loopholes that allow *TSE* infected animal parts to enter the food chain. It can be accomplished by amending and expanding the FDA rule banning the feeding of ruminants to ruminants³⁶⁹ to include a ban on feeding any *TSE* infected animal to any animal as called for by the Consumers Union.³⁷⁰ Among the other recommendations the consumer watchdog group is lobbying for is a total ban on recycling any animal remains to animals used as food as has been done in the United Kingdom.³⁷¹ Currently, the FDA rule allows for cattle remains to be ground up and fed to pigs or chickens, which in turn are allowed to be recycled into feed given back to cattle.³⁷² The consumers group is also calling for additional screening of United States cattle and believes that because of the long incubation period necessary for cattle to test positive for *BSE*, food mills should be required to keep records longer than one year.³⁷³ This they believe would allow for the better traceability of tainted feed.³⁷⁴

On the international front, the only country other than Sweden to ban the practice outright has been the United Kingdom. This type of blanket ban can be achieved by utilizing Article 5, Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection, contained in the international law rules of GATT. For those countries that have not yet experienced the ravages of *BSE*, they could apply the same provision under the theory that faced with scientific uncertainty, they are trying to avert a *BSE* crisis.

Under the global economy in which we function in today, there needs to be an agreement on what we are willing to feed our animals. These animals and their parts are part of our everyday lives. They ultimately end up on our dinner plates. They are in our bathrooms in the form of cosmetics and ingested in our bodies in the form of medications. Until there is a global agreement, consumers cannot be assured that the product they are using or ingesting is truly free of disease.

³⁶⁹ See Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (2003).

³⁷⁰ See 'Mad-Cow Disease' Where do we go From Here?, *supra* note 65.

³⁷¹ See *id.*

³⁷² See *id.*

³⁷³ See *id.*

³⁷⁴ See *id.*

Banning animal cannibalism is only addressing part of the problem. For the problem to be truly eradicated, there needs to be a shift in how we treat our animals, which play a vital role in our daily lives and the environment in which we all must live. Small steps in preserving the environment have been taken under the Persistent Organic Pollutants Treaty signed by ninety countries this past spring. Like the United States rule, which bans feeding ruminants to ruminants, the POP Treaty also stops short in addressing the entire problem, as organophosphates such as Phosmet are not among the original twelve chemical compounds listed in the Treaty. However, the framework is in place for additional ones to be added. Nationally, the United States does not have to wait for the members of POP to act. The EPA could ban the use of Phosmet, utilizing the NEPA and it could revoke its license under FIFRA, or New York State and any one of the other forty-nine states could ban its use under its own laws and regulations. At the very least, an environmental impact study should be done as called for under Section 102 (2)(c) of NEPA to assess the current dangers Phosmet poses to the environment.

Sweden has already proven to the world community that both issues, animal cannibalism, and destruction of the environment through pesticide use can be addressed successfully without economic harm to the farmers or retribution from international trading partners. It is now time for the rest of the world to follow Sweden's example.

But even if the global community, including the United States, ultimately decides to put this type of ban into effect, the laws are only as good as the enforcement. Clearly, in the United States today, there is a need for a coherent testing policy that evenly distributes random testing proportionately to the amount of cattle present in each state. And, when an animal is tested, the test needs to be administered with the most accurate and up to date testing available. This is the only way for consumers to be assured that the food they are purchasing and the medicinal and cosmetic products they are utilizing are safe.