Mad Cow Disease Policies in the U.S.A.

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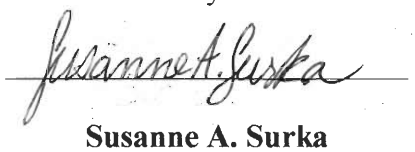

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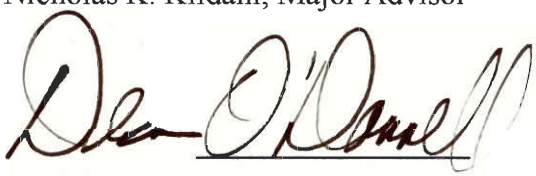

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1. **Policies**
2. **Science**
3. **Public Opinion**

Abstract

The U.S.A.'s Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) policies are discussed. An analysis of the policies, their evolution, and the Vermont sheep crisis is conducted to show that the policies cover every aspect of the BSE issue and are constantly updated based on new data as it becomes available. This analysis shows that despite dissent from some involved parties (e.g. farmers, some environmentalists) the approach and policies of U.S. government regarding BSE are reasonable and appropriate.

USDA Node

USDA - US. Department of Agriculture
- *FSIS* - Food Safety Inspection Service
- *APHIS* - Animal & Plant Health Inspection Service
  - NVSL - National Veterinary Service Laboratories
- *ARS- NADC* - National Animal Disease Center

FDA - Food & Drug Administration
- *CBER* - Center for Biologics Evaluation & Research
- *CFSAN* - Center for Food Safety & Applied Nutrition
- *CVM* - Center for Veterinary Medicine

CDC - Center for Disease Control & Prevention
- *NCID* - National Center for Infectious Diseases

AANP - American Association of Neuropathologists
NPDPSC - National Prion Disease Pathology Surveillance Center
NIH - National Institutes of Health
- *NINDS* - National Institute of Neurological Disorders & Stroke
- *NIAID - National Institute of Allergy & Infectious Diseases*

USAHA - US. Animal Health Association
- *CCWAL* - Committee of Captive Wildlife & Alternative Livestock

AAVLD - American Association of Veterinary Lab. Diagnosticians
CSPI - Center for Science in the Public Interest

NCBA Node

AABP - American Association of Bovine Practitioners
AAFCO - Association of American Feed Control Officials
AAMP - American Association of Meat Processors
AAVMC - Association of American Veterinary Medical Colleges
AFBF - American Farm Bureau Federation
AFIA - American Feed Industry Association
- *FCI* - Facility Certification Institute

AIF - Animal Industrial Foundation
AMI - American Meat Institute
APPI - Animal Protein Producers Industry
ASI - American Sheep Industry Association
AVMA - American Veterinary Medical Association
FASS - Federation of Animal Science Societies
FSC - Food Safety Consortium
NAMP - North American Meat Processors Association
NCBA - National Cattlemen's Beef Association
NGFA - National Grain & Feed Association
NMA - National Meat Association
NMPF - National Milk Producers Federation
NRA - National Renderers Association

USMEF - US. Meat Export Federation

Congressional Node

HAC - House Agriculture Committee
SAC - Senate Agriculture Committee

Table of Contents

Introduction

This report examines the Bovine Spongiform Encepalopathy (BSE) policies in the U.S.A. Identifying the BSE issue network helps us see how all sides are represented in BSE legislation. Everyone included in the policymaking has the same goal (to prevent the spread this disease to the U.S.A.) but with different agendas. Still, they put together an efficient BSE response plan, by learning from the UK's previous mistakes and making adjustments accordingly. BSE policymaking is based more on science and circumstantial evidence than on public panic and politics, although those still do have an effect. The BSE response plan is efficient and was properly followed in the Vermont Sheep case, as we will show. The people who do not want to comply with USDA BSE regulations underestimate the situation that non-compliance could cause. This report should encourage compliance with the USDA and other involved government agencies in preventing BSE here.

First, it is necessary to describe the history and biology of BSE to understand why these policies are supposed to be effective in protecting the U.S. from BSE infection. We do not understand some scientific issues of BSE in full detail yet. Understood is that this is a prion disease in cows and other animals that creates holes in the brain and causes it to look like a sponge. It causes a neurodegenerative disorder similar to scrapie (also a Transmissible Spongiform Encephalopathy) found in sheep. It is clear that it threatens humans because it transmits to us through infected beef. The human variant is called variant Creutzfeldt-Jakob disease (vCJD). It is a rare, lethal disease for which there is no cure or test that can detect it in live humans. Although it is rare now, it does not have to

be later on if we do not take measures now to stop it. The characteristics of this disease are horrible and it would be a disaster if it were to spread.

Second, it is essential to describe the basic structure of an issue network, in order to understand later how things tie together. Generally, in the middle of the mass of organizations involved is an "iron triangle", which in the case of BSE, consists of the USDA, NCBA, and the Congressional Committees on Agriculture. Each works together with other organizations and hires other researchers, creating the network. These networks, identified and presented on a "map" show their relationships to each other.

Third, we look at the initial U.S. response and the basis for their decisions. In order to understand the basis for the U.S.A.'s decisions, it is necessary to explore Britain's mistakes in handling the BSE situation which, caused infection in continental Europe. From this we can see how the U.S. learned from them. Was it too little science or politics? This leads to the fourth point, the evolution of U.S. policies. We look at the effect science, public panic, politics, Europe and trade had on forming our current BSE policies.

Fifth, used as an example is the Vermont sheep crisis. It shows how the U.S. handled a BSE scare, what they based their decisions on and who agreed and disagreed with the actions taken. We hear Shepherd's opinions to discover their main concerns, and their reasons for supporting the Vermont sheep farmers or not supporting them. In addition, the views of animal rights organizations and of farmers from infected farms will be discussed.

The information on issue networks and interest groups is collected through books and articles. Newspapers and journals provide up-to-date information on the biology of

the disease, current policies in place, as well as public reaction. Web pages of all the organizations and researchers involved provide information on the role each plays and their contacts. Interviews through e-mail, telephone, and in person help explain details, give examples and provide contacts that tie it all together and fill in any gaps.

Methodology

As stated in the introduction, this research will measure the efficiency and fairness of the BSE policies the U.S. has set forth after the BSE outbreak on the UK. The USDA, FDA, CDC and other federal and state agencies have used several methods to prevent BSE from entering the country. The collection and analysis of the policy data should prove that the U.S. BSE policies are reasonable and very well justified. The research will identify the different groups involved in BSE legislation and show how they put together an efficient BSE response plan even with their different agendas. Also, we will analyze the U.K.'s previous mistakes to show how the U.S. adjusted its policies accordingly.

The first step of the active research is outlining the initial U.S. response to BSE which set policies on imports, feed, vaccines, blood donors, and started inspections and surveillance. Then correlate the adjustments to policies with new discoveries the UK made regarding BSE and the mistakes they made before in dealing with BSE in their country. Past articles in journals and newspapers are a good source to find out what was going on back then. We also monitor the U.S. response to the European Union's warnings and suggestions, since the EU is more experienced with dealing with BSE, their suggestions should be followed. The policies, their history and who makes them are the first things researched and with them we can start building a chain to the final result.

The second area of research here is the evolution of the U.S. policies. We examine the roles science, public opinion, politics, Europe, etc ... play in the evolution of U.S. policies. We do this by looking at all the main BSE policies since the initiation and seeing when and which policies were revised and what the reasons were for the revision. Also, we can see why the U.S. government approached the BSE issue like it did. The analysis uncovers what the policymakers

hold most important when they adjust policies. In addition, it is important to show how interest groups influence the BSE legislation, making it more fair and representative of all affected by BSE. The interest groups and federal and state agencies for the most part all agree with each other and work together on this issue, but some have different agendas than others. We discover their agendas through what other sources wrote about them, and through dissecting the other things they became involved in and what they have to lose or gain.

Lastly, we study the Vermont sheep crisis as an example of how the BSE U.S. response plan was followed (response plan in section 1.). By analyzing the actions and arguments of the USDA, farmers, and protestors we prove that the arguments of the groups against the USDA's actions in the Vermont sheep case are the arguments of misled people who do not have knowledge about BSE or any TSE's. Their arguments can be found in newspapers or through interviews, then are compared to what we know is true and false about BSE and its history. There are also interviews with shepherds to support those theories.

In the end, it is proven that the current BSE policies in the U.S. are the best they can be at this point in time. The analysis will hopefully help others to understand why these policies were instated, and as a result, they will be more likely to comply with them.

Biology

Mad Cow Disease first broke out in the U.K. in 1986. It was unknown where it came from or what it exactly was. One cow after another died of this strange disease that made holes in their brains. After analyzing the manifestations of the disease they named Bovine Spongiform Encephalopathy (BSE), and the properties of the infectious agent, scientists concluded that it most likely came from sheep scrapie and is a prion disease.

Manifestations of the Disease

Since the average incubation time for BSE is 5 years in cattle, most cattle never showed signs of the disease because typical slaughter occurs between two to three years of age. In spite of that, more than 160,000 cattle, primarily dairy cows, died of BSE between 1988-1998 in the UK. [1]

BSE affects the brain and spinal cord of cattle. The BSE agent makes holes in the brain, making it look "sponge-like". This causes serious and fatal neurological signs and symptoms. [2] At the beginning of the onset of BSE the cow seems alert but restless and anxious. As the disease advances, the cow starts to take a wide base posture, the abdomen is drawn up, the way of walking becomes abnormal, and results in tumbling and skin wounds. There is a loss of ability to coordinate muscular movement due to loss of motor control. [3] Small muscle jerk are seen over the surface of the neck and body with

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[1] Stanley B. Pruisner. *Prions - Nobel Lecture.* (Proceedings of the National Academy of Sciences, 95: 13363-13383. 1998).

[2] USDA - APHIS. *BSE.* (2001). [Online] Available: http://www.aphis.usda.gov/oa/bse/ [17 April 2001]

[3] Stanley B. Pruisner, 1998.

occasional larger muscle jerks. The cow loses weight, makes frantic movements, which include aimless head-butting. [4]

The human version of BSE, called vCJD, outwardly manifests itself as a progressive dementia. vCJD affects the brain and spinal cord of humans, and also makes the brain into a spongy form. One of the factors that make it different from the classical CJD, is that it affects younger patients (around the age of 29 as opposed to 65), and has a longer duration of illness. The physical symptoms are basically the same. After the incubation period, the first signs of the disease are changes in sleeping and eating habits, and it progresses over a couple weeks to months to a completely neurological syndrome. This includes muscle spasms, dementia, loss of higher brain function, and behavioral irregularities. The disease continues even further, with deterioration in cerebral and cerebellar function to mostly decreased neurological activity, sensory and visual function decay. Inevitably the patient dies, possibly after a decrease in lower motor neurological function and seizures. Most die in about a year, but some can suffer for as long as 10 years. [5]

BSE is known to be the most probable cause of vCJD. Scientists found that BSE and vCJD agents have similar glycoforms, in other words, they have the same sugar side chains. This shows that vCJD was derived from BSE, but it is still not known exactly how this happened. Also tests confirmed that scrapie can be orally transmitted to sheep with as little as 1/2 a gram of infected brain tissue. When studies were done on the sheep brains of the experimentally infected sheep, it was shown that the agent in their brains

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[4] Steve Dealler. *BSE is a new disease; you should realize its history.* (1998). [Online] Available: http://sparc.airtime.co.uk/bse/hist.htm. [17 April 2001]

[5] Steve Dealler, 1998.

was more similar to the BSE agent than the scrapie agent. It is possible for sheep to get BSE; it is just a matter of time before it is found to have happened naturally and not experimentally. [6]

Nature of Transmissible Agent

In the early days of studying Transmissible Spongiform Encephalopathies (TSEs), suggestions as to the nature of the disease-causing agent ranged from small DNA viruses to membrane fragments to polysaccharides to proteins. [7] Subsequent research on the agents causing scrapie and CJD showed these pathogenic particles to be extremely resistant to procedures that alter nucleic acids, such as ultraviolet light, ionizing radiation, phenolic disinfectants, and even autoclaving at 132-138 degrees C. [8] These results suggested to researchers that perhaps nucleic acids are not a required component of the disease-causing agent. [9] In addition, the factor responsible for scrapie was found to be resistant to inactivation by formalin and heat treatments, two popular techniques used to inactivate viruses, suggesting that the scrapie agent might be different from viruses. Over time, data began to accumulate indicating that scrapie infectivity could be reduced by procedures that modify proteins but not by procedures that alter nucleic acids or viruses. The only methods that appear to be completely effective under worst-case conditions are immersion of contaminated material in strong sodium hypochlorite solutions (bleach) or hot solutions of sodium hydroxide. While this may be effective, these are both harsh

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[6] Steve Dealler, 1998.
[7] Stanley B. Pruisner, 1998.
[8] D.M.Taylor. *Inactivation of prions by physical and chemical means.* (Journal of Hospital Infectivity, 1999): Vol.43.

[9] Stanley B. Pruisner, 1998.

chemicals and have no place in food production and limited applications for sterilizing high-tech hospital instruments. [10] Seeing that scrapie infectivity could only be reduced by procedures that modify proteins, it was for the first time established that a protein was required for infectivity. [11] The resulting 'protein-only' hypothesis maintains that the disease-causing agent, or prion, lacks genomic nucleic acid and that the essential pathogenic component is a protein. [12] Because the concept of a protein as an infectious entity is unique in biology and some features of the disease caused by prions and viruses are similar, some scientists refuse to accept the 'protein-only' hypothesis. Instead, this group of researchers claims that the agent responsible for TSE is some sort of virus with unusual properties. According to Stanley Pruisner, winner of the 1997 Nobel Prize for his work with prions, "numerous attempts to disprove the prion (protein-only) hypothesis over the past 15 years have failed." [13] In fact, no evidence exists for a virus-like particle or a nucleic acid genome being responsible for TSE infectivity. In addition, the discovery of unrelated prion-like events in yeast and fungi serves both to broaden and strengthen the prion 'protein-only' hypothesis. [14] Because of these, and other more detailed reasons, most TSE researchers today adhere to the 'protein-only' hypothesis. [15]

Prions are unique pathogens that induce a variety of fatal neurodegenerative diseases by way of a unique mechanism. Examples of prion diseases include Bovine Spongiform Encephalopathy (BSE) in cattle, scrapie in sheep, which is not transmissible to humans, Creutzfeldt-Jakob disease (CJD) in humans, variant CJD in humans derived

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[10] D.M. Taylor, 1999.
[11] Stanley B. Pruisner, 1998.

[12] A. Aguzzi and C. Weissmann. *Prion research: The next frontiers.* (Nature, 389: 795-798. Oct. 23, 1997).

[13] Stanley B. Pruisner, 1998.
[14] Stanley B. Pruisner, 1998.

from BSE, chronic wasting disease (CWD) in deer and elk, and a variety of other transmissible spongiform encephalopathies (TSE). Prions are completely devoid of nucleic acid and seem to be composed entirely of a modified cellular protein. The disease progresses and spreads when a normal cellular protein, found in the brain and other organs of all vertebrates examined so far, is converted into a modified version through a process in which the prion acts as a template upon which the normal cellular protein is refolded into the modified version. On the basis of genetic studies, Pruisner and colleagues have postulated that an unidentified 'protein X' may interact with the normal protein and help in its conversion to the modified protein. [16] Considering the substantial structural transition that takes place during prion formation, it seems entirely likely that a 'chaperone' protein may participate in the refolding process. Whether or not 'protein X' actually exists still remains to be determined. [17]

The structural transition of the prion protein results in significant changes in the physiochemical properties of the protein, in turn leading to the fatal consequences associated with TSE. In tissues of individuals dying of prion diseases, only the modified protein has been detected to be specific for the encepalopathies. The exceeding specificity of the modified protein for prion disease is an important feature of the protein and is consistent with its postulated role as both the transmissible and pathogenic agent of TSE. [18] Interestingly, the physiological role of the normal prion protein has yet to be determined. Mice engineered not to produce the normal protein develop normally and

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[15] A. Aguzzi and C. Weissmann, Oct. 23, 1997.
[16] A. Aguzzi and C. Weissmann, Oct. 23, 1997.

[17] Stanley B. Pruisner, 1998.
[18] Stanley B. Pruisner, 1998.

suffer from surprisingly few defects. [19] Nevertheless, the results of many studies have shown that two prion protein isoforms play a central role in the transmission and pathogenesis of prion diseases and the abnormal isoform is an essential component of the prion particle. [20]

Currently, little is understood about mechanisms through which prions elicit brain damage. The symptoms of prion pathogenesis, however, have been well documented in the literature. Prions cause the formation of cavities within the brain, death of nerve cells, activation of astrocytes and microgial cells (two components of the central nervous system), and eventually lead to the lethal breakdown of electrical functions of the brain. The precise contribution of the various types of cells in the central nervous system (CNS) to prion pathogenesis remains to be determined, however by the time the first symptoms of a spongiform encephalopathy are recognized, there is already substantial damage to the CNS. [21]

Research has found prions to be most damaging when delivered directly to the brain, however this is not a normal route of infection. Most cases of CJD transmission in humans have been traced to intramuscular injection of prion-contaminated pituitary hormones. Oral uptake of prions has also resulted in infection, for example, cannibalistic rituals have been linked with incidences of kuru (another spongiform encephalopathy) in Papua New Guinea in the 1950s. Among animals, BSE is a more recent and significant example of a disease that is caused by oral uptake of prions. Once in the body, prions seem to be able to travel through the body to the brain of the host, yet they only cause

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[19] A. Aguzzi and C. Weissmann, Oct. 23, 1997.

[20] Stanley B. Pruisner, 1998.

[21] A. Aguzzi and C. Weissmann, Oct. 23, 1997.

noticeable damage in the central nervous system. It is suspected that during the incubation phase of TSE that prions may multiply in 'reservoirs' without causing harm to the body. One such reservoir may be the lymphoid organs of the immune system. Although the lymphoid organs are a suspected reservoir of TSE it is unlikely that immune cells transport prions all the way from lymphoid tissue to the central nervous system during the infectious stage. Instead it is suspected that the infectious agents probably spread through the peripheral nervous system (PNS) to the central nervous system (CNS), much like rabies and herpes viruses. [22]

Vertical Transfer of BSE

Vertical transfer is the transfer of the infectious agent from the dam to the calf before or around its birth. There is still no scientific proof that this happens in BSE, but there is a lot of circumstantial evidence that supports the vertical transfer theory. First of all, similar diseases such as scrapie, are vertically transmitted. Second, the number of BSE cases reported in June 1994 was 700 per week, which is far too high six years after the feed ban, to be solely explained by a feed source. Also overall, over 9,000 BSE cattle were born after the feed ban and over 600 BSE calves were born from BSE dams. [23] These numbers of newborn cases are too high to have happened by chance. Third, the most frequent age of death of BSE animals is four years and this favors vertical transfer rather than a feed source. The dormant period for BSE is around four years in cows, so if they died at four years of age, it means they must have had the BSE since they were born.

[22] A. Aguzzi and C. Weissmann, Oct. 23, 1997.

[23] Steve Dealler, 1998.

The most important implication of vertical transfer is that it means the infective agents must be in the blood, and therefore widely distributed in the infected animal. [24]

[24] Richard W.Lacey. *BSE: A "Progress" Report.* (British Food Journal, 96(7): 46-48. 1994a).

History of BSE

The complete history and epidemiology of BSE and other related prion diseases is too extensive to be included in this report, for that reason a shortened chronology is included to give the reader a sense of how the policies, and scientific knowledge evolved up until now. The first known instance of a prion disease, or transmissible spongiform encephalopathy (TSE), occurred in 1732 when scrapie, a prion disease related to BSE, was first recorded in sheep. [1] The next significant event in history of BSE came in 1900 when meat and bone meal (MBM) first became used as a feed for ruminant animals. [2] By the 1920's, rendering, which is the use of slaughterhouse remains for animal feed farmers, began on a widespread scale as a way of feeding the protein needed for fast growth and high milk production. In the 1960s and 1970s, large-scale continuous rendering plants were developed in the USA and were adopted by an increasing number of large rendering companies. Compared with the previous batch techniques, continuous plants offered savings in labor and energy costs at levels of high capacity utilization. [3] Today, many scientists believe that this change allowed the agent responsible for BSE to survive the rendering process and become incorporated into the animal feed. [4]

On December 22, 1984, Dr. David Bee, a veterinary surgeon, was called to examine Cow 133, which was suffering from an arched back and weight loss on the Pitsham Farm in Great Britain. Later, on February 11, 1985, Cow 133 died, having earlier

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[1] The Guardian. *BSE crisis: Timeline.* (Oct. 26, 2000). [Online] Available: http://www.guardianunlimited.co.uk/Print/0,3858,4081978,00.html [17 April 2001]

[2] The BSE Inquiry. *The BSE Inquiry: The Report.* (2000). [Online] Available: http://www.bse.org.uk/report/volume16/chapter1.htm [17 April 2001]

[3] The BSE Inquiry, 2000.

[4] The Guardian, Oct. 26, 2000.

developed head tremors and loss of coordination. A clinical report published on the case later that year described the cow as suffering from "a novel progressive spongiform encephalopathy." [5] This was the first know case of BSE.

In November of 1986, BSE became officially recognized as an entity in the UK. [6] In August 1987, development of a BSE database began at Britain's Central Veterinary Laboratory (CVL) to keep track of all confirmed BSE cases. By December 15, 1987, initial epidemiological studies were completed, showing some evidence to suggest that ruminant-derived MBM is a factor in the cause of BSE. [7] Before the year's end, UK government ministers were first told about the disease.

On July 7, 1988, the UK government announced the slaughter policy, which mandates the destruction of all animals showing clinical symptoms of BSE. Later that month, the UK banned all ruminant MBM from inclusion into cattle feed until December 31, 1988 while a review of the rendering process was conducted. The result of this review led to the BSE Order of 1988 which prolonged the ruminant feed ban and prohibited the use of milk from suspected cattle for any purpose other than feeding to a cow's own calf.[8]

In July 1989, Europe banned export of British cattle born before July 1988 as well as any animals showing BSE symptoms. [9] Later that year, the UK government instated a total ban from human consumption of high-risk offal, such as the brain, spinal cord, and

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[5] The BSE Inquiry, 2000.

[6] CNN. *Timeline: How the Crisis Unfolded.* (Jan. 15, 2001). [Online] Available: http://europe.cnn.com/2000/WORLD/europe/UK/10/25/bse.timeline/. [17 April 2001]

[7] The BSE Inquiry, 2000.

[8] The BSE Inquiry, 2000.

[9] CNN, Jan. 15, 2001.

spleen of ruminant animals. Finally, the BSE Amendment Order came into force on December 31, 1989, making the ruminant feed ban permanent. [10]

In 1990 the first CJD surveillance unit was set up in Edinburgh, England to find out if BSE was giving rise to extra cases of CJD. The cases of BSE that year averaged at 300 per week in the UK! [11] There were demands that all infected herds should be slaughtered and that restocking should take place from abroad. The German Government banned imports of beef from the UK because of the potential risk it had to their population. Various schools also banned beef in meals. The beef consumption in the UK dropped to the lowest level since 1962, and 65% of doctors stopped eating beef due to BSE. [12] Finally, Professor Richard Lacey made the first call for slaughter of all infected herds in the UK. [13] The Minister of Agriculture in the UK, John Gummer, kept on insisting that there was no risk and the beef was safe, because there was no scientific proof that BSE caused CJD. Since researchers thought at this time that BSE was a variant of scrapie, they assumed it was not a danger to other species just like scrapie. However, later that year a domestic cat developed BSE. More proof that BSE was not the same as scrapie came when an American had inoculated scrapie into a cow and it developed a TSE, but it was not BSE. [14]

Harash Narang was told by the UK government to stop carrying on his research of BSE and its risk to humans. Despite this there was still research going on in 1991. That year a case of BSE appeared in a cow that was born after the feed ban and it was sure it

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[10] The BSE Inquiry, 2000.
[11] CNN, Jan. 15, 2001.

[12] Steve Dealler. *BSE is a new disease; you should realize its history.* (1998). [Online] Available: http://sparc.airtime.co.uk/bse/hist.htm. [17 April 2001]

[13] CNN, Jan. 15, 2001.

could not have been fed infective material. [15] This supported the vertical transfer theory, along with a second case when a calf born to a cow with BSE developed it also.

In 1992 a cheetah and puma died of a TSE now thought to be BSE in the food that they had eaten. But it was not clear how they could have gotten this since they did not eat the brain of the cow, and that was the only known way at the time to contract BSE. [16] This was evidence to suggest that BSE was not only carried through in the brain but also the bones, liver and maybe blood. It also again proved that BSE could spread to species other than cows.

By 1993 BSE in the UK reached its peak with around 100,000 confirmed cases. [17] The rate of diagnosis of BSE by vets was approximately 85%, when they examined the brains under a microscope. As a result of the high rate of BSE increase, changes were made in the way that cattle could be sold. The number of vets at auctions decreased and a computer system was used instead, to estimate the probability that a cow was infected by BSE. The computer used the ear tags on the cow to find out if it was from an infected herd or not. [18]

An interesting case that was too coincidental happened later that year. Two dairy farmers with BSE in their herds were found to have died of CJD! In 1994, a 16 year old from Wales died of CJD because she had eaten BSE infected beef when she was little, and a butcher from Whitby died of CJD also. [19] The research that was being conducted on

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[14] Steve Dealler, 1998.
[15] Steve Dealler, 1998.

[16] Steve Dealler, 1998.
[17] CNN, Jan. 15, 2001.
[18] Steve Dealler, 1998.

[19] Steve Dealler, 1998.

the relationship between BSE and these CJD cases, showed that this CJD caused by BSE was a variant form of the original CJD, so they called it vCJD.

Later in 1994, it was found out that cattle meat was being exported for sale in Europe without evidence that it came from a BSE-free herd. Claims were made that pressure was being put on the vets to sign certificates without evidence. The European Commission now made it essential that any beef on the bone being exported could only come from herds that were unaffected by BSE in the past 6 years. However, it was found out that abattoirs were attempting to export beef from infected herds anyway, and the computer that had the information about the cattle, was not allowed to give that information out for data control reasons! [20] So the computer system that had been set up previously was now found to be ineffective.

By the end of 1994 a large number of cattle infected with BSE had been born after the feed ban. 700 cases per week are far too high, 6 years after the feed ban, to be explained solely by a feed source. [21] This again supports the theory of vertical transfer, or endemic infection. Some of the BSE infected calves born that year in the UK had infectivity in the gut. As a result all gut and thymus from calves could not then be eaten. [22] The Spongiform Encephalopathy Research Campaign was started that year.

In 1995 it was estimated that 1.8 million infected cattle from the UK farms would be eaten by the year 2001 and that most of these had already been eaten. This was because of the underreporting of cases in 1992 and 1993 was shown to reach 60%. 90% of the cattle in the UK turned out to be in an infected herd. Apparently due to the limited

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[20] Steve Dealler, 1998.

[21] Richard W. Lacey. *BSE: A "Progress" Report.* (British Food Journal, 96(7): 46-48. 1994a).

in-herd rate the disease was, running out of cattle to involve by 1988. [23] Two more farmers died of vCJD, and they were both from BSE affected farms. Two teenagers died of vCJD, and only four were reported at any time throughout the world. [24]

The UK Health Secretary, Stephen Dorrell officially announced there is a link between BSE and vCJD in 1996. [25] He and Mr. Hogg, the Minister for Agriculture Fisheries and Food, also admitted that ten people with a vCJD had been found and eight had already died. The scientific evidence that vCJD really was derived from BSE came when Collinge's group in London showed them to be of the same glycoform. The European Union quickly banned the export of cattle and all bovine products from the UK. It was thought that as long as these guidelines were followed, it would be enough. However, it was not enough. The renderers had been letting tissue from infected cattle reach further cattle food, and the farmers had been letting cattle with infection reach human food also. It was declared on TV that certain tissues of a cow cannot be declared safe unless they were deboned in certain places and overseen. [26] The UK government started a legal challenge against the export ban, and came up with a scheme to slaughter and destroy all cattle over the age of 30 months. [27]

An investigation conducted in 1996 showed that the European Commission had deliberately played down BSE and its potential hazards earlier, and that there had been a sort of agreement to silence among the Agriculture Commission. Consequently, the

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[22] Steve Dealler, 1998.
[23] Steve Dealler, 1998.
[24] CNN, Jan. 15, 2001.
[25] CNN, Jan. 15, 2001.
[26] Steve Dealler, 1998.
[27] CNN, Jan. 15, 2001.

European Parliament set up a committee to look into the matter, and they decided that the silence from the EC was unacceptable and many official groups were guilty of inaction.[28]

Later in 1996, it was found through lab work that sheep could easily be infected with BSE. As a result, the French put a brain and spinal cord offals ban on all sheep for human consumption, as they did the beef. Experimenting with sheep and looking for a cure for BSE, researchers discovered that Dolly the sheep made from a single breast cell was resistant to BSE and scrapie. [29] This gave hope and research money arrived.

In 1997, the UK government imposed the "beef-on-the-bone" ban and several other scientific discoveries were made. [30] A scientific publication by Moira Bruce said that BSE, when inoculated into mice, made the same disease as vCJD. It was realized that blood transfusion could be a risk, because it might carry vCJD. This became a big problem for the Government because there appeared to be no way in which UK blood could be looked at as being completely safe. Bone, the dorsal root ganglia, and the lung were added to the list of Specified Bovine Materials. 12 more cases of vCJD appeared, and compensation reached about 1 billion pounds in the UK! Research budgeting was put as "unlimited." [31]

An investigation started in 1998 that looked into the care, diagnosis and information given to vCJD victims and their families. [32] Also, a public judicial inquiry began into BSE and vCJD, and it aims to find out why it all took place, and why such poor action was taken. [33]

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[28] Steve Dealler, 1998.
[29] Steve Dealler, 1998.

[30] CNN, Jan. 15, 2001.
[31] Steve Dealler, 1998.
[32] CNN, Jan. 15, 2001.
[33] The BSE Inquiry, 2000.

Three years after the ban on British beef was imposed the EC lifted it in 1999, but France continued to enforce the restriction. The UK "beef-on-the-bone" ban was also lifted. [34]

Another case that supports the theory of vertical transmission appeared in 2000. A baby girl was born to a mother with vCJD and it was found that the baby also had vCJD. It is evident in this way that vertical transmission has taken place, but it is still not scientifically proven. There was also an investigation into a "cluster" of vCJD cases around a village called Queniborough in Leicestershire. The oldest know victim of vCJD, a 74-year-old British man, died. This generated further fears about the extent on the illness. Switzerland, Spain, Germany, and Portugal imposed bans that year regarding BSE, due to the public fear of BSE and vCJD spreading as much in their country as it did in the U.K. [35] In December, the World Health Org. (WHO) announced they are moving to address global concerns over BSE. They said they will convene a major meeting for experts and officials from all regions.

This year Germany's health and agriculture ministers resigned after heavy criticism over their handling of the BSE outbreak. [36] The UK Food Standard Agency announced they will be conducting tests to see if BSE can be transmitted through milk.

Since 1985 when the first case of BSE was detected until 2001, some new scientific revelations were made, such as Dolly the mutant sheep begin immune to BSE and scrapie, and BSE being found in bones, lungs, and thymus. The UK underestimated BSE and in part because of that there is BSE spreading in the rest of Europe. It is obvious

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[34] CNN, Jan. 15, 2001.

[35] CNN, Jan. 15, 2001.

that there are some loopholes in the policies, probably because the entire nature of the prion, which causes BSE, is still unknown.

[36] C. Rohwedder. *German Officials Quit Posts.* (The Wall Street Journal, Jan. 10, 2001).

Issue Networks

In order to understand how BSE policies are made and know who has the most control and authority to make them, one must first look at the general policy making system in Washington. "It is not as important to find the few powerful players, as it is to notice the power and influence that comes out of configurations through which the main policy makers move and do business with each other." [1] In other words, by looking for the closed triangle of control, one tends to ignore the open networks of people that increasingly try to influence government.

The idea is that control in policy making is in a series of informal "iron triangles" that link executive bureaus, congressional committees and interest groups that have a stake in the reformed processes and specific programs. All these triangles and connections between the shared-knowledge groups, having to do with some aspect of public policy, make up issue networks. In the case of BSE legislature the main executive bureau would be the U.S. Department of Agriculture (USDA), the Congressional Committees are the House and Senate agriculture committees, and the main interest group is the National Cattlemen's Beef Association (NCBA).

The BSE network can also be divided into different kinds of groups; the groups that make the policies, those that enforce them, and those that influence them like researchers and some interest groups. Congressional Committees on Agriculture, the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA) created the current policies, and enforce them with help from organizations like the National Cattlemen's Beef Association (NCBA) and the Center for Disease Control and

[1] Hugh Heclo. *Issue Networks and the Executive Establishment.* (The New American Political System. 1978, pp. 88).

Prevention (CDC). Organizations such as the National Institutes of Health (NIH) and independent researchers are information providers on which the policies are based. Organizations such as the Center for Science in the Public Interest (CSPI), US Animal Health Association (USAHA) and interest groups advise and try to influence the policy makers. "As more and more confusing, unfamiliar policy issues are pushed on the government, more and more variable groups are unexpectedly mobilized." [2] Some groups are actually cultivated by the government's own need for administrative help. The interest groups are basically used as administrative middlemen and facilitators. As a result, a growing number of these groups find it useful to make their headquarters in Washington. As there are more public policies, more groups are being mobilized and more complex relationships form between them, as will be shown with the BSE issue network. The Issue Network's webs of influence provoke and guide the exercise of power. The different tactics they use can be grouped in three general categories. First there are "techniques that are characterized by direct communication between lobbyists and government officials." [3] Examples are: "private presentations before people in government; testifying before congressional committees; and formal legal action such as litigation and intervention in administrative proceedings." [4] Secondly, there are ways by which groups lobby through their constituents. "They act as mediators, motivating lobbying by citizens toward their government." [5] The third technique they use to try to change governmental policy is influencing elections or altering public opinion. They do

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[2] Hugh Heclo, 1978, pp. 94.
[3] Jeffrey M. Berry. (Lobbying for the People: The Political Behavior of Public Interest Groups. Princeton University Press, 1977. pp. 213.)

[4] Jeffrey M. Berry, 1977. pp. 213.
[5] Jeffrey M. Berry, 1977. pp. 214.

this by giving money to political campaigns, publishing voting records, releasing research results, and running public relations campaigns.

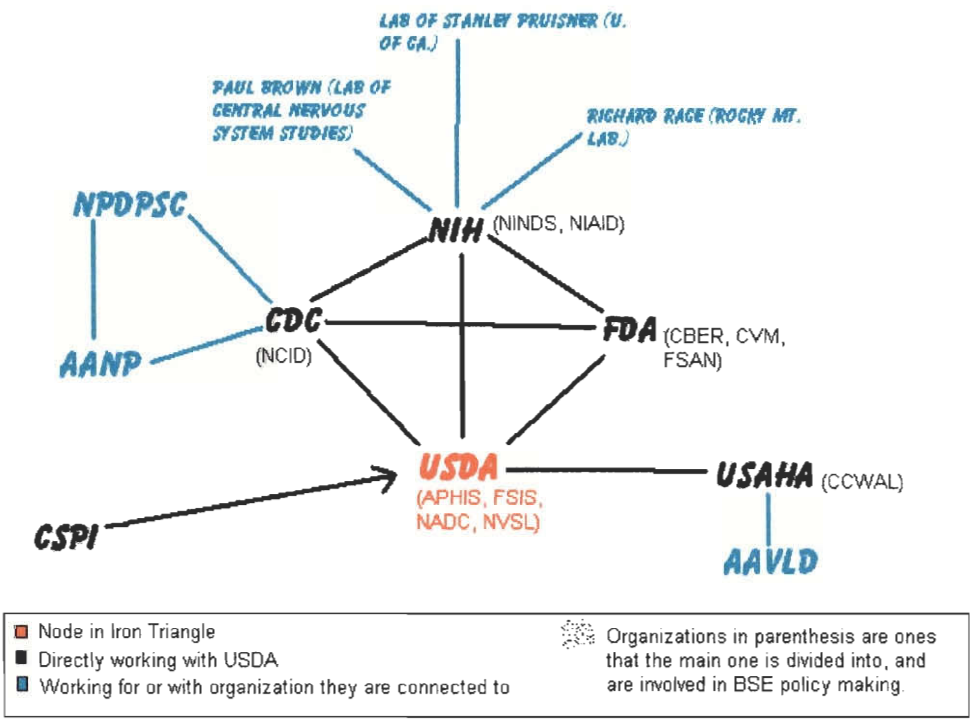
"Issue Networks are made up of a large number of contributors with variable degrees of mutual commitment." [6] One part of the network may be active and through time the different connections may intensify or fade. For example, the congressional committees are not as active in the BSE issue right now as they were over a year ago. Currently there are no more policies to add, so only the enforcement, research and interest groups are active. Participants move in and out of the networks constantly. Issue networks operate on many levels. They consist of powerful interest groups and also individuals in or out of government who have a reputation for being knowledgeable. Heclo speculates that some participants come to Washington because "they would like complete power over the issues in question, and others seem to want a little more than the security that comes with being well informed." [7]

[6] Hugh Heclo, 1978, pp. 103.
[7] Hugh Heclo, 1978, pp. 107.

USDA Node

As explained in the previous section, at the core of policy making there is an "iron triangle". Each node of the triangle represents the three main groups of organizations that have a stake in policy making of this particular issue, which is BSE. This section discusses the role of each organization in the U.S. Department of Agriculture (USDA) node of the iron triangle and their connection to each other. First the USDA and its sections that have to do with BSE policy making will be discussed. Then the USDA's direct connection to the Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the U.S. Animal Health Association (USAHA) will be explained, as well as the roles of each of those organizations. The roles of those organizations include having contact or complying with other organizations that do not have a direct connection to the USDA or the other organizations. The part of the more distant organizations will also be explained. An example is: the USDA has a direct relationship with the CDC, within the CDC, the National Center for Infectious Diseases (NCID) works on the BSE problem. They hired the American Association of Neuropathologists (AANP), who made the National Prion Disease Pathology Surveillance Center (NPDPSC) to help with the BSE research and therefore suggesting and implementing new and improved policies (refer to figure 1).

Figure 1.



US Department of Agriculture (USDA):

Animal and Plant Health Inspection Service (APHIS)

The APHIS of the USDA meets with the CDC, NIH, FDA, FSIS of USDA and stakeholders to share information and to assure that the U.S. is taking the proper actions in response to changing knowledge and information concerning BSE. The APHIS has taken measures in surveillance, testing, prevention, education, and emergency preparation. They put the first import restrictions in place in 1989 and began actively inspecting in 1990. The USDA supervises and assesses all ongoing events and research findings regarding Transmissible Spongiform Encephalopathies (TSEs), because new information and knowledge might lead to improved conclusions and prevention measures. In order to analyze risks of BSE to the U.S. the APHIS has created a TSE

Working Group. They also distribute accurate information about the TSE's, and work as a reference source for responding to questions about TSE's. [1]

Food Safety and Inspection Service (FSIS) of the USDA

The FSIS is responsible for ensuring the safety and accurate labeling of all meat, meat food products and poultry products. The FSIS inspects cattle before they go to slaughter for signs of BSE or other central nervous system impairments. [2]

Agriculture Research Service (ARS) - National Animal Disease Center (NADC) of the USDA

In the Virus and Prion Diseases of Livestock Research Unit of the NADC scientists identify and characterize viruses and prions and develop methods to control or eliminate the diseases. Their objectives are "to validate the capillary immunoelectrophoresis (CIE) assay, determine the natural routes of infection and the pathogenesis of TSEs, and to determine potential transmission among species of the abnormal prion proteins that are believed to cause TSEs." [3]

ARS- NADC works with field veterinarians, university scientists and diagnosticians, federal regulatory officials, as well as livestock producers and their national organizations in diagnosing and controlling virus and prion induced diseases of livestock. [4]

Food and Drug Administration (FDA)

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[1] USDA - APHIS. *BSE.* (2001). [Online] Available: http://www.aphis.usda.gov/oa/bse/ [17 April 2001]

[2] USDA – APHIS, 2001.

[3] USDA - NADC. *TSE in Animals.* (2001). [Online] Available: http://www.nadc.ars.usda.gov/Research/vpdl/tse/ [17 April 2001]

The FDA is the primary agency responsible for the regulation of food products intended for human consumption. They have responsibility for the safety of milk and dairy products, as well as animal drug products. Their restrictions on certain animal feed ingredients and import alerts on cattle products are a critical part of the BSE surveillance and prevention program. [5]

Center for Veterinary Medicine (CVM) of the FDA

The CVM ensures the safety of animal drug residues, which are regulated as indirect food additives. The CVM furthers those regulations prohibiting ruminant protein in ruminant feeds. The CVM has also collected data from the inspections conducted so far, and presented the data in a conference call the FDA held with Federal and State feed control officials. [6]

Center for Biologics Evaluation and Research (CBER) of the FDA

The CBER of the FDA has been trying to eliminate any possibility for contamination of medical products (such as drugs, blood, vaccines, and medical devices) by the BSE agent. In order to protect the public from the BSE agent, CBER strengthened its review of new product applications for human medical products derived from or

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[4] USDA – NADC, 2001.
[5] FDA. *BSE: Background, current concerns, and U.S. response.* (Mar. 1, 2001). [Online] Available: http://www.fda.gov/opacom/backgrounders/bse.html [17 April 2001]

[6] FDA - CVM. *Substances Prohibited From Use In Animal Food; Animal Proteins Prohibited In Ruminant Feed; Proposed Rule.* (Feb. 13, 1997). [Online] Available: http://www.fda.gov/cvm/index/bse/0212fda.htm [17 April 2001]

containing cattle sources. The CBER plans to continue its close collaboration with the scientific community and with public health officials, at home and abroad. [7]

National Institutes of Health (NIH):

National Institute of Neurological Disorders and Stroke (NINDS)

The NINDS, is one of the National Institutes of Health and is the nation's leading supporter of research on the brain and nervous system. Scientists at NINDS are working to develop laboratory tests for CJD. One example of their work is a test that is performed on a person's cerebrospinal fluid and detects a protein marker that indicates neuronal degeneration. This can help diagnose CJD in people who already show the symptoms of the disease. This test is much easier and safer than a brain biopsy, but the false positive rate is about five to ten percent. They have also discovered other ways of diagnosing the disease, such as tonsil biopsies, which may lead to other tests. [8]

Many researchers at universities associated with NINDS are also examining whether the transmissible agent is actually a prion or a product of the infection. They are attempting to discover factors that influence prion infectivity and how the TSEs damage the brain. [9] The NINDS hopes to spot factors that impact susceptibility to CJD and that direct when the disease appears, so they can use this knowledge to develop improved tests for CJD.

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[7] FDA-CBER. *BSE.* (Mar. 29, 2001a). [Online] Available: http://www.fda.gov/cber/bse/bse.htm [17 April 2001]

[8] S.Clipper, M. Warren, N. Larsen. *Protein Marker Found in TSEs: Finding May Lead to Diagnostic Test for Human, Cattle Disorders.* (Sept. 25, 1996). [Online] Available: http://www.ninds.nih.gov/news_and_events/pressrelease_transmissible_spongiform_encephalopathies_092596.htm [17 April 2001]

[9] NINDS. *CJD Fact Sheet.* (Jun. 10, 2000). [Online] Available: http://www.ninds.nih.gov/health_and_medical/pubs/creutzfeldt-jakob_disease_fact_sheet.htm [17 April 2001]

National Institute of Allergy and Infectious Diseases (NIAID)

The NIAID is another institute that is a part of NIH. Researchers at the Rocky Mountain Laboratories (RML) in the NIAID conducted a recent study which raises the possibility that resistant animals could act as carriers of the agents that cause BSE or related diseases. [10] This kind of study can bring about adjustment of current policies. Also researchers from the NIAID are making steps in finding a treatment for TSEs. They have recognized a new class of compounds that slows the development of a "mad cow" like prion disease in mice. [11]

Center for Disease Control and Prevention (CDC):

National Center for Infectious Diseases (NCID)

The CDC has established surveillance and investigation programs for suspected CJD cases. CDC conducts surveillance for CJD through examination of death certificate data for U.S. residents for whom CJD was listed as one of the multiple causes of death. Based on this surveillance, during 1979-1993, the annual occurrence of CJD stayed stable at about one case per million persons. [12]

In 1996 an interagency meeting including representatives from the CDC, NIH, FDA, USDA, and the U.S. Department of Defense was held to distribute conclusions from the World Health Organization (WHO) consultation and to coordinate preventive

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[10] John Bowersox. *Resistance and Persistence: Study Raises New Questions About Prion Diseases.* (Sept. 1998). [Online] Available: http://www.niaid.nih.gov/publications/dateline/0998/page6.htm [17 April 2001]

[11] NIAID News. *NIAID Researchers Identify New Drugs to Treat "Mad Cow"-Like Disease in Mice.* (Feb. 24, 2000). [Online] Available: http://www.niaid.nih.gov/newsroom/prionmice.htm [17 April 2001]

[12] CDC. *Surveillance for CJD - U.S.* (CDC - MMWR Weekly. 45(31): 665-668. Aug. 9, 1996). [Online] Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/00043220.htm [17 April 2001]

activities for BSE and CJD. The CDC is also working with its four established Emerging Infections Disease Programs, the Georgia Department of Human Resources, and the Atlanta Metropolitan Active Surveillance Program to direct enhanced surveillance efforts for CJD, including an active search for vCJD. To do this, they are considering an expansion on the current CJD surveillance unit, with the help of the Council of State and Territorial Epidemiologists (CSTE). Also with the support of the CSTE, CDC started an ongoing follow-up review of clinical and neuropathology records of CJD decedents aged less than 55 years who are identified through the national mortality data analysis. Additionally in 1996, the American Association of Neuropathologists (AANP), in collaboration with CDC, alerted its members about the new variant CJD neuropathology and demanded reports of any cases. [13] These surveillance efforts have not found evidence of the occurrence of vCJD in the US.

National Prion Disease Pathology Surveillance Center (NPDPSC) & American Association of Neuropathologists (AANP)

The NPDPSC was established in September 1997, at the Division of Neuropathology of Case Western Reserve University by the American Association of Neuropathologists (AANP). They work in collaboration with the AANP and the Center for Disease Control and Prevention (CDC). The NPDPSC consists of a group of scientists specialized in researching prion diseases. Their purpose is:

> "**1)** to help monitor the possible occurrence of vCJD in the US, **2)** to help establish the diagnosis of prion disease by analyzing cerebrospinal fluid (CSF),

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[13] CDC. *Questions and answers regarding BSE and CJD.* (Jan. 4, 2001). [Online] Available: http://www.cdc.gov/ncidod/diseases/cjd/bse_cjd_qa.htm [17 April 2001]

blood, and brain tissue obtained either by a biopsy or autopsy, **3)** to identify the exact type of prion disease (sporadic or familial) by examining the prion protein and the prion protein gene, once the diagnosis of prion disease has been established, **4)** to transfer the data obtained to the Centers for Disease Control and Prevention (CDC) in order to monitor the prevalence of prion diseases in the USA and investigate possible cases in which the disease has been acquired from other humans or from animals, and **5)** to store tissues for future studies." [14]

US Animal Health Association (USAHA)

The USAHA is a national non-profit organization, which works with state and federal animal health officials, veterinarians, livestock producers, national livestock and poultry organizations, research scientists, the extension service and seven foreign countries to manage livestock diseases in the US. The USAHA serves as a consultant to the USDA and they help in the development and execution of federal laws involved with the inspection of meat and poultry products. [15]

The USAHA requested that USDA-APHIS in collaboration with the States:

"**1.** Establish a herd-certified-status program for CWD in domestic elk, based on the 'Model Program for the Surveillance, Control, and Eradication of Chronic Wasting Disease (CWD) in domestic Elk' by USAHA in 1998.

2. Specifically allocate funds for CWD testing in captive cervids.

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[14] NPDPSC. *Homepage.* (2001). [Online] Available: http://www.cjdsurveillance.com/ [19 April 2001]

[15] USAHA. *Homepage.* (Feb. 2, 2001). [Online] Available: http://www.usaha.org/index.html [19 April 2001]

3. Specifically allocate funds for CWD testing in free-ranging cervids.

4. Conduct thorough epidemiologic investigations of CWD cases." [16]

To pay for these actions, they encourage increased funding of APHIS.

American Association of Veterinary Laboratory Diagnosticians (AAVLD)

AAVLD is an advisor to USAHA on "uniform diagnostic criteria involved in regulatory animal disease programs." Their objective is to establish standardized diagnostic techniques, improve existing ones and develop new ones. They also manage analytic activities of regulatory, research and service laboratories, distribute information relating to the diagnosis of animal diseases and establish regular guidelines for the enhancement of diagnostic lab organizations. [17]

Center for Science in the Public Interest (CSPI)

The CSPI is a consumer group that tries to influence the actions of the USDA, FDA and all other organization involved in BSE policy and research, but is not directly involved with them. [18] They represent the interests of the consumers and push for more enforcement of the policies. In simple terms, they make sure things get done.

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[16] USAHA. *Report of the Committee on Captive Wildlife & Alternative Livestock.* (1999). [Online] Available: http://www.usaha.org/reports/reports99/r99cwal.html [17 April 2001]

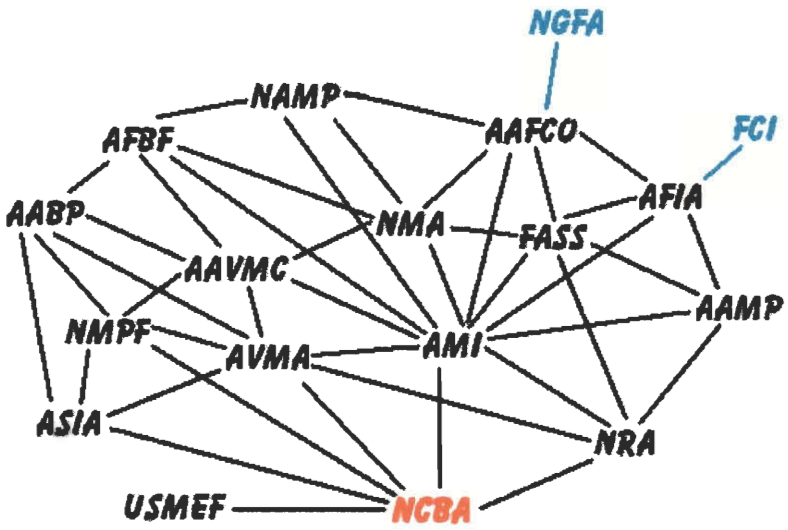
[17] AAVLD. *Homepage.* (Aug. 1, 2000). [Online] Available: http://www.aavld.org/ [17 April 2001]

[18] CSPI. *Homepage.* (2001). [Online] Available: http://www.cspinet.org/ [17 April 2001]

Interest Groups

The National Cattlemen's Beef Association is the nodal point on the "iron triangle" for the interest groups (refer to figure 2).

Figure 2.



It has direct relationships to most of the other interest groups, and then those groups have direct relationships to each other. This node is different from the USDA node, in that it is much more messy and almost everyone has a relationship to each other and have similar interests. They comply with the current policies in place and try to improve them and add more suggestions and make programs to enforce the policies. These interest groups are all involved to represent each of their interests. The interests of the farmers, processors, renderer's, etc. are represented.

Official Statement made by the following:

The National Cattlemen's Beef Association, American Feed Industry Association, American Veterinary Medical Association, American Meat Institute, National Meat

Association, National Renderers Association, North American Meat Processors Association, National Milk Producers Federation, American Farm Bureau Federation, American Association of Meat Processors, Federation of Animal Science Societies, and National Grain and Feed Association

> "As representatives of cattle producers, feed manufacturers, renderers, processors and veterinarians, we reaffirm our commitment to effective implementation and enforcement of sound, science-based measures to prevent BSE in the United States. This includes import restrictions, feed bans, and active surveillance. Three components of BSE prevention that remain the highest priority of industry and government are: 1) Strict enforcement of import restrictions designed to keep the BSE agent out of the U.S., 2) To achieve 100% compliance with the FDA feed ban, and 3) Continued support for active USDA BSE surveillance in the U.S. We pledge our continued vigilance and commitment to BSE prevention in the U.S." [1]

American Meat Institute (AMI)

The AMI represents the interests of the U.S. meat and poultry industry to the federal government, Congress, the media and the customer. The representatives are leaders in both the supplier and packer/processor parts of the industry. The AMI has policy committees and advisory committees within its membership to allow member companies to propose AMI policies in their main areas of interest. Policy committees focus on "broad functional and operational areas and develop policy recommendations

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[1] AFIA. *Joint Industry Statement on BSE.* (Jan. 29, 2001b). [Online] Available: http://www.afia.org/News.html?Source=/Archive/2001/1/31-15862.html [18 April 2001]

for specific issues within these areas." [2] Advisory committees give specialized advice to policy committees.

"The AMI Foundation is a nonprofit organization dedicated to scientific and economic research, education and information that benefit the meat and poultry industry. The AMI Foundation seeks grants from government, industry and other organizations to fund a varied range of food safety, worker safety, nutrition and consumer information projects." [3]

National Meat Association (NMA)

The NMA is an association, which tries to ensure that regulations are fairly implemented, that information is evenly distributed and that nothing is overlooked. The NMA's mission is to promote the interests of the meat industry in federal regulatory issues and national lawmaking that affects the industry. The officials visit Washington D.C. once a year to speak with Senators, Congressmen and the USDA in person. In order to achieve 100 percent compliance with the regulations and keep its member's businesses booming, the NMA helps its members to follow the guidelines for producing safe food in a competitive market environment, by giving them more information and consulting them. [4]

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[2] AMI. *Who We Are*. (2001). [Online] Available: http://www.meatami.com/content/AboutAMI/Organization/whoweare.htm [18 April 2001]

[3] AMI. *U.S. is well positioned to prevent BSE, meat scientist says.* (Apr. 4, 2001). [Online] Available: http://www.meatami.com/Template.cfm?Section=Current&NavMenuID=274&template=PressReleaseDisplay.cfm&PressReleaseID=424 [18 April 2001]

[4] NMA. *About NMA*. (2001) [Online] Available: http://www.nmaonline.org/ABOUT_NMA/about_nma.html [18 April 2001]

Animal Industry Foundation (AIF)

The AIF sponsors and encourages scientific research on animal well-being, production techniques and feed and food safety. [5]

Animal Protein Producers Industry (APPI)

The APPI is a non-profit industry corporation, which has several functions.

> "1) To promote and increase production. 2) To produce safe animal by-products by improving the microbiological & chemical quality of feed fat & animal proteins. 3) To develop and spread educational materials and conduct seminars on rendering plant sanitation. 4) To take part in all other lawful trade association activities on behalf of the membership. The APPI is the biosecurity arm of the North American Rendering Industry." [6]

The Industry also funds and takes part in research projects related to disease issues of interest to the industry. In order to give their perspective on regulations, laws, and policies that affect the industry. In order to give their perspective on regulations, laws and policies that affect the industry, they serve as a contact with the Center for Veterinary Medicine of the FDA, the USDA, and the USAHA; serving on government/industry task forces. They also serve as "a resource to the Fats and Proteins Research Foundation

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[5] AIF. *About AIF*. (Jun. 7, 2000). [Online] Available: http://www.aif.org/ [18 April 2001]

[6] APPI. *Association Profile*. (Apr. 3, 2001). [Online] Available: http://www.animalprotein.org/ [18 April 2001]

(FPRF) to objectify research in the area of biosecurity and serve as a professional collaborator in the planning and oversight of that research." [7]

The Board of Directors of the APPI voted on February 16th, 2001, to increase the "guarantee of compliance," for producers of animal protein ingredients, with the feed ban, since they were not complying 100%. [8]

North American Meat Processor's Association (NAMP)

"The NAMP is a non-profit trade association consisting of meat processing companies and associates, who try to provide their foodservice customers with reliable and consistent meat, poultry, seafood, game and other food products." [9] NAMP also provides support programs, services and governmental representation to their members to ensure the success of their businesses. They keep an eye on developing lawmaking and regulations that could negatively affect the meat processing industry and they provide their members with a voice in the public policy process. [10]

National Milk Producers Federation (NMPF)

The NMPF is a farm commodity organization that represents most of the dairy marketing cooperatives in the U.S. NMPF members market a majority of the milk

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[7] APPI, Apr. 3, 2001.

[8] APPI. *The APPI Responds To BSE Concerns: Recommends Immediate Third Party Action.* (Feb. 21, 2001). [Online] Available: http://www.animalprotein.org/new/whatsnew_frm.htm [18 April 2001]

[9] NAMP. *About NAMPA.* (2001a). [Online] Available: http://www.namp.com/about/index.html [18 April 2001]

[10] NAMP. *Government Relations.* (2001b). [Online] Available: http://www.namp.com/news/index.html [18 April 2001]

produced in the U.S., so the NMPF is a fairly effective voice on national issues for dairy cooperations and their dairy farmer members. The NMPF gives their members a forum through which they formulate policy on national issues that effect milk production and marketing. "NMPF's mission is to improve the economic welfare of dairy farmers, thus assuring the nation's consumers a sufficient supply of pure, wholesome milk and dairy products." [11] The NMPF claims that the policy positions expressed by them are "the only nationwide expression of dairy farmers and their cooperatives on national public policy." [12] In addition, lots of the staff's time at NMPF is spent on developing, understanding, and helping members comply with animal and product regulations. [13]

American Farm Bureau Federation (AFBF)

The Farm Bureau represents farmers and ranchers at local meetings, state legislatures and in Washington D.C. The AFBF's goal is "to put into effect policies that members developed and provide programs that will improve the financial well-being and quality of life for farmers and ranchers." [14]American Farm Bureau's Governmental Relations team (based in Washington D.C.) is made up of registered lobbyists who are specialists on Farm Bureau issues. The Public Policy team is responsible for research, education and policy support for AFBF and the state Farm Bureaus. "Their staff gives

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[11] NMPF. *Mission.* (2001b). [Online] Available: http://www.nmpf.org/about/index.cfm [18 April 2001]

[12] NMPF, 2001b.

[13] NMPF. *Dairy Industry Fact Sheet on Mad Cow Disease.* (2001a). [Online] Available: http://www.nmpf.org/files/DAIRY_INDUSTRY_FACT_SHEET_ON_MAD_COW_DISEASE.htm [18 April 2001]

[14] AFBF. *The Voice of Agriculture: About Farm Bureau.* (Jan. 18, 2001). [Online] Available: http://www.fb.org/about/thisis/ [18 April 2001]

information and analysis on current issues such as health care, animal welfare, farm programs, and dairy policy." [15]

In order to be able to guarantee the safety of American beef, the AFBF is urging livestock and government officials to find and destroy all British imported cattle found on U.S. farms and to provide adequate compensation to the owners. [16]

American Association of Meat Processors (AAMP)

The AAMP is North America's largest meat trade organization. They help their members with regulatory and legislative affairs. This is one of their most important functions because the meat industry is one of the most heavily regulated in the U.S. It must function under a network of laws and regulations set by Congress, the USDA, FDA, OSHA, and the DOL including employment regulations, and the Environmental Protection Agency (EPA). "The AAMP also provides its members with government representation and watches legislation that Congress proposes which affects the meat and poultry business." [17] Members also speak at hearings about how proposals would affect their business.

Federation of Animal Science Societies (FASS)

FASS's Goals are:

"1) To provide a forum for the societies to discuss common issues and to make plans of action to meet public needs and benefit animal agriculture. 2) To finance

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[15] AFBF, Jan. 18, 2001.

[16] D. Lane, D. Kelly. *Farm Bureau Urges Destruction of British-Imported Cattle.* (Apr. 10, 1996). [Online] Available: http://www.fb.org/news/nr/nr96/nr0410.html [18 April 2001]

an annual Congressional Science Fellowship Program that identifies an individual that will work with Congress on the main issues of interest to animal agriculture. 3) To identify and address research priorities in animal agriculture." [18]

One research priority they promote is research on the mechanism of development of TSEs in wildlife and transfer of TSEs between animal species. Another major area of research is in consumer education on the handling of animal food products.

"4) To offer a stronger unified voice in Washington, D.C. to influence legislation and funding on behalf of animal agriculture. 5) To promote cooperation among scientific societies, those who promote and support animal agriculture." [19]

They promote education and research on animal agriculture by bringing together scientists and educators in animal agriculture represented by the Member Societies. The scientific and technical information is spread through publications and scientific meetings. [20]

American Association of Bovine Practitioners (AABP)

The AABP are associated with the American Veterinary Medical Association (AVMA). It is an international association of veterinarians interested in bovine medicine. It tries to enhance the professional lives of its members through "continuing education that will better the well-being of cattle and the economic success of the owners, increase

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[17] AAMP. *Regulatory Affairs.* (2001). [Online] Available: http://www.aamp.com/reg.html [18 April 2001]

[18] W. Sandine, C.B. Theurer, J. Van Horn. *FASS History.* (Apr. 9, 2001). [Online] Available: http://www.fass.org/ [18 April 2001]

[19] W. Sandine, C.B. Theurer, J. Van Horn, Apr. 9, 2001.

[20] W. Sandine, C.B. Theurer, J. Van Horn, Apr. 9, 2001.

awareness and promote leadership for issues critical to cattle industries, and improve opportunities for careers in bovine medicine." [21]

The AABP monitors and reviews issues of interest on bovine food product safety concerns, and provides information and formulates recommendations on food safety issues to which AABP action may be in the best interest of its members. As a means of information exchange, the AABP:

> "1) Assures that liaison and cooperation exist with the AVMA through its appropriate Divisions, Staff, Councils and Committees. 2) Assures liaison with other food animal commodity organizations. 3) Assures liaison with appropriate Federal and State entities that affect food safety issues." [22]

Association of American Veterinary Medical Colleges (AAVMC)

The AAVMC tries to improve food safety and addresses society's concerns about it. Their goal is "to advance veterinary medical education, enhance animal health and well-being, strengthen biomedical research, and nurture environmental quality." [23]

American Sheep Industry Association (ASI)

The ASI are lobbyists for the sheep industry. Some of their goals that possibly pertain to TSEs are:

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[21] AABP. *Organization: General Information*. (2001b). [Online] Available: http://www.aabp.org/indexes/main.cfm?ID=1&objectID=392&page=EWorkGroup/default.cfm [18 April 2001]

[22] AABP. *AABP Committees: Food Safety*. (2001a). [Online] Available: http://www.aabp.org/indexes/main.cfm?ID=1&objectID=392&page=EWorkGroup/default.cfm [18 April 2001]

[23] AAVMC. *Mission of the AAVMC*. (2001). [Online] Available: http://aavmc.org/purpose.htm [18 April 2001]

"1) To advance and manage the science and technology of production, management and marketing of sheep, goats and their products. 2) To inform the industry of advancements in research. 3) To promote communication and cooperation between all segments of the industry, related businesses and government agencies. 4) To advocate for and affect public policy that protects, promotes and supports the economic capability of the industry, particularly the producer sector. 5) To be a strong, unified and recognized voice for sheep and goat producers before the government on all issues that affect production, from the environment to country-of-origin labeling, and animal health and food safety."[24]

Association of American Feed Control Officials (AAFCO)

"The basic goal of AAFCO is to provide a system for developing and implementing standardized and reasonable laws, regulations, standards and enforcement policies for regulating the manufacture, distribution and sale of animal feeds, resulting in safe, effective, and useful feeds." [25] The association unifies officials of any state, dominion, federal or other governmental agency and "employees who are charged with a responsibility in enforcing the laws regulating the production, labeling, distribution, or sale of animal feeds or livestock remedies." [26]

The AAFCO supports the enforcement of the feed regulation that prohibits the feeding of ruminant-derived protein to ruminants. They maintain regular contact with the

[24] ASI. *About ASI.* (2001). [Online] Available: http://www.sheepusa.org/ [18 April 2001]

[25] AAFCO. *Homepage.* (2001a). [Online] Available: http://www.aafco.org/ [18 April 2001]
[26] AAFCO, 2001a.

FDA and USDA because the enforcement crosses numerous jurisdictional responsibilities. [27]

American Feed Industry Association (AFIA) & Facility Certification Institute (FCI)

"The AFIA deals regularly with Congress, Environmental Protection Agency, FDA, AAFCO, OSHA, USDA, and other state and federal government agencies to improve the business, lawmaking and regulatory outlook for the feed and pet food industries and their suppliers." [28] One of the activities of the AFIA is to determine from FDA's records which agencies are not doing the BSE inspections. The AFIA then contacts their states and tells on them. Some states have said that lack of inspection resources might be a deciding factor in participating in this program. Therefore, the AFIA urges the FDA to fund this program. They plan to ask the FDA Commissioner and the Congress to fully fund inspections.

The AFIA has launched a new Facility Certification Institute (FCI). Creation of the institute came about as the result of two measures adopted by the AFIA Board of Directors. One advocated the voluntary withdrawal of ruminant-derived meat and bone meal byproducts from facilities that produce feed for ruminant animals. The other measure pertained to the establishment of a certification program. It has programs for endorsing compliance with the FDA's regulation governing the mammalian protein feeding prohibition. The new institute gives facilities the means to obtain credible documentation of compliance with federal rules. The plan incorporates FDA's inspection

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[27] AAFCO. *Policy Statement Regarding the BSE Feed Regulation.* (2001b). [Online] Available: http://www.aafco.org/bse.htm [18 April 2001]

[28] AFIA. *AFIA Strongly Encourages Completion of Industry Inspections.* (Jan. 29, 2001a). [Online] Available: http://www.afia.org/index.html?Source=/Archive/2001/2/2-29690.html [18 April 2001]

program for meeting requirements of the BSE feed regulation. FCI with independent agents inspects facilities that use restricted protein products as well as those which do not. The agents review procedures, examine records and issue certifications to those facilities successfully meeting the program requirements. Many producers and meat packers are requiring third party certification that cattle they are receiving have not been fed restricted use proteins. The FCI's program provides this documentation. [29]

National Grain and Feed Association (NGFA)

"The NGFA hopes to foster an efficient free market environment that achieves an adequate, safe, and high-quality food supply for domestic and world consumers. They accomplish this through representation of member interests in front of government and other entities, plus effective education and communication to members, the public and government." [30] The NGFA has developed the first industry wide feed quality assurance program and educational workshops. They also work with the FDA and state feed control officials on feed regulatory issues.

The NGFA uses science-based measures to prevent the BSE agent from entering the U.S., including strict enforcement of import restrictions. The NGFA supports the FDA's regulations that prohibit the feeding of ruminant-derived protein to cattle and other ruminant animals. However, consistently with its belief in science-based standards, the NGFA fully supports the continued use of ruminant-derived protein as a safe, nutritious

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[29] AFIA. *AFIA Creates Facility Certification Institute, Offers Compliance Proof with BSE Regulation.* (2001). [Online] Available: http://www.afia.org/News.html?Source=/Archive/2001/3/22-75784.html [18 April 2001]

[30] NGFA. *What it Is, Who it Represents and What it Does.* (2001). [Online] Available: http://www.ngfa.org/ngfaprofile.htm [18 April 2001]

and wholesome feed ingredient for non-ruminant species, for which it is legally approved. [31]

"The NGFA recommends that FDA develop a statistically valid random inspection program that traces the movement and use of ruminant-derived protein forward from rendering plants through the supply chain to facilitate continued compliance with the agency's BSE-prevention rule." [32] They support all efforts to prevent BSE.

"To further reassure consumers, the NGFA works with other involved parties to provide a way through which feed manufacturers can affirm their compliance with FDA's BSE-prevention regulations on the basis of existing government-based inspections." [33] In particular, the NGFA works to encourage marketplace acceptance of individual company-to-company guarantees. The NGFA states they will "continue their intensive ongoing BSE-prevention education, training and information efforts, in cooperation with its 38 affiliated State and Regional Grain and Feed Associations, to complement the efforts of government and industry to ensure a continued safe, abundant and wholesome food supply." [34]

National Cattlemen's Beef Association (NCBA)

The NCBA Policy Division oversees policy-making, governmental affairs and related activities financed by sources other than the beef council check off, which monitors all beef transactions. It represents more than 230,000 cattle breeders, producers

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[31] NGFA. *Policy Statement of the NGFA Concerning Efforts to Prevent BSE in the U.S.* (Mar. 16, 2001). [Online] Available: http://www.ngfa.org/3-20-BSE-PreventionPolicyStatement.htm [18 April 2001]

[32] NGFA, Mar. 16, 2001.
[33] NGFA, Mar. 16, 2001.
[34] NGFA, Mar. 16, 2001.

and feeders. "The NCBA works to improve the economic, political and social interests of the U.S. cattle business and to be a promoter for the cattle industry's policy positions and economic interests. Through research and educational programs, the NCBA ensures that consumers have confidence in the safety of beef." [35]

The NCBA works with our government, the feed industry, the rendering industry, processors and veterinarians to ensure full compliance with all measures to prevent BSE. [36] The NCBA is working insistently to educate reporters and the public about BSE and steps the industry and government have taken to prevent the disease from entering the U.S. The NCBA spokespersons have done many interviews with network and cable television, newspaper and radio reporters. They also set up a very helpful website called BSEinfo. It is coordinating with USDA/APHIS to assist in acquiring the remaining imported animals and getting rid of them. They support the feed regulation that prohibits ruminant-derived protein to be fed to ruminants (cud-chewing animals such as cattle, goats, camels and deer that have a four-chambered stomach). [37]

U.S. Meat Export Federation (USMEF)

"The USMEF is a non-profit trade association working to create new opportunities and develop existing international markets for U.S. beef, pork, lamb and veal." [38] The USMEF has eight distinct sectors, representing the entire U.S. production,

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[35] NCBA. *Homepage.* (2001). [Online] Available: http://www.beef.org/groups/ncba/ [18 April 2001]

[36] NCBA. *Statement Regarding Efforts to Prevent BSE.* (Feb. 2, 2001). [Online] Available: http://www.beef.org/newsroom/bse/ncba01_0202.htm [18 April 2001]

[37] NCBA. *Mad Cow Disease Not a Problem in the U.S.* (Dec. 6, 2000). [Online] Available: http://www.beef.org/newsroom/ncba/2000/ncba00_1206a.htm [18 April 2001]

[38] USMEF. *What We Do.* (2001). [Online] Available: http://www.usmef.org/about/about.cfm [18 April 2001]

processing and distribution system. Allied industries, which provide valuable inputs to the red meat industry, are also active on the USMEF Board of Directors. The USMEF gets funding and support from USDA, exporting companies and the beef, pork, corn, sorghum and soybean check off programs.

Food Safety Consortium (FSC)

The FSC consists of researchers from the University of Arkansas, Iowa State University and Kansas State University. Congress established the Consortium in 1988. The Consortium's responsibility is "to conduct wide-ranging investigations into all areas of poultry, beef and pork meat production, from the farm to the consumer's table." [39] Each of the university members of the Consortium is mainly performing research related to the specific animal species for which that university is uniquely qualified. Researchers at Kansas State University are the think tank focusing on beef research. [40]

American Veterinary Medical Association (AVMA)

In 1996, the AVMA was one of the first organizations to push for the establishment of an aggressive voluntary program to assure that ruminant-derived protein is no longer used in ruminant feed products. The voluntary ban became official government policy in 1997. "The AVMA is an active voice in food safety and aggressive animal disease surveillance and prevention. The veterinarian is the first line of defense in the diagnosis, treatment, and prevention of animal disease." [41]

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[39] FSC. *Homepage.* (2001). [Online] Available: http://www.uark.edu/depts/fsc/ [18 April 2001]

[40] FSC, 2001.

[41] AVMA. *Veterinarians Reaffirm Commitment to Keeping U.S. Free of BSE.* (Jan. 29, 2001). [Online] Available: http://www.avma.org/press/pibse01.asp [18 April 2001]

The objective of the association is to improve the science of veterinary medicine, including its relationship to public health, biological science, and agriculture. The association is the authorized voice for the profession (including individual vets) in presenting its views to government, academia, agriculture, pet owners, the media, and other concerned publics. [42] "The AVMA council studies problems and recommends appropriate action to the policy-making and governing bodies." [43]

The AVMA with other organizations urges continued attention and commitment to BSE prevention in the U.S. In a joint statement, the association said:

> "To preserve the preeminent health of the U.S. cattle herd, 3 components of BSE prevention should remain the highest priority of industry and government. 1) Strict enforcement of import restrictions designed to keep the BSE agent out of the U.S. 2) To achieve 100% compliance with the FDA feed ban. 3) Continued support for active USDA BSE surveillance in the U.S." [44]

In Washington, the AVMA continues to interact with producer organizations relative to the BSE issue and ensures that accurate, scientifically based information is spread to the news media. The AVMA met with the NCBA, American Meat Institute, and National Renderers Association in this regard. [45]

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[42] AVMA. *About the AVMA.* (2001a). [Online] Available: http://www.avma.org/membshp/about.asp [18 April 2001]

[43] AVMA. *AVMA sponsors activities and programs for your professional development.* (2001b). [Online] Available: http://www.avma.org/membshp/membap.asp [18 April 2001]

[44] AVMA, Jan. 29, 2001.

[45] Susan C. Kahler. *BSE Emergency Meeting Inspires Confidence over US Safeguards.* (1998). [Online] Available: http://www.avma.org/pubhlth/madcow2.html [18 April 2001]

USA Policies

CJD is currently a deadly incurable disease, which can be contracted just by eating infected meat. Due to this, countries around the world have instated policies and regulations on the cattle industry. They are meant to protect humans from getting CJD and vCJD, and to eliminate BSE from the bovine population. The U.S. policies were made by federal agencies like the USDA, FDA, CDC, and by state regulatory and health agencies with their main objective being prevention. [1] They made these policies using the scientific knowledge they had about the disease at this time. These regulations cover all the routes that could lead to BSE infection in the USA: imports, contaminated feed, contaminated vaccines, infected blood donations, and non-compliance with the regulations. Some may seem extreme to people who do not have much knowledge about the history and biology of BSE. However, when one looks at how BSE spread from the UK to mainland Europe, the implications of BSE in the U.K., and the victims of vCJD one will see that all the actions the USA has taken to prevent BSE are completely justified.

Feed and Inspections

In August 1997, the FDA made a feed regulation in order to make sure that animal feeds are safe and produce no human health hazards when used in food-producing animals. The regulation prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants and requires manufacturers to use suitable processes and control systems to ensure that feed for ruminants does not contain the prohibited

[1] Linda, Bren. *Trying to keep "Mad Cow Disease" out of U.S. herds*. (FDA Consumer Magazine, Mar.-Apr. 2001). [Online] Available: http://www.fda.gov/fdac/features/2001/201_cow.html [17 April 2001]

mammalian tissue. [2] They forbid this because even though the mammalian protein did not come from another country, it can still have scrapie or some other TSE, which can cause BSE in cows if fed to them (this is said to be the most likely way cows got BSE in the UK). "Renderers, cattle ranchers, feed manufacturers, feed lot operators, and state and federal government agencies will all have to continue to work together to assure safe cattle-feeding practices are thoroughly followed. This is our first line of defense against the disease getting into American cattle herds." [3]

With the support and cooperation of all these groups of people involved in the cattle and feed business, the FDA started a compliance, education and inspection program. "The FDA and state regulators have conducted nearly 10,000 inspections of renderers, feed mills, ruminant feeders, dairy farms, protein blenders, feed haulers, and distributors since January 1998. More than 3/4 of these establishments were found to be in compliance." [4] The establishments that were found non-compliant became compliant and were re-inspected to make sure they stayed that way. After an evaluation of the inspections made between 1998 and 2000, the FDA will revise its compliance strategy. They hope to better their tactics so that they will end up with 100 percent compliance with the feeding regulations. Additionally, education is also an extremely important part of the compliance program. Workshops for state veterinarians and feed control officials from the U.S., Puerto Rico, U.S. Virgin Islands, and Canada have been sponsored by the FDA. They provide information on the regulation and what is expected of those to whom the regulation applies, through an interactive CD-ROM they developed. The FDA has

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[2] FDA. *BSE: Background, current concerns, and U.S. response.* (Mar. 1, 2001). [Online] Available: http://www.fda.gov/opacom/backgrounders/bse.html [17 April 2001]
[3] Linda, Bren.
[4] Linda, Bren.

also held briefing sessions with trade associations and consumer groups. [5] They help these groups comply with the regulation and explain why it is necessary.

Imports

Since 1989 the USDA's Animal and Plant Health Inspection Service (APHIS), has prohibited the import of live ruminants (cattle, sheep, goats) and most ruminant products from countries where BSE has been reported. [6] In 1991, the USA first became very concerned about the safety of bovine sourced material because of the increasing number of BSE in the UK. In 1993, the FDA issued the first letter advising that bovine-derived materials from animals born in or residing in countries where BSE had occurred should not be used to manufacture FDA-regulated products intended for human use or consumption. [7] The products can be food, vaccines or fats. The only bovine materials that could be imported from those countries were under special permit for scientific, educational or research purposes, or under special conditions to be used in cosmetics. In 1997, APHIS extended the import ban temporarily to include all of Europe until a thorough evaluation of the risks could be made. The reason for the action is that there is evidence that European countries may have had high BSE risk factors for several years and less-than-adequate surveillance. This decision was made to protect human and animal health, to ensure the security of U.S. export markets, and to protect the safety and the integrity of our food supply. [8] "On December 7, 2000, APHIS banned all imports of

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[5] Linda, Bren.
[6] Linda, Bren.

[7] FDA-CBER. *Summary of CBER Policies on BSE.* (Apr. 16, 2001). [Online] Available: http://www.fda.gov/cber/summaries/bse041601me.htm [1 July 2001]

[8] USDA-APHIS. *BSE.* (Jan. 2001). [Online] Available: http://www.aphis.usda.gov/oa/pubs/fsbse.html [17 April 2001]

rendered animal proteins, regardless of species, from the more than 30 countries that either are known to have BSE in their cattle or present excessive risk for introducing BSE here." [9] That year, the USDA list of BSE-countries expanded to include countries where BSE might exist but has not yet been found. They did this because BSE has a long incubation period and it is possible that the BSE is there but will show up in a couple months or years. As an additional precaution, the FDA announced "an import alert which lets its inspectors delay shipments of animal feed, animal feed ingredients, and certain other products of animal origin intended for animal use, from these countries." [10] This action was taken by the USDA and FDA to prevent potentially cross-contaminated products from entering the U.S. This measure may seem extreme to some, but it really is not if one considers the probability of outbreak there and the devastating effects it could have, like it has in the UK.

Vaccines

The regulations affected vaccine manufacture too, since bovine materials are used in some vaccines. Just last year, a review of new license applications showed that some material used during manufacture of a vaccine came from countries on the USDA, BSE list. This provoked an inquiry about all licensed vaccines. To assess the risk of disease that might result from a vaccine manufactured with a process that uses bovine materials potentially contaminated with the BSE agent, CBER performed risk evaluations and organized a special joint meeting. [11] The meeting was with the Transmissible Spongiform

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[9] Linda, Bren.

[10] Linda, Bren.

[11] FDA-CBER. *BSE*. (Mar. 29, 2001a). [Online] Available: http://www.fda.gov/cber/bse/bse.htm [17 April 2001]

Encephalopathy Advisory Committee and the Vaccines and Related Biological Products Advisory Committee in July 2000. The joint Committees concluded that the risk of vCJD posed by vaccines was theoretical and unlikely. They also noted that "the benefits of vaccination far outweigh any remote risks of vCJD." Nevertheless, to make certain of the safety of vaccines and other biologics the CBER issued letters to the manufacturers of drugs, biologics, vaccines and medical devices directing them that "in the manufacture of FDA-regulated products intended for human use, they should not use materials derived from cattle born, raised or slaughtered in countries where BSE is known to exist." [12] The manufacturers have to evaluate all bovine material used at any stage of manufacture and identify all other material of animal origin. If they identify prohibited material, they must change the source of that material." [13] The actions of the CBER are precautionary and have been taken to reduce even the slightest risk of vCJD and to maintain public confidence in the safety of vaccines

Blood Supply

In 1995, the FDA took action to make sure the blood supply was not infected with CJD or vCJD. They added recommendations to defer blood donors at increased risk of CJD, which are those with a family history of CJD or receipt of a dura mater graft. In 1996, the FDA issued a Memo to all Registered Blood Establishments and Plasma Establishments to "quarantine and destroy all whole blood and blood components, including plasma, plasma derivatives, and transfusion products prepared from donors who were later recognized to be at increased risk of developing CJD or who were

[12] FDA-CBER. *Questions and answers on BSE.* (Mar. 29, 2001b) [Online] Available: http://www.fda.gov/cber/bse/bseqa.htm [17 April 2001]

[13] FDA-CBER (Apr. 16, 2001).

subsequently diagnosed with CJD." [14] In 1998, based on a decision of the Surgeon General and new scientific tests, the FDA modified its policy regarding blood donations. Plasma derivatives from donors with "classic" forms of CJD (not related to BSE like vCJD is) would no longer be withdrawn, but donors would still be permanently deferred and any of their previously donated blood and blood components still in inventory would be retrieved and not used. This modified policy is considered reasonable because transmission of "classic" CJD by human blood has never been convincingly documented. Also, "the process of fractionating plasma was demonstrated to remove very large amounts of infectivity from blood experimentally infected with the agents of forms of "classic " CJD. [15] These unnecessary blood withdrawals were contributing to a serious shortage of some important plasma derivatives. This recognition of severity in the original policy shows how the USA adjusts its policies when new information becomes known. The FDA continued to recommend that only all pooled plasma, manufacturing intermediates and finished plasma derivatives, from any donor later diagnosed with vCJD, should be withdrawn. Currently, no case of vCJD has been confirmed in the USA.

Although it has not been proved, health experts fear that there is a good probability that people who have eaten contaminated beef might transmit the vCJD through donated blood. As a result, in 1999, the FDA added as an additional precaution that, potential blood donors be deferred from donating blood if they had resided in the UK for a period of six months or more from January 1980 to the end of 1996, since it is the country with by far the highest incidence of BSE and vCJD. Earlier this year, the

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[14] FDA-CBER (Apr. 16, 2001).

[15] FDA-CBER (Apr. 16, 2001).

FDA banned donations from anyone who has lived in France or Portugal for a total of 10 years since 1980. The Red Cross, which collects about half of the 13 million units of blood used annually in the U.S., wants even tougher restrictions. Their proposed restrictions forbid donations from "anyone who lived in Europe for any period of six months since 1980, or three months in the United Kingdom." [16] America's Blood Centers, a network of community blood centers, also wants to ban people who have spent three months or more in the United Kingdom from 1980 to 1996. It is estimated that the Red Cross plan would cause a 9 percent decrease in available blood units, but would be eliminating 92 percent of the risk of collecting blood infected with vCJD. The Red Cross is supposed to start with its plans this fall. Jackie Fredericks said, "We believe our donor deferral plan is cautious and prudent." Also, the Red Cross will start a national drive to recruit new donors. [17]

On June, 29, 2001, the FDA Advisory committee approved a proposal by a vote of 10-7. The FDA proposal extends the ban to include donors who have lived five years or more in Europe from 1980 until now, or who have spent a total of three months in the U.K. from 1980 through the end of 1996. Additionally, the proposal recommends that "American military personnel or dependents who have spent six months or more on a base in Europe from the years 1980 through the end of 1996 be excluded from blood donation. Also excluded would be people who have received blood transfusions in

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[16] CNN. *FDA Studies Mad Cow, Donated Blood.* (Jun. 28, 2001). [Online] Available: http://www.cnn.com/2001/HEALTH/06/28/mad.cow.blood.ap/index.html. [9 July 2001]

[17] CNN. *Advisory Committee Recommends Tighter Restrictions on Blood Donors.* (Jun. 29, 2001). [Online] Available: http://www.cnn.com/2001/HEALTH/06/28/madcow.blood.ap/index.html. [9 July 2001]

Britain any time from 1980 to the present." [18] Knowing that there are concerns about a great reduction of blood supply, especially in New York City, the committee added an amendment that calls for a national donor recruitment campaign.

It is challenging to find a good intermediate between protecting the blood supply from BSE and providing sufficient blood for medical use. Yes, it is not good if we have a shortage, but would we rather have infected blood just to not have a shortage of nine percent. Plus, the shortage should not last long since the U.S. is taking steps to recruit new donors, with healthy blood. So far, FDA inspections show that manufacturing companies have consistently tried to comply with donor deferral recommendations that the FDA gave them.

Surveillance

In 1990, APHIS started a program to actively monitor certain American cows for signs of BSE. The USDA surveillance program finds cows that show signs of neurological problems at slaughter, and condemns and tests them. One of the most important parts of the surveillance program is the training of veterinary practitioners by the USDA in the clinical signs, diagnosis and sample submission of BSE. [19] BSE fact sheets, risk assessments, and reviews have also been sent to State and Federal veterinarians, private practitioners, other industries, and to producers. Any animals displaying the signs are condemned, and the meat is banned from use in human food. [20]

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[18] CNN, (Jun. 29, 2001).

[19] USDA - APHIS. *USDA Actions to Prevent BSE.* (Apr. 1998). [Online] Available: http://www.aphis.usda.gov/oa/bse/bsechron.html [17 April 2001]

[20] USDA - APHIS. *BSE.* (2001). [Online] Available: http://www.aphis.usda.gov/oa/bse/ [17 April 2001]

The infected animal brains are submitted to USDA's National Veterinary Services Laboratories (NVSL) for analysis. As of October 2000, approximately 12,000 cattle brains from the U.S. and Puerto Rico had been examined, with no evidence of BSE found. There are more than 60 diagnostic laboratories in the U.S. which continue to dissect hundreds of cattle brains each year, making sure the neurological disease they had was not BSE. [21]

BSE Response Plan

BSE has affected animal and public health and international trade. As a result, this has brought great attention to the U.S. Government's accountability for a safe food supply. So far, the U.S. Government proven it has efficient policies in place for BSE. In the 14 years since it has broken out in the U.K., there have been no confirmed cases of it or vCJD here. The surveillance program we have in place allows for the quick detection of BSE in the U.S. if it were to happen. As an emergency preparedness measure, the USDA put together a BSE response team in 1990 that made a BSE Response Plan to be initiated if a BSE case were to be detected in the U.S. The plan is regularly updated as new information becomes evident. The plan shows how the USDA has not only set regulations and programs to prevent BSE here, but has also prepared a response plan in the event that something goes wrong and BSE is detected here. The plan gives instructions "to USDA staff as to who is to do what, when, where, and how." [22] In 1996,

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[21] Linda, Bren.
[22] USDA – APHIS. *BSE Response Plan.* (Oct. 1998). [Online] Available: http://www.aphis.usda.gov/oa/bse/bsesum.pdf [10 July 2001]

after the U.K. announced that BSE is linked to vCJD, the response team revised the response plan, realizing they needed to address communication issues within the USDA, the Federal Government and the public. The members that make up the BSE response team were picked carefully to represent a variety of issues concerning BSE. The members represent veterinary medicine, food safety, public health, epidemiology, pathology, international trade, and public affairs. Two leaders coordinate them, one from APHIS and the other from FSIS. They share their plan with the FDA, CDC, NIH and others like the Animal Agricultural Coalition. [23]

The BSE response Plan is not initiated until after a series of events that confirm we have BSE here. First, an animal has to be identified by a veterinary pathologist or field investigator from APHIS or FSIS, to be a suspect for BSE. It is prohibited from slaughter, and referred to APHIS for examination. Second, "pathologists at APHIS' National Veterinary Services Laboratories (NVSL) histopathologically examine the brain of the condemned animal." [24] NVSL has 14 to 18 days to confirm a diagnosis of BSE. Third, if the additional tests show it is BSE, a NVSL pathologist carries the sample to the U.K. for confirmation. At this point, when the pathologist is on his way to the U.K. for confirmation, the BSE Response Plan is initiated.

The NVSL director first notifies the APHIS, Veterinary Services (VS) deputy administrator. APHIS then receives a notification from the U.K. confirming NVSL's diagnosis within 24-96 hours. APHIS and FSIS field activities are started. The NVSL continues to provide laboratory support and serves as a contact with the U.K. lab. The

[23] USDA – APHIS, (Oct. 1998).
[24] USDA – APHIS, (Oct. 1998).

NVSL starts to process additional samples from the infected animal's progeny and herd mates. The APHIS' VS deputy administrator notifies the FSIS, Office of Public Health and Science (OPHS) deputy administrator. These two deputy administrators then together inform the BSE response team and tell them to assemble and also notify the VS regional director of the state the animal came from. The deputy administrators are a liaison between the BSE response team and the APHIS administrator. The APHIS administrator notifies the USDA Assistant Secretary for Marketing and Regulatory Programs. The administrator also secures compensation funds for depopulation of the herd. He then sends an official memorandum from the administrator (prepared by the BSE response team), through the Assistant Secretary of Marketing and Regulatory Programs and the Undersecretary for Food Safety, to the Secretary of Agriculture. The Secretary of Agriculture then has the authority to declare a Federal emergency and approve funding as necessary. The APHIS regional director in charge of the affected state notifies the VS Area Veterinarian-in-Charge (AVIC) for that state. The regional director shares all information with the BSE response team and is a liaison between the VS deputy Administrator and the VS field staff. The VS AVIC with the state animal health authorities coordinates the field activities. Their field activities include: tracing the progeny, herd mates and beginning an epidemiologic investigation. "The VS AVIC works with the state Vet to quarantine the infected animal's herd of origin. The state has the authority to order a routine quarantine for a neurological disease." [25]

The BSE response team asked every state if they would use this authority in the event of a BSE infection; all states said that they would issue a quarantine. It is the BSE

[25] USDA – APHIS, (Oct. 1998).

response team's responsibility to ensure that decision makers get all the technical information and expert recommendations they need and on time. They will also prepare a letter to the Office of International Epizootics (OIE), for the APHIS, VS deputy administrator. They will hold a teleconference to inform all APHIS regional directors, AVIC's, regional and field FSIS offices, other Federal agencies, key industry/consumer representatives, and foreign embassies. Lastly, they will establish an 800-telephone line for industry representatives, reporters, and the public, and then with the APHIS Legislative and Public Affairs and USDA Office of Communications issue a press release the day the diagnosis is confirmed. The press release announces a press conference that will be held the next morning. [26] (Refer to Fig. 3, 4, & 5 in Appendix).

U.K. Impact

Some say that the U.S. is overreacting to BSE. The import policies, feed regulations and especially blood donor bans are becoming increasingly strict. Maybe the U.S. is overreacting, but if they are, they are justified in doing so. Would it be better if we did not and ran a bigger risk of getting BSE and vCJD? This is a reason for the way the USDA is acting; they looked at the chaos BSE has caused in the U.K. because of the consistent downplaying of BSE and its threat to humans. The British government failed to properly coordinate a response. The BSE inquiry says that the officials and ministers in the U.K. were, "haunted by fears of consumer panic and the loss of valuable beef exports, and persistently stuck to a mistaken 'campaign of reassurance'." Each time they claimed, " there is no evidence that BSE is transmissible to humans; it is safe to eat beef." [27]

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[26] USDA – APHIS, (Oct. 1998).
[27] CNN. *Mad Cow Report Criticizes British Officials.* (Reuters, Oct. 26, 2000). [Online] Available: http://www.cnn.com/2000/WORLD/europe/UK/10/26/bse.report/index.html [10 July 2001]

However, no evidence it is transmissible does not mean it is not. Surely, in 1996 scientists in the U.K. discovered it is transmissible to humans and causes vCJD. When the U.S. says, "our beef is safe," they want to make sure they KNOW it is safe, this means taking all these measures. The BSE inquiry also highlighted that there was ignorance and failure of communication between government departments in the U.K. This is why the U.S. BSE response team put emphasis in the BSE Response Plan on making sure there is effective communication between government agencies in the event of a BSE case here. Another interesting point is that the BSE inquiry report states that there was "no deliberate intention to deceive or protect farming interests at the expense of consumers."[28] However, they did say earlier that the U.K. acted so negligently because they did not want "consumer panic and loss of valuable beef exports." This is also why the U.S. bases its BSE policy decisions more on the public's health and not on beef exports and the welfare of individual cattle and sheep farms, (more of this is discussed in the next section). The British government is now "holding a civil service review to examine whether any officials criticized by the report should face disciplinary action." [29] The BSE crisis ended up devastating the U.K.'s beef farming industry anyway and cost the government billions in compensation.

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[28] CNN, (Oct. 26, 2000).
[29] CNN, (Oct. 26, 2000).

Evolution of U.S. Policies

When looking at the current U.S. policies, we can see how science, politics, the public, and events in Europe shaped them. Concern for the public's health is of the most importance and that is evident when looking at the United States' reaction to BSE. The U.S. realizes that as long as the public's health is foremost, they cannot be blamed for negligence and if there is no infection in the U.S. from BSE then the beef industry will not plummet. Proper adjustments were made when new scientific evidence became known. However, that is the only area that could still be stronger.

Science

It is hard to make policies on BSE according to what is known scientifically, since we do not know that much about the mechanism of BSE infection. "Prions reproduce without using DNA and are so stable they resist boiling, alcohol and radiation, they violate all the principles of cell biology we thought we knew." [1] One policy made and continually being adjusted on circumstancial evidence is the blood ban. The U.S. remembers France's AIDS scandal which was the result of the government's lack of panic and tries to do the opposite for BSE. Hundreds of hemophiliacs were infected with the HIV virus in France because the health ministers claimed there was nothing to worry about. Although it is not scientifically proven yet that BSE can be transfered through blood, there are bans on blood from people who have lived in Europe or visited Europe

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[1] McNeil Jr., Donald G. *AIDS and Mad Cow Disease: Two Epidemics That are Alike.* (New York Times, Feb. 4, 2001). [Online] Available: http://healtoronto.com/twoepid.html [11 July, 2001]

for an extended period of time (see U.S. Policies section on Blood Supply). Some say "there maybe no point to this since prions are found in the brain, spine, gut, and not blood." [2] This is not true, because they are assuming that since there is no scientific proof, it is not possible. They are forgetting the lessons of the past in the U.K. and France. There is much circumstancial evidence that BSE is transmitted through blood. Evidence points out BSE is probably vertically transferrable, which means that if it is, then it must be in the blood (see Biology section on Vertical Transfer). The executive director in charge of communicable diseases for the World Health Organization , Dr. David L. Heymann says, "we have to make recommendations based on limited information, but it's better to be on the conservative side and change the rules later." [3]

The only precaution I feel the U.S. is not taking and should be taking is stopping the feeding of ruminant proteins to all animals not just cattle and sheep. If scrapie spread from sheep to cows through feed and is now BSE and subsequently spread to humans and became vCJD, then why would it not eventually spread to pigs and chickens if they are fed the ruminant-derived protein? It has already affected cats, elk, and deer naturally. Pigs have not been infected by BSE naturally yet, but can be infected experimentally by injecting BSE-infected material directly into the brain. It is probably only a matter of time before pigs get it in nature too. Studies do show that it is possible that pigs could carry the disease and even pass it on to other species. It is not known whether chickens can contract this disease, but they have been fed with BSE-infected feed and it has been found in their manure. "Chicken manure has then been recycled as feedstock for other

[2] McNeil Jr., Donald G., Feb. 4, 2001.
[3] McNeil Jr., Donald G., Feb. 4, 2001.

livestock who could incubate the disease." [4] Therefore, the only policy that could be modified soon is the feed ban.

Public Panic

Britain worried about public panic, so they made false assurances; the U.S. does not make false assurances, they set strong policies and continue to modify them as needed. Although the U.S. had some advantage over Britain in being ready for BSE, they still made sure they did not make the same mistakes. In order to prevent public panic, the U.S. made programs to educate people in the beef industry and the public, and pacified fears through policy. Policy is not driven by public panic but by concern for the consumer's health. If consumers get vCJD or panic about getting it, the beef industry will suffer like in the U.K. Consumer's health is directly related to the success of beef industries. In an interview with Charles P. Schroeder (the National Cattlemen's Beef Association's chief executive) the Greg Winter of the *New York Times* asked him "Do you think government supervision of food safety is adequate?" he responded,

> "We have the safest food supply in meat and other food products, so we can't be doing too badly. Food safety is a threshold issue for consumers, and we recognize that if we aren't delivering a safe product, we're out of business, regardless of

[4] Mundi Club, The. *The Facts About BSE.* (Apr. 21, 2001). [Online] Available: http://www.geocities.com/carbonomics/MCtfirm/10tf10c_f.html. [10 July 2001]

who the regulators are. So I wouldn't say that we're under-regulated; we just feel that food safety needs to be based on good science and not convenient politics." [5]

The NCBA realizes this connection between the consumer's health and their success in the beef business. This is also why some interest groups are pushing others to comply with the regulations; it does not matter who makes the mistake, they would all be out of business. What the U.K. failed to realize is that if BSE is transmissible to humans, they are compromising the public's health and the beef industry, not saving the beef industry.

Politics

Part of the reason the British claimed that no evidence of transmittance means no transmittance possible is because they did not want to panic the public and ruin their beef export industry as a consequence. Part of the reason that the U.S. hurried in setting BSE policies, some extreme at first (ex: no import of any meat from Europe until investigation is done), was because the politicians did not want to be accused of negligence like the British officials were. In 2000, German ministers resigned after criticism of the way they handled the outbreak of mad cow disease. "Health Minister Andrea Fischer said she was stepping down because people had lost faith in her ministry." [6] In fact the reality was even worse, she was going to be fired because the U.K. sent her a letter of emergency warning that they discovered it is possible a certain brand of their sausages that is sold in Germany might be contaminated with BSE, and she let the warning sit in her office for

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[5] Winter, Greg. *Five Questions for Charles P. Schroeder: Of Mad Cows and Anxious Ranchers.* (New York Times, Feb. 11, 2001). [Online] Available: http://www.plant.uoguelph.ca/safefood/archives/fsnet/2001/2-2001/fs-02-11-01-01.txt. [11 July 2001]

[6] CNN. *Mad Cow Report Criticizes British Officials.* (Reuters, Oct. 26, 2000). [Online] Available: http://www.cnn.com/2000/WORLD/europe/UK/10/26/bse.report/index.html. [10 July 2001]

almost a week before she did anything with it. "Agriculture Minister Karl-Heinz Funke quit when a series of measures aimed at cracking down on the disease were announced and then withdrawn after he complained he had not been consulted." [7] In November of 2000, the French had similar problems. France is now facing at least two lawsuits alleging that "it failed to take sufficient action to prevent the spread of mad cow disease in France. In addition, a warning was issued by the junior health minister, Dominique Gillot, that the country should prepare itself for "several dozen" cases of vCJD." [8] In part because of all these things, the U.S. is not so afraid to take immediate action when it comes to BSE. Officials are protecting the public, the cow population, the farmer's business from ruin by BSE and in the process they protect themselves from being kicked out.

Europe & Trade

The U.S. adjusts its policies as soon as it comes across new information from Europe. In the beginning, in 1987 the U.S. banned imports of live ruminant animals from the U.K. In 1989, the policy was adjusted to ban all live ruminants from countries that are infected with BSE. As the list is BSE countries, especially in Europe, grew to include France, Germany, Portugal, Spain, Ireland, Switzerland, Belgium, Denmark, Italy, the Netherlands, Luxembourg and Liechtenstein, the U.S. realized that soon if not already all of Europe will be infected so they adjusted the policy once again, this time to ban all live

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[7] CNN, Oct. 26, 2000.

[8] Henly, Jon. *BSE Gives the French Food for Thought.* (Guardian Unlimited. Guardian Newspapars Limited, Nov. 7, 2000). [Online] Available: http://www.guardian.co.uk/bse/article/0,2763,394060,00.html. [10 July 2001]

ruminants from all of Europe and or countries that are infected as well. The fact is we do not know how many countries are infected by BSE and vCJD yet, because the incubation of the diseases is very long and new countries show up to be infected every year, that is why some European countries that have not had a case yet are banned also.

Vermont Sheep Crisis

On March 21, 2001 the USDA seized 233 sheep from the Houghton Freeman Vermont farm in Greensboro. Days later 126 more sheep were seized from the Faillace Farm in East Warren, Vermont. Events starting in 1996 all led up to the seizure of 359 possibly BSE infected sheep. It was the first seizure in the United States because of worries over BSE in sheep.

In 1996 the Vermont farmers decided to import the extraordinary milk-producing sheep from Belgium and the Netherlands to make gourmet cheeses. Unfortunately, 1996 was also the same year that the BSE outbreak in Great Britain was at its highest. The farmers went through complex negotiations and regulations before they were allowed to import the sheep. [1] For example, the sheep had to come from farms that had certified feeding statements and were enrolled in the Belgium scrapie program, and the sheep could not come from countries with previous cases of BSE. As soon as the sheep were finally imported, they were placed under certain federal restrictions as part of the USDA's scrapie control efforts. The USDA figured it was fine to import them as long as they followed the regulations set to prevent scrapie. The USDA restricted their movement and tracked their offspring. Since 1996 the flocks have been constantly monitored for evidence of any kind of Transmissible Spongiform Encephalopathy (TSE). The Vermont farmers imported their sheep during a period in 1996 when there was "a brief window of time" when imports were allowed from certain countries. Late in 1996 the "window was closed" when new experimental information was published stating that experimental transmission of BSE to sheep by oral inoculation was possible. Before this, it was thought

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[1] Bill Delaney. *USDA seizes possibly diseased sheep in Vermont.* (CNN, Mar. 21, 2001b). [Online] Available: http://www.cnn/2001/US/03/21/vermont.sheep.01/. [9 June 2001]

that BSE could not be transferred to sheep. [2] It is already known that BSE from cows is linked to variant CJD in humans, so if sheep have it, they too can infect humans. In 1998, the USDA found out that it is likely that the sheep were fed BSE contaminated feed while in Belgium and the Netherlands. [3] In this year the first cases of BSE were discovered in Belgium and the Netherlands, and it was found out in this way that the farms which had confirmed BSE cases in their cattle also had certified feeding statements showing there was no meat and bone meal fed to the cows and sheep. Therefore, the feeding statements lost all credibility. Also it was found out that not all the Belgian flocks from which the Vermont sheep came, were enrolled in the scrapie and TSE prevention program for long. One farm was enrolled their sheep into the program just 6 days before the sheep were imported to the U.S. [4] After this new information came to light, Vermont quarantined these flocks of imported sheep and their offspring, at the request of the USDA. The quarantine banned slaughter or sale for breeding purposes, and they were tested when they were ill or died. In July of 2000, four out of nine tested positive for some kind of TSE. A state of extraordinary emergency was declared by the USDA to acquire the sheep. One flock owner voluntarily handed his flock of 21 sheep to the USDA, which was related to the Freeman-Fallaice flocks. The Freemans and Fallaices contested the action of the USDA, but lost. They "appealed to the Second Circuit Court requesting a

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[2] USDA – APHIS. Factsheet: Vermont Sheep Questions and Answers. (Aug. 2000). [Online] Available: http://www.aphis.usda.gov/oa/pubs/qavtshee.pdf. [8 June 2001]

[3] Jim Rogers; Anna Cherry; Kevin Herglotz. *USDA Removes Quarantined Sheep from Vermont Farm.* (USDA News Release, Mar. 21, 2001). [Online] Available: http://www.usda.gov/news/releases/2001/03/0051.htm. [9 June 2001]

[4] USDA – APHIS. *Additional Information on the TSE Sheep in Vermont.* (2000). [Online] Available: http://www.aphis.usda.gov/oa/tse/addinfo.html. [8 June 2001]

stay, but were denied." [5] The Federal District Court ruled in favor of the USDA and ordered the farmers to comply. The USDA Senior Staff Veterinarian, Linda Dewiler said the farmers will be "compensated for the fair market value of their sheep", by the USDA. [6] Thus the sheep were trucked to the National Veterinary Services Laboratories in Ames, Iowa. There they were killed and examined for spongy tissue in the brain and spinal cord, which is characteristic of prion diseases. However, it will take two to three years before it is known if the TSE they had was BSE or scrapie, because the only test that can determine this is one that involves infecting rats with the sheep's disease and waiting a couple years to see what happens when the rats develop it.

There has been much commotion about the seizure of the flocks from activist groups and some citizens. On the other hand, other farmers in Vermont and around the U.S. had been pressing the USDA to get rid of the flocks. Their milk and cheese sales have suffered, because people were afraid the milk and cheese might be contaminated since the infected sheep where still around. The Vermont Congressional delegation, Vermont Farm Bureau, Vermont Veterinary Medical Association and the Vermont Sheep Breeders Association also wanted the sheep seized because they do not want "a black eye" on Vermont agriculture. [7] Even before declaring the extraordinary emergency, the USDA had the most knowledgeable people in the field on their side. The USDA consulted the Centers for Disease Control, the National Institutes of Health, the Food &

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[5] Jim Rogers; Anna Cherry; Kevin Herglotz, Mar. 21, 2001.

[6] Linda Moulton Howe. *USDA Finally Removes 233 European Sheep from Vermont Farm After Court Battles.* (Earthfiles, Mar. 21, 2001). [Online] Available: http://www.earthfiles.com/earth220.htm . [8 June 2001]

[7] Delaney, Bill. *Bill Delaney: Sheep seized in Vermont.* (CNN, Mar.21, 2001a). [Online] Available: http://www.cnn.com/2001/US/03/21/delaney.debrief/. [9 June 2001] and Linda Moulton Howe, Mar. 21, 2001.

Drug Administration, and many prominent researchers in the field. Dr. Pruisner, Dr. Rohwer, and Dr. Wells all supported the USDA, and stated their decision is the "most responsible one under the circumstances." [8] The farmers and their supporters argued that the Western-blot test is not a reliable test for TSEs, however it is an approved test authorized by USDA's APHIS. The method is a widely known and published one in today's literature, plus the tissue samples were taken from the best location in the brain to find the indicator of TSE infection. The only problem with the Western-blot test is that it cannot tell the difference between BSE and scrapie. The only method that works to differentiate these two requires series of mouse bioassay systems which take two to three years for completion due to the long incubation period of the BSE and scrapie agents. [9]

These extreme steps had been taken by the USDA in order to protect out food supply and health. Yes, little is know about the disease, but it is known that it is 100% fatal and has potential to spread quickly, and is difficult to detect for years because of the incubation period.

[8] USDA – APHIS, 2000.
[9] USDA – APHIS, Aug. 2000.

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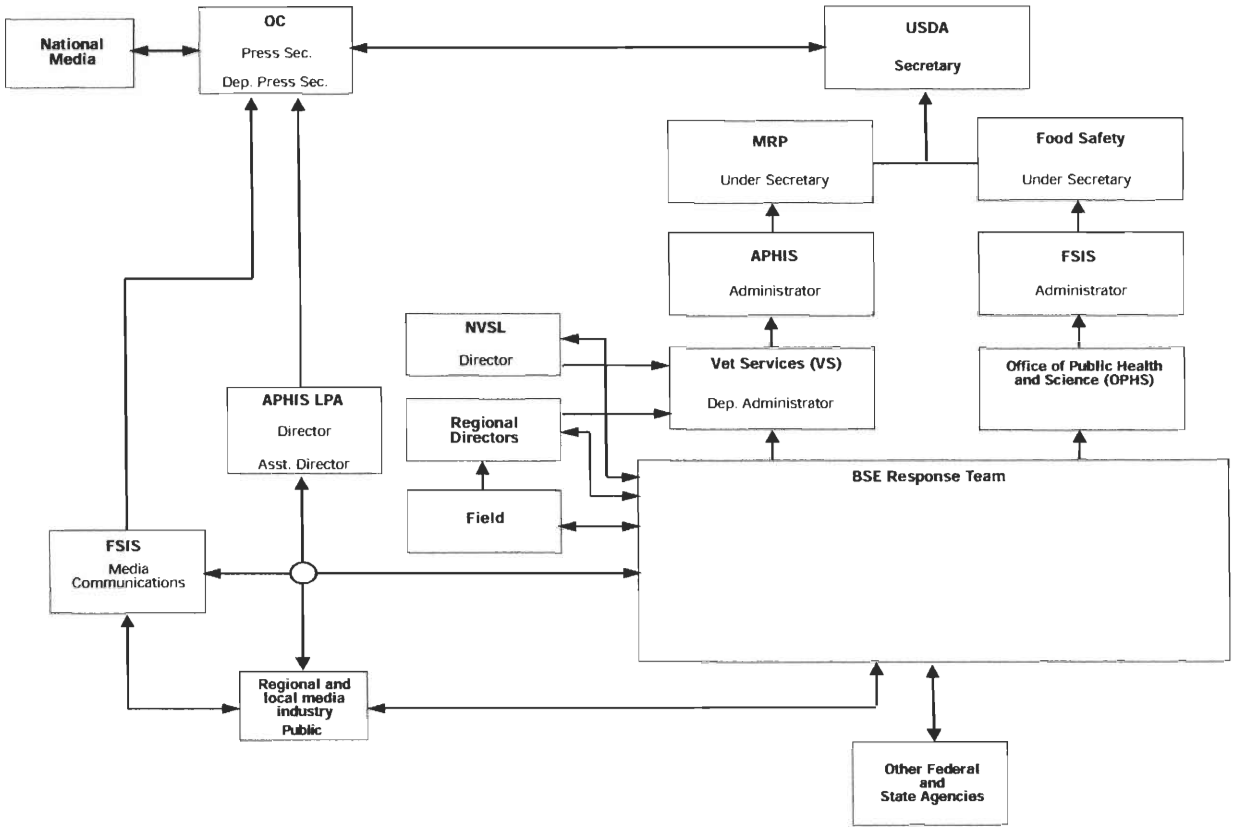
Appendix

BSE Response Plan Flow Chart



BSE Response Plan Flow Chart

BSE Response Timeline

Presumptive diagnosis of BSE identified	48–96 hours post suspect	Day 1 Case confirmed	Day 2	Day 3
NVSL Suspect diagnosed	H&E slides prepared and read Immunohistochemistry Hand carried to UK	Diagnosis confirmed in concurrence with CVL, UK		Readiness status to receive and process brain specimens on any herdmates, progeny or other suspects (see BSE Laboratory Testing timeline)
APHIS Field Personnel Routine State Quarantine of herd	Trace progeny Trace adult herdmates Epi investigation (ongoing)	Expand quarantine to include progeny		Complete animal trace out on herdmates and progeny
FSIS ERP, Field Operations Obtain carcass disposition Obtain animal identification/origin information	Trace all food items Trace to renderer	Districts notify all field personnel of confirmation		Complete trace out on brain, spinal cord
BSE Response Team (Riverdale) Assemble BSE Response Team	Update information packet, briefing papers, etc. Obtain funds for depopulation	Confirmation received Statement to Secretary APHIS/FSIS teleconference Government/Industry/ Consumer teleconference Distribute information packet Notify OIE Notify embassies MRP Alert Press Release	Conduct briefings Congressional briefing Press conference	Provide daily/weekly briefing updates as needed Hold daily/weekly conference calls to government agencies and industry Update USDA, APHIS, FSIS homepages Provide daily updates on trade restrictions placed on US Fax updates to APHIS and FSIS field, FAS, NASDA, USTR, and industry groups

BSE Response Plan Checklist

Initial BSE Case

Action	Respnsibility	Date	Progress
Presumptive Dx	NVSL/EP		
Immediate notification to USDA Sec., Undersec., Asst. Secs., Administrators	EP Staff		
Advance notification to key contacts at CDC, FDA, NIH	USDA officials		
If slaughter sample trace to farm of origin	FSIS/APHIS		
Traceout of product if slaughter animal	FSIS, ERP		
Quarantine index herd	VS Area/State	Immediately upon presumptive dx	
Herd epidemiological investigation	VS Area/State	Ongoing while dx confirmed	
Progeny traceouts	VS Area/State	Ongoing	
Movement traceouts	VS Area/State	Ongoing	
Prepare situation room	EP Staff	Immediately after presumptive dx	
Assemble BSE Response Team in Riverdale, MD	EP Staff Chief	Immediately after presumptive dx	
Identify spokespersons and backups	APHIS/FSIS Administrator	During time waiting for confirmation	Completed
Update press releases, info package for APHIS/FSIS offices; info pkg. for industry etc.	EP/BSE Response Team	During time waiting for confirmation	

Continued

Action	Respnsibility	Date	Progress
Designate individual to post and update APHIS home page; designate individual to monitor internet and list servers	EP/BSE Response Team		
Set up phone lines (800 numbers)	EP/BSE Response Team	During time waiting for confirmation	
Confirm Dx	NVSL in concurrence with CVL, England		

After Confirmation

Action	Respnsibility	Date	Progress
Briefing for Sec/Asst. Sec (paper and in person)	Administrators, Communications Liaison		
Provide advance notification to AVIC's/State Vets; NIH, CDC, FDA; Select industry and trading partners (teleconference)	APHIS/FSIS Administrators EP/BSE Response Team	Immediately after confirmation (near end of day)	
Congressional briefing	Asst. Sec., Admin., Spokesperson	After teleconference	
Information pkg. to APHIS, FSIS, State personnel, CSREES, ARS, GIPSA, FAS	EP/BSE Response Team	After teleconference above (at end of day)	
Information to other government, industry contacts —see list (basic info)	EP/BSE Response Team	After teleconference (at end of day)	
MRP Alert	LPA	Day 1	
Information to embassies	EP/BSE Response Team	After teleconference	

Continued

Action	Respnsibility	Date	Progress
Press release to media, press conference, media advisory to APHIS and FSIS employees	LPA/EP/BSE Response Team	Day 2	
Scientific meeting with USDA, CDC, FDA, NIH	EP/BSE Response Team		
Informational meeting for industry, constituent groups	EP/BSE Response Team		
Obtain funds for depopulation	EP Staff		
Disposition of index herd	Area/State personnel		
Disposition of progeny	Area/State personnel		
Notify foreign countries	APHIS, IS/FSIS Int. personnel	Day after confirmation	
Notify all FAS posts	VS prepare for FAS transmission	Day after confirmation	

Ongoing

Action	Respnsibility	Date	Progress
Daily updates on trade restrictions placed on US	APHIS, Chief of Import/Export Staff/ FSIS International		
Prepare daily report of updates current happenings	EP/BSE Response Team		
Prepare daily briefings for Asst. Sec/Sec	EP/BSE Response Team		
Meeting within USDA agencies to examine necessity for further controls	Administrators		