



Bovine Spongiform Encephalopathy: The Past Present and Future of Mad Cow Disease in the United States

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Bovine Spongiform Encephalopathy

The Past Present and future of Mad Cow Disease in the United States

**Food and Drug Law
Course Paper
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January 23, 1998**

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Bovine Spongiform Encephalopathy

The past, present and future of Mad Cow Disease in the United States.

I. Introduction

The food we eat in the United States is among the safest in the world. We are not faced each morning with case after case of food poisoning as we listen to the news or read the newspaper. We feel very safe going to a restaurant, supermarket, or even a roadside stand to purchase food for our families and pets. We do not fear food-borne diseases. Nor do we fear the consequences of the drugs and food additives we give our pets and food-producing animals. These drugs and food additives are among the most thoroughly tested and safest in the world.¹

Despite the extensive precautions taken by our government to ensure the safety of our nation's food supply, some food-borne illnesses do occur. The Food and Drug Administration and other governmental agencies must constantly monitor outbreaks of food-borne illnesses around the world and devise precautionary measures to prevent similar outbreaks in the United States. Recently, a variant form of a terminal disease, known as Creutzfeldt-Jakob Disease, has manifested itself in several countries, including

¹<http://www.cvm.fda.gov/default.html>, page 1.

the United States. Governmental agencies and health organizations around the globe are desperately attempting to ascertain the cause of this disease while also attempting to devise strategies to minimize the likelihood of a future outbreak.

In an attempt to provide an introductory, yet thorough, discussion of Bovine Spongiform Encephalopathy and its ramifications in the United States, this paper shall:

discuss the history of and explain the disease known as Bovine Spongiform Encephalopathy; explain Creutzfeldt-Jakob Disease; outline the history, responsibility and structure of the Food and Drug Administration Center for Veterinary Medicine; provide a comparative analysis of the steps that the United States and other countries have taken to minimize the threat of future outbreaks of Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease; provide a brief overview of the Food and Drug Administration's rule prohibiting the use of animal proteins in ruminant feed; and finally discuss the adequacy of said rule as well as other possible steps the FDA and USDA could take to further minimize the threat of Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease in the United States.

II. Bovine Spongiform Encephalopathy

A. Introduction

Bovine Spongiform Encephalopathy (BSE) is associated with a transmissible agent (the prion), the nature of which is not yet fully understood. The agent affects the brain and spinal cord of cattle and is characterized by sponge-like changes in the brain and spinal tissue. It is a highly stable agent, resisting levels of heat from normal cooking

temperatures up to those used for sterilization, freezing and drying. The disease is fatal to cattle within weeks to months of its outset.²

BSE is a disease found in cattle which was first identified in 1987. The animals affected become unsteady on their feet, lose weight and often assume a fearful disposition. The term Mad Cow Disease is not always appropriate as many animals do not become overtly aggressive, and towards the end, may lose interest in their surroundings, and become too unsteady to even stand.³

B. History of BSE

On March 20, 1996, the British government announced a possible link between Bovine Spongiform Encephalopathy (BSE), a chronic disease affecting the central nervous system of cattle, and ten cases of a variant form of Creutzfeldt-Jacob Disease (CJD), a related disease among humans. At a World Health Organization consultation in April, a group of international experts concluded that there is no *definite* link between BSE and the new variant CJD, but that epidemiological evidence *suggests* exposure to BSE may be the most likely explanation for the ten cases of variant CJD in the United Kingdom.⁴ In October 1996, John Collinge, one of the foremost British authorities on CJD, and his colleagues published results of their research on various strains of prions, which are thought to transmit BSE. Their results suggest that the new variant CJD resembles BSE rather than other forms of CJD.⁵

² World Health Organization, Emerging and Other Communicable Diseases (EMC), Bovine

Spongiform Encephalopathy (BSE) Fact Sheet; WHO Fact Sheet N 113 March 1996.

³ Creutzfeldt-Jacob Disease: A Guide; <http://www.cjd.ed.ac.uk/booklet.html>

⁴<http://www.cvm.fda.gov/fdalinfores/updates/bse/bsefact.html>

⁵ Id.

C. Estimated Risk in the United States

In ten years of monitoring for BSE, the USDA has never identified a single case of BSE in the United States. However, scrapie, another transmissible spongiform encephalopathy (TSE), does exist in the US livestock population in an apparently low number of cases.⁶ Since 1989, no cattle have been imported from countries with confirmed cases of naturally occurring BSE. In addition, no beef has been imported from foreign countries with native cattle cases of BSE since 1985. Although BSE remains a disease among cattle in some foreign countries, the US government is taking steps to even further reduce the risk of BSE and enhance surveillance and study of CJD among humans.⁷

Despite our inability to identify the presence of BSE in the US, the specter of BSE continues to haunt beef eaters on both sides of the Atlantic. Britain is still trying to persuade the European Union to lift its ban on British Beef, and in April of 1997 the commodity prices for beef sank in the United States after Joseph Gabor, an Indiana farmer, died of CJD.⁸ Cattle prices also sank a year earlier in April of 1996 when talk-show host Oprah Winfrey partly explored Mad Cow Disease on her daily talk show.⁹

Although the risk from eating meat or other products from BSE affected animals is almost certainly remote, any theoretical risk has been minimized by the destruction of all affected animals, and the ban on the use of certain tissues from cattle for human

⁶ WHO consultation on Public Health Issues Related to BSE and the Emergence of a New Variant of Creutzfeldt-Jakob Disease, 2-3 April 1996, conclusions summarized in Weekly Epidemiological Record, 1996, No. 15 (12 April 1996).

⁷ CVM BSE and CJD Fact Sheet dated January 2, 1997.

⁸ Don't Be Cowed by This Disease; by Scott C. Ratzan, *The Wall Street Journal*, May 11, 1997.

⁹ Oprah Winfrey Show; April 16, 1996. The show's topic was food safety. After the airing of the show, the April futures contract sank the daily allowable limit of 1.5 cents a pound.

consumption. The FDA has also promulgated special rules intended to prevent the establishment and amplification of BSE in the United States through exposure to contaminated animal feed.¹⁰

III. Creutzfeldt-Jakob Disease

A. What is Creutzfeldt-Jakob Disease (CJD)?

CJD is a rare, fatal brain disorder of unknown cause which produces a rapid, progressive dementia and associated neuromuscular disturbances. The disease is often referred to as a subacute spongiform encephalopathy because it usually produces microscopic vacuoles that appear sponge-like.

The identification of this transmissible agent has been the subject of much scientific inquiry and debate. Initially the agent was thought to be a slow virus due to the unusually long incubation period between the time of exposure to the pathogen and the onset of symptoms. Further research, however, has indicated that this agent differs significantly from viruses and other conventional agents. Whereas viruses and other known infectious agents contain nucleic acids which house a cell's genetic material, researchers have been unable to identify any nucleic acids in the CJD agent. Additionally, the chemical and physical procedures that inactivate most viruses have proved ineffective in decreasing the infectivity of the CJD pathogen. In contrast, the

¹⁰ See 21 Code of Federal Regulations Part 589; Federal Register: June 5, 1997 (Volume 62, No. 108); page 30935.

CJD Brochure Website produced by the Creutzfeldt-Jakob Disease Foundation @ <http://members.aol.com/crjakob/brochure.html>. Page 1.

procedures that degrade protein have been found to inactivate the pathogen. Accordingly, a new theory regarding the transmissible agent has emerged and recently gained widespread acceptability. This theory holds that the transmissible agent is neither a virus nor other previously known infectious agent, but rather an unconventional agent consisting of protein. This newly-discovered pathogen is called prion, short for proteinaceous infectious particle. Prions are thought to transform normal, benign protein molecules into infectious, deadly ones by altering the shape of the healthy molecules to the dangerous conformation. At the present time, there is no known effective treatment or cure for CJD. The disease is inevitably fatal.¹²

B. Historical Note

Creutzfeldt-Jacob disease was named after the two doctors from Austria (H.G. Creutzfeldt and A. Jakob) who in 1920 separately described a total of six patients with peculiar neurological illnesses. Although the illnesses were not very similar, the appearances of the brain when viewed under the microscope were alike; many of the normal brain nerve cells had died, and the brain had developed numerous tiny holes, too small to be seen by the naked eye, and a meshwork of delicate fibers. The entire appearance resembled a microscopic sponge, and thus was born the expression spongiform encephalopathy.¹³

¹² Id.

See Note 3.

C. Occurrence

CJD occurs worldwide, from Chile to Japan, and from Australia to the United States. There is approximately one new case per two million people per year, and about 30 cases occur per year in the United Kingdom. The most common age of onset is over the age of 55, but it appears to be rare over the age of 80.⁵

D. Transmission

CJD can be transmitted through infection, however the issue of whether there is a direct link between the exposure to diseased animals and the acquisition of CJD has been the subject of much scientific study and debate. British scientists and the World Health Organization (WHO) have reversed their previous positions and have stated that there is a possible link between BSE and CJD.⁵ This new acknowledgment arose from the identification of an apparently new strain of CJD which was discovered in 10 people under the age of 42, including some teenagers. Additionally five of the people were associated with the meat and livestock industry. Scientists advising the British government decided that the most likely explanation for this unusual outbreak was the consumption of beef from diseased cattle before 1989, when regulations were adopted for the disposal of potentially infectious cattle offal, including brains, and the use of sheep entrails as feed ceased.⁶

⁵ Creutzfeldt-Jakob Disease: A Guide; Produced by The University of Edinburgh and The UK CreutzfeldtJakob Disease Surveillance Unit. This guide may be found at <http://www.cjd.ed.ac.uk/booklet/htm>.

⁶ See Note 4.

⁶1d.

E. Description of CJD

The following are features of CJD as described in the CJD handbook produced by the University of Edinburgh and The UK Creutzfeldt-Jakob Disease Surveillance Unit.⁷

The exact time of onset of the illness can be very difficult to determine. Often, at first, there are subtle lapses of memory for day-to-day events, although sometimes mood changes, in particular a loss of interest and withdrawal from involvement in social activities, are apparent. Decline in ability at work for tasks that were previously simple is often noted. At this point, the illness may be passed off by friends, relatives and doctors as mild depression. However, within a few weeks other features quickly appear: a vague unsteadiness and hesitancy in walking, deteriorating vision (often the patient may mistake everyday objects for something else, or even experience hallucinations), slight slurring and slowing of speech, and a difficulty in finding the right word when trying to hold a conversation. Symptoms often continue to progressively worsen, with the development of incontinence of urine, jerky movements, shakiness, stiffness of limbs, and loss of the ability to move or speak.

Mercifully, only in the very early stages are the patients aware of anything amiss, and usually complain of clumsiness, feeling muddled, or blurring of eyesight. As the disease progresses, patients lose awareness of their surroundings and of their disabilities. Some of the agitation that may be seen is a reflex phenomenon rather than true distress. This is particularly the case as regards the shakiness.

Individuals affected by CJD usually succumb within six months of the onset of the disease, often through pneumonia. In only 10% of cases does the disease run a more

⁷ See Note 14.

⁸ See Note 2.

⁹ The Prion Diseases by Stanley B. Prusiner; located at <http://www.nmia.com/kmdibble/prion.html>.

prolonged course of 2-5 years, and in these cases, the first years may only involve loss of memory and some difficulty with complex tasks. Sadly, there is no known cure or treatment that can halt the progress of the disease. However, there are many drugs which can be used to make the last weeks and months easier for the sufferer.

F. Britain

Between May 1995 and March 1996 ten humans in the United Kingdom were identified with what appears to be a variant of CJD. Eight of the ten patients to date have died. These ten cases all occurred in patients under the age of 42 years and some had behavioral changes at the onset. All ten cases experienced the prolonged course of the disease.⁸

G. Discussion of Prions

Protein rods known as Prions, once dismissed as an impossibility, have now gained wide recognition as extraordinary agents that cause a number of infectious, genetic and spontaneous disorders. Fifteen years ago dogma held that the conveyers of transmissible diseases required genetic material, composed of nucleic acid (DNA or RNA), in order to establish an infection in a host. Even viruses, among the simplest microbes, rely on such material to direct synthesis of the proteins needed for survival and replication. Today, however, a wealth of experimental and clinical data has made a convincing case that prions are indeed responsible for transmissible and inherited disorders of protein conformation. ⁹

20 Id.

The known prion diseases, all fatal, are sometimes referred to as spongiform encephalopathies. They are so named because, as previously mentioned, they frequently cause the brain to become riddled with holes. Prion diseases are widespread in animals, with BSE being the most worrisome. The human prion diseases such as CJD are more obscure.²⁰

IV. FDA Center for Veterinary Medicine

A. Overview

The responsibility for protecting and assuring the unparalleled level of consumer confidence and food supply safely rests with the Food and Drug Administration (FDA) and with the United States Department of Agriculture (USDA). Within the FDA, there are two Centers responsible for the safety and wholesomeness of the human food supply. The Center for Food Safety and Applied Nutrition (CSFAN) regulates food intended for human consumption. The Center for Veterinary Medicine (FDA-C VM) regulates the manufacture and distribution of food additives and drugs that will be given to animals from which human foods are derived, as well as food additives and drugs for pets (and companion animals).

The FDA-CVM regulates the manufacture and distribution of drugs and feed additives intended for animals. These include animals from which human foods are derived (i.e. poultry, cattle and sheep), as well as drugs and feed additives for household pets. CVM is responsible for regulating drugs, devices, and feed additives given to, or

used on, over one hundred million companion animals, plus millions of poultry, cattle, swine, sheep, and minor animal species.²¹

B. FDA-CVM Beginnings

In order to better understand the role of the CVM, it may be useful to look at the Center's historical background. Additionally, a cursory examination of the developmental history of the watchdog roles played by the FDA and USDA may facilitate an understanding of the present role each agency should play in preventing outbreaks of BSE and CJD in the United States.

*WHEREAS some evilly disposed persons, from motives of avarice and filthy lucre, have been induced to sell diseased, corrupted, contagious or unwholesome provisions, to the great nuisance of public health and peace: Be it therefore enacted by the Senate and House of representatives, in General Court assembled, and by the authority of the same, that if any person shall sell any such diseased, corrupted, contagious or unwholesome provisions, whether for meat or drink, knowing the same without making it known to the buyer, and being thereof convicted before the Justices of the General Sessions of the Peace, in the county where such offense shall be committed, or the Justices of the Supreme Judicial Court, he shall be punished by fine, imprisonment, standing in the pillory, and binding to the good behavior, or one or more of these punishments, to be inflicted according to the degree and aggravation of the offense.*²²

The regulation of food in the United States dates back to 1784, when Massachusetts enacted the first general food law. National drug control began in 1848 with the Import Drugs Act. This was the first Federal Statute designed to guarantee the quality of medicines. In 1850, the first Pure Food and Drug Law was passed by the State of California. Eventually, most of the other states enacted similar legislation. In 1880,

²¹ <http://www.cvm.fda.gov/default.html>, page 2.

after a year's investigation into food and drug alteration, Mr. Peter Collier, Chief of the Division of Chemistry at the USDA, began advocating enactment of a national food and drug law. Mr. Collier was succeeded in 1883 by Dr. Harvey W. Wiley, who embarked on a long and stormy crusade for reforms.²³

In 1906, the first Federal Food and Drugs Act was signed into law by president Theodore Roosevelt. The Act was administered by USDA's Bureau of Chemistry; it prohibited the interstate shipment of adulterated or misbranded food, drinks and drugs. The practices existing in the food industry at that time were reflected in the restrictions spelled out by the Act. In essence, food was declared adulterated, or unfit for consumption if:

it is mixed or packed with another substance so as to

reduce or lower or injuriously affect its quality or strength *W**any substance has been substituted wholly ore in part; ~f any valuable constituent has been wholly or in part abstracted, W**it has been colored, powdered, coated, or strained to conceal damage or inferiority; W**poisonous or deleterious substances have been added; W**it consists wholly or in part offilthy, putrid, or decomposed animal or vegetable substance, or any portion of an animal unfit for food; or W**the product is from a diseased animal or one that died otherwise than by slaughter.*²⁴

Dr. Carl I. Alsberg, who succeeded Dr. Riley as USDA's Chief Chemist in 1912, initiated the regulatory and research function of the Bureau of Chemistry with an investigation of drug labeling to determine if the claims were false or misleading. By 1921, attention was directed toward truthful labeling as it applied to quantity information, such as net weight, particularly in wrapped meats. In 1927, a separate law enforcement

²² Massachusetts Law of 1785

²³ <http://www.cvm.fda.gov/fdaIaboutcvmlbeginnings.html>

agency was formed, known first as the Food, Drug, and Insecticide Administration, and later as the Food and Drug Administration. The agency employed its first veterinarian, Dr. Henry Moskey, to evaluate vitamins and minerals in light of their claimed nutritional and treatment uses. In 1938, the more stringent and inclusive Federal Food, Drug, and Cosmetic Act (The Act) was enacted. For the first time, manufacturers were required to provide evidence of product safety before distributing new drugs. The Act also granted FDA explicit authority to conduct factory inspections and to use court injunctions as enforcement tools, in addition to prior available penalties of seizure and prosecution. Other provisions stipulated the establishment of acceptable tolerances for unavoidable poisonous substances. FDA was transferred in 1940 from USDA to the Federal Security Agency, and the Office of Commissioner of Food and Drugs was established.²⁵

The Durham-Humphrey Amendment of 1951 required that human drugs which cannot be safely used without medical supervision must be dispensed only on the prescription of a licensed practitioner, and must bear the Rx legend. The veterinary prescription legend was subsequently effected through a rulemaking procedure. In 1953, the Federal Security Agency became part of the Department of Health, Education and Welfare (DHEW), and the following year FDA was organized into five Bureaus, including a Bureau of Medicine. With the establishment of this Bureau, a Veterinary Medical Branch was created with Dr. John Collins as the first chief. The Branch's primary function was to determine the safety of animal drugs, both for animals and for consumers of food derived from treated animals. The great expansion in the development

²⁴ Id.

²⁵ Id.

²⁶ Id.

²⁷ Id.

and use of animal drugs and medicated feeds during this period presaged the increasingly prominent role that veterinary medicine was to play in FDA and in animal and human health. By 1959, the Veterinary Medical Branch had developed into a Division headed by Dr. Charles G. Durbin. The Food Additive Amendments of 1958 expanded regulatory authority over animal food additives and drug residues in animal-derived foods.²⁶

Enactment of the Kefauver-Harris Drug Amendments of 1962 brought the most significant and sweeping changes in The Act since its passage 24 years earlier. These Amendments authorized FDA to monitor the clinical trials of investigational drugs and strengthened the agency's factory inspection authority. For the first time, manufacturers were required to test new drugs for effectiveness as well as safety before clearing them for marketing. The Amendments also imposed a retroactive efficacy requirement for drugs previously approved for safety alone. Furthermore, the Amendments required manufacturers to report promptly to FDA any adverse reaction or effects and other clinical experience relative to the safety and efficacy of drugs already on the market. Additional provisions stipulated that new drugs may not be cleared for marketing if the labeling is in any way false or misleading.²⁷

Animal drugs were regulated under three sections of the Act. They were first regulated as either new drugs under Section 505, or as antibiotics under Section 507. If used in the feed or drinking water of food-producing animals they were, in addition, regulated as food additives under Section 409. In September 1965, recognizing the importance of animal health to the country, the Secretary of DHEW established the

Bureau of Veterinary Medicine (BVM). Dr. M.R. Clarkson was the Bureau's first director. In 1968, the Act was amended to include the animal drug provisions of each of these Sections under a new Section 512. In 1984, BVM became the Center for Veterinary Medicine (CVM).²⁸

C. FDA CVM Responsibilities

The responsibilities of the CVM have a direct effect on the safety of the human food supply and on the safety to animals of veterinary products. CVM works to educate consumers as well as regulated industry; evaluates data on proposed veterinary products before permitting them to be marketed; discovers violative marketed products through surveillance programs and initiates legal action, if necessary, to bring violators into compliance with the law; and conducts research to support Center activities.²⁹

D. FDA CVM Research

Decisionmaking within CVM must reflect the state of the art in science and technology. In order to maintain the level of scientific credibility necessary to support the authority of regulatory decisions, it is essential that CVM scientists be involved in the conduct of research programs that reflect scientific excellence. The Office of Science conducts intramural research and coordinates extramural research grants and contracts that support pre- and post-marketing responsibilities by providing information to aid CVM scientists in their review and decisionmaking process.³⁰

The research group's responsibilities include the following:

²⁸ Id.

²⁹<http://www.fda.gov/cvm/aboutcvm.shtml>

³⁰<http://www.fda.gov/cvm/aboutcvmresearch.htm>

Id.

- Develops and validates quantitative, qualitative analytical procedures for analyzing drugs, additives, and contaminants in animal tissues and food.
- Investigates the absorption, distribution, metabolism, and excretion of drugs, feed additives, and contaminants in food animals.
- Investigates the effects of drugs, food additives, and contaminants on immunological and physiological functions of domestic animals.
- Investigates interactions between diet and drugs in food producing animals.³¹

Clearly the Office of Science's high standards of scientific excellence will require it to dedicate significant resources to the study of Bovine Spongiform Encephalopathy in order to develop a better understanding of how the disease is transmitted. More specifically, enormous amounts of research will be required to develop a satisfactory understanding of prions. In the interim, most actions taken by the FDA to minimize the potential risk of BSE and CJD in the United States will be based on highly speculative and controversial information.

V. Actions to Minimize BSE Risk

A. World Health Organization Recommendations

At a consultation organized by the World Health Organization (WHO) in Geneva, Switzerland from April 2-3, a group of international experts reviewed the public health issues related to Bovine Spongiform Encephalopathy and the emergence of a new variant of Creutzfeldt-Jakob disease, as officially reported by the United Kingdom on March

20.32 The advisors made recommendations to minimize the potential transmission of BSE among animals and to reduce human exposure to the BSE agent. The WHO

recommendations listed below are followed by notations on how each recommendation related to the United States as of November of 1996.

Recommendation #1

No part of any animal that has shown signs of transmissible spongiform encephalopathy (TSE) should enter any food chain, human or animal. All countries must ensure the slaughter and safe disposal of TSE-affected animals so that TSE infectivity

cannot enter any food chain. All countries should review their rendering procedures to ensure that they effectively inactivate TSE agents.

In 10 years of monitoring for Bovine Spongiform Encephalopathy, the USDA has never identified a single case in the United States except the one that was assumed from a cow that was fed to a farm full of mink and seemed to cause an outbreak of transmissible spongiform encephalopathy (the Stetsonville outbreak). However, scrapie (another TSE) does exist in the US livestock population in an apparently low number of cases.³⁴ To

allay concern about the possible spread of TSEs, the rendering industry previously

implemented a voluntary ban on the use of adult sheep in ruminant feed. On March

29, 1996, the beef and sheep industry announced it was implementing a voluntary ban on ruminant-to-ruminant feed, as another safeguard against BSE. It should be remembered

³² WHO Consultation on Public Health Issues Related to BSE and the Emergence of a New Variant of

Creutzfeldt-Jakob Disease, 2-3 April 1996, conclusions summarized in Weekly Epidemiological Record, 1996, No. 15 (12 April 1996).

³⁴ Id. Note, November 1993 is prior to the date that 21 CFR Part 589 became effective. See Part V.C. of this paper for a discussion of 21 CFR 589 which prohibits the use of certain animal protein

products in ruminant feed.

that this is an extremely expensive thing to have done as large amounts of rendering products will now have to be fed to pigs and chickens instead, and more expensive materials used for cattle. Presently, USDA veterinarians condemn animals with neurologic signs on antemortem inspection. The National Renderers Association is initiating research studies to determine whether their procedures inactivate TSE agents. Dr. Don Franco, director of scientific services for the NRA, told Journal of the American Veterinary Medical Association (JAVMA), What were considering doing is very complex research to decide the time and temperature [needed] to inactivate the prion diseases.

Note: *rendering plants* are factories that melt carcasses and waste meat products into protein used in animal feeds, cosmetics, nutritional supplements, medicines and other products. As little as one teaspoon of feed derived from a infected bovine can transmit the disease to another cow. In the US, rendering plants process billions of pounds of protein from dead cows, sheep, pigs, chickens and other animals into animal feed each

year.³⁵ 36

Recommendation #2

All countries should establish continuous surveillance and compulsory notification for BSE, according to recommendations established by the Office International des Epizooties in Paris. In the absence of surveillance data, the BSE status

~ See Note 5.

The U.S. Mad Cow Cover-Up; Earth Island Journal; by John Stauber and Sheldon Rampton. Article found on-line at <http://www.greenlink.org/affinity/101196/madcow.html>. **36** that 21 CFR Part 589, as discussed below, codified WHO Recommendation #1 by placing a ban on all mammalian-to-ruminant feed. Additionally, 21 CFR Part 589 established a system of flexible controls to ensure that US rendering plants effectively inactivate TSE agents.

of a country must be considered as unknown. As BSE is not known to exist in the United States, the measures taken have been in surveillance, prevention and education. Import restrictions have been in place since 1989, and active surveillance efforts began in 1990. In its surveillance program, the USDA has examined over 2,791 brain specimens from cattle in 43 states, and BSE has never been detected

The USDA-FSIS has now expanded its sampling of animals with neurologic signs. In the United States, BSE is a reportable disease under Title 9 Code of Federal Regulations, Parts 71 and 161.

Recommendation # 3

Countries where BSE exists in native cattle should not permit tissues that are likely to contain the BSE agent to enter any food chain, human or animal.

BSE does not exist in the US domestic cattle population. Moreover, while research to date does not show connection with meat; the brain, spinal cord, and retina from natural infected animals have been found to be infective. Additionally, the caudal portion of the ileum from inoculated cattle was also found to be infective.

Recommendation # 4

All countries should ban the use of ruminant tissues in ruminant feed

At the time of this WHO recommendation, the United States did not restrict the feeding of ruminant-derived meat and bonemeal to cattle. However, on March 29, 1996, several national livestock organizations and professional animal health organizations announced they would immediately establish an aggressive, voluntary program to ensure that ruminant-derived protein is not used in ruminant feed products. Issuing the joint

See Note 36.

statement were the National Cattlemen's Beef Association, American Sheep Industry Association, National Milk Producers Federation, AVMA, AABP, and Association of American Veterinary Medical Colleges. The USDA and US Public Health Service supported these voluntary measures. As recommended by the industry groups, the FDACVM has since promulgated regulations prohibiting ruminant protein in ruminant feeds.³⁷

Recommendation # 5

With respect to specific products: Tests on milk from BSE-infected animals have not shown any BSE infectivity, and there is evidence from other animal and human spongiform encephalopathies to suggest that milk will not transmit these diseases. Milk and milk products, even in countries with high incidence of BSE, are, therefore, considered safe. Gelatin is considered safe for human consumption, since its preparation involves a chemical extraction process that destroys BSE infectivity. Tallow is likewise considered safe. Effective rendering procedures are in place.

With respect to medicinal products, which differ from food in that they can be injected as well as taken orally, measures to minimize the risk of transmitting the BSE agent were developed at a previous WHO consultation in 1991 and continue to be applicable. As more information becomes available, these measures will be reviewed and strengthened, where necessary.

Recommendation # 6

The importance of obtaining materials destined for the pharmaceutical industry from countries that have a BSE surveillance system in place and report either no or

sporadic cases of BSE is reiterated Removal and inactivation procedures contribute to reduced risk of infection. But it must be recognized that the BSE agent is remarkably resistant to physicochemical procedures that destroy the infectivity of common microorganisms.

In the United States, the FDA regulates the use of cattle derivatives in products destined for human use, such as pharmaceuticals, cosmetics, and medical devices. In the Federal Register, the FDA has advised against using cattle-derived materials from countries affected with BSE. Since 1989, APHIS regulations have restricted the importation of most ruminant materials from BSE-affected countries.³⁸

Recommendation # 7

Research on TSE should be promoted, especially on rapid diagnosis, agent characterization, and epidemiology of TSEs in human beings and animals.

The USDA recently has called for further BSE research in the United States. The United States is currently the world's main center for research into TSEs with six major research centers.

B. British Legislation

The United Kingdom, which has experienced more cases of fatal BSE and CJD than any other country in the world, has taken extensive steps to minimize the occurrence of BSE and CJD in Britain. The following sequence of sample UK legislation, as

³⁸ These references to the Federal Register and APHIS regulations are contained in the above referenced

1996 WHO recommendations. I was unable to ascertain the exact location of such regulations.

reported by the Institute for Food Science and Technology³⁹, provides a useful model of steps that could be taken in the US to reduce the threat of BSE and CJD in the US.

1988:

1. *The Bovine Spongiform Encephalopathy Order 1988 (S.i 1988/1039) coming into force 21st June 1988.* Provided for compulsory notification of BSE / suspected BSE; veterinary investigation; prohibition on sale and supply for feeding to ruminants and the feeding to ruminants of any feeding stuff in which animal protein has been incorporated.

2. *The Bovine Spongiform Encephalopathy (Amendment) Order 1988 (S.i 1988/1346).* Enables the Minister to cause animals to be slaughtered on account of BSE.

3. *The Bovine Spongiform Encephalopathy Compensation Order 1988 (S.i 1988/1346).* Prescribes the amount of compensation payable for bovines slaughtered on account of BSE (50% for confirmed cases, 100% for negative cases, both subject to a ceiling).

1990:

4. *The Bovine Spongiform Encephalopathy Compensation Order 1990 (S.i 1990/222).* Changed amount of compensation payable for animals slaughtered on account of BSE (full compensation for affected animals, subject to a ceiling).

5. *The Bovine Animals (Identification, Marking and Breeding Records) Order 1990 (Si 1990/1)*
Requires bovine animals to be identified by an approved

- The Institute of Food Science and Technology (UK), through its Public Affairs and Technical & Legislative Committees, authorized a Position Statement, dated 9 September 1997. See part 6/6. BSE Legislation Appendix.

identification; introduces new record keeping arrangements requiring cattle farmers to maintain breeding records for ten years.

1991:

6. The Export of Goods (Control) (Amendment No. 7) Order 1991 (S.I. 1991/1583). Controls exports to third countries of bovine offal, protein derived from bovine offal and feedingstuffs containing such offal or protein.

1995:

7. The Fresh Meat (Hygiene and Inspection) Regulations 1995 (S.I. 1995/539). Requires meat cutting premises to remove spinal cord from bovines over six months of age, and removal and collection of obvious nervous and lymphatic tissue and prohibition on its use for human consumption.

8. The Specified Bovine Offal (SBO) Order 1995 (S.I. 1995/613). Consolidates and streamlines rules on SBO; places tighter controls on record keeping; creates procedures for rendering plants processing SBO; prohibits the removal of brains and eyes; prohibits the removal of spinal cord from vertebral column except in a slaughterhouse.

9. The Specified Bovine Offal (Amendment) Order 1995 (S.L. 1995/3246). Prohibits the use of bovine vertebral column for the mechanical recovery of meat and the production of certain other products for human consumption; prohibits the use of meat recovered by mechanical means from the vertebral column of a bovine animal in food for sale for human consumption; requires registration of plants recovering meat by

mechanical means from bovine animals; prohibits the export of meat recovered by mechanical means from bovine vertebral column to other member states.

1996:

10. *The Bovine Spongiform Encephalopathy (Amendment) Order 1996 (S.L 1996/962)*. Prohibits the use of mammalian meat and bone meal in the preparation of feedingstuff for livestock, fish and equine animals.

11. *The Fertilizers (Mammalian Meat and Bone Meal) Regulations 1996(5.1. 1996/1125)*. Controls the sale of mammalian meat and bone meal for use as or in a fertilizer on agricultural land.

12. *The Fresh Meat (Hygiene and Inspection) (Amendment) Regulations 1996 (S.L 1996/1148)*. Extended the circumstances in which a person may use a slaughterhouse for the slaughter of animals, the meat of which is not intended for human consumption.

13. *The Heads of Sheep and Goats Order 1996 (S.1 1996/2264)*. Sets out controls regarding the removal and disposal of the heads of sheep and goats after slaughter and prohibits them from entering the human food chain.

1997:

14. *The Specified Bovine Material (SBM) Order 1997 (SI 1997/617)*. Consolidates SBM legislations and introduces further controls in relation to use of SBM in cosmetic, pharmaceutical and medical products, in relation to straining requirements for SBM, and in relation to the definition of premises which can use SBM for manufacturing processes.

C. US Actions to Minimize Possible Risk

A complete examination of BSE and CJD requires an analysis of the actions that the USDA and FDA have taken to minimize the potential risk of such diseases in the United States. Such an analysis is essential in facilitating the identification of the areas in which the US government needs to take additional preventive measures. More specifically, such an examination allows one to identify areas in which current US regulation of BSE is lacking in light of the WHO recommendations and British legislation discussed above.

Department of Agriculture

The United States Department of Agriculture (USDA) is responsible for the health of US livestock. USDA's Food Safety and Inspection Service operates a substantial program for inspecting animals intended for human consumption. The USDA's Animal and Plant Health Inspection Service enforces explicit import regulations covering animals and animal products offered for import into the US, to prevent the importation of foreign exotic diseases such as Foot-and-Mouth Disease, Rinderpest, and African Swine Fever. USDA examines all cattle before they can be approved for use as human food. USDA examines over 33 million head of cattle each year.⁴⁰

In 1989, the USDA issued restrictive import prohibitions designed to prevent the entry of BSE into US livestock herds. Its aggressive BSE monitoring program has examined more than 5,100 brains of US cattle exhibiting various abnormal behaviors, including neurological symptoms. USDA veterinary pathologists have performed

⁴⁰ Center for Veterinary Medicine BSE and CJD Fact Sheet dated January 2, 1997.

Id.

histopathological examinations of brain tissue, as well as immunohistochemistry to detect possible spongiform encephalopathy. No evidence of BSE has ever been found in these US cattle specimens.⁴¹

HHS Protections

Agencies of the US Public Health Service have a long-standing commitment to research, epidemiological studies, and consumer protection involving BSE and CJD.

Cattle Feed Restrictions: As recommended by the WHO consultation in April, the FDA and the livestock industry are moving to ban the use of ruminant protein in all ruminant feeds. As of August 4, 1997, 21 Code of Federal Regulations Part 589 became effective, which prohibits the use of animal proteins in ruminant feed.⁴²

For many years, FDA has carefully reviewed pharmaceutical products marketed in the US for possible or potential contamination with conventional microorganisms (bacteria, yeast and mold) during their manufacture. In 1990, FDA intensified its microbiological review of its new drug applications for human drug products derived from bovine sources. Manufacturers are required to document that: animal tissues used in the manufacturer of these drug products did not originate in a country where native cattle have been diagnosed with BSE; the animals had been inspected by the source country's veterinary authorities, both before and after slaughter; and that the animals are suitable for food use. As a condition of approval, drug manufacturers of bovine-derived pharmaceuticals are required to report outbreaks of BSE in countries where the bovine

materials originate. Also, in 1992 and 1996 FDA issued a series of letters advising all manufacturers of FDA regulated products derived from bovine tissue materials that source materials should not come from cattle that ever resided in a BSE country.⁴³

Research: The National Institutes of Health (NIH) has long been actively researching CJD and kuru, a related disease among humans, and BSE in animals. NIH research has independently confirmed findings to date from the Department of Agriculture and the Centers for Disease Control and Prevention (CDC). In the 1960s and 1970s, a Nobel Prize-winning team at the NIH laboratory of Central Nervous System Studies conducted experiments on the oral transmission of CJD, kuru and scrapie (a similar disease that affects sheep and goats).⁴⁴ Today, researchers in the US and around the world are collaborating in the search for methods to detect, prevent and treat prion-linked diseases. NIH scientists are providing input to the current investigation of the ten cases of variant CJD in the UK and have developed a diagnostic test that can be performed before death. This collaboration between NIH and international experts fuels the ongoing search for clues that one day might lead to a treatment for this group of diseases.⁴⁵

Disease Surveillance: The Centers for Disease Control and Prevention (CDC) in Atlanta conduct surveillance for CJD through direct examination of death certificate data for US residents. Based on this surveillance, during the period 1979 to 1993, the annual incidence of CJD remained stable at approximately one case per million persons. In light of concern about the new variant CJD cases in the UK, CDC is working with the Council

⁴² Federal Register: June 5, 1997 (Volume 62, Number 108), page 30935-30978.

Id at page 2.

Id.

Id.

of State and Territorial Epidemiologists to expand current CJD surveillance. CDC is piloting enhanced surveillance efforts, including an active search for variant CJD as described in the UK. This enhanced surveillance is coordinated through CDC's Emerging Infections Programs in Minnesota, Oregon, Connecticut and California.⁴⁶

Id at 2-3.

Voluntary Compliance

On March 29, 1996, the beef and sheep industries and veterinary medical groups announced their implementation of a voluntary ban on ruminant-to-ruminant feed as a safeguard against BSE. The groups supporting the voluntary ban included the National Cattlemen's Beef Association, the American Sheep Industry Association, the National Milk Producers Federation, the American Veterinary Medical Association, the American Association of Bovine Practitioners and the American Association of Veterinary Medical Colleges.⁴⁷ The voluntary ban was in response to the BSE epidemic in Britain in March of the same year.

At the time of the voluntary ban, the FDA had yet to implement any rule or regulation prohibiting the use of animal proteins in animal feed.⁴⁸ While 21 CFR Part 589 (as discussed below) negates the need for such a voluntary ban by prohibiting ruminant-to-ruminant feed, such a voluntary ban sends an interesting signal to the FDA. The voluntary ban indicates the cattle industry's willingness to embrace and comply with the ruminant-to-ruminant prohibitions. While rendering facility and slaughter house practices must still be policed by the FDA to ensure regulatory compliance, the industry has an extremely strong economic incentive to fully comply with the regulations in an attempt to prevent an outbreak of BSE in the United States. While the industry's incentive is clearly not a humanitarian one, its effect is equally satisfying. Simply put, the cattle industry stands to suffer financially if an outbreak of BSE occurs in the United

⁴⁷ See Note 21.

⁴⁸ Safeguards Against Mad-Cow Disease Planned in US; by Lawrence K. Altman; New York Times, March 30, 1996.

States, thus a high level of voluntary compliance with the now mandatory statutory prohibitions is quite likely.

21 CFR Part 589

Proposal Discussion: The FDA-CVM and the Office of Consumer Affairs sponsored a public meeting February 13, 1997 for consumers regarding Federal Register 21 CFR Part 589, which was designed to protect against BSE.⁴⁹ The meeting was designed to provide a forum for industry and consumers to provide comment on the proposed rule which was published in the Federal Register of January 3, 1997.⁵⁰ FDA published a proposed rule that would regulate persons that manufacture, blend, process and distribute certain animal protein products and ruminant feeds containing such products. The proposed rule would have created a new Sec. 589.2000 entitled Animal proteins prohibited in ruminant feed. In general, the proposed rule would state that protein derived from ruminant and mink tissues is not generally recognized as safe (GRAS) for use in ruminant feed, but rather a food additive subject to certain requirements under the Act. The proposed rule would also require certain cautionary statements on products that contain or may contain such proteins, and establish recordkeeping requirements. These proposed recordkeeping requirements were intended to facilitate compliance with the rule. For example, an invoice obtained from a feed manufacturer for a protein product not labeled with the cautionary statement could be used to trace the product back to the supplier to ensure that the supplier manufactures and distributes animal protein products from nonruminant sources. The proposed rule also would reduce or eliminate certain

⁴⁹ See FDA-CVM BSE Open Forum Transcript. Said Public Meeting was held Thursday, February 13,

regulatory requirements upon the development of methods for detecting or deactivating TSE agents, or for verifying product identity.

The proposed rule was the latest in a series of preventive measures that FDA, other federal agencies, and industry have taken to protect animals from transmissible degenerative neurological diseases, including BSE, and to minimize any potential risk that such diseases could be transmitted from animals to humans. The preamble to the proposed restriction also contained five alternatives to the proposed restriction on the use of ruminant protein in ruminant feed. These alternatives included a restriction on the use of all ruminant and mink materials (except those that have not been found to present a risk of transmitting TSEs) in ruminant feed, a restriction on the use of all mammalian protein in ruminant feed, a restriction on the use of materials from domestic species (such as sheep, goats, mink, deer and elk) diagnosed as having TSE, a restriction on the use of specified sheep and goat offal in ruminant feed, and a no action alternative.⁵²

The FDA's proposal to ban ruminant-to-ruminant feed was seen as problematic by many industry members as well as consumers. The agency received over 700 comments on the proposed rule and 60 comments on the codified provisions of the draft final rule.⁵³ The comments came from a wide variety of organizations, such as cattlemen, renderers, feed manufacturers, and pharmaceutical firms, federal agencies, foreign governments,

1997 at the Holiday Inn-Capitol; Washington DC.

62 FR 552

~ 21 CFR Part 589 at 30936

⁵² Id.

~ 21 CFR Part 589 at 30937.

State agricultural departments, trade associations, professional organizations, universities and research institutions, consumer organizations and individual consumers.⁵⁴

A large number of comments encouraged FDA to increase the scope of the regulations to include a partial or complete mammalian-to-ruminant prohibition or a mammalian-to-farm animal prohibition, or to apply a feed prohibition on all food-producing animals, either to achieve a greater reduction in the potential risk of human exposure or easier compliance with less need for enforcement actions. For example, a few comments asked that the proposed regulations be expanded to prohibit the feeding of ruminant proteins to felines and zoo animals, and the feeding of proteins from these animals to ruminants. Some comments noted the presence of scrapie and other TSE diseases in the United States and the epidemiological association between scrapie or a modified scrapie agent and BSE in the United Kingdom in support of enlarging the scope of the rule. One comment requested a ban on the feeding of all animal remains to other animals, regardless of species or processing method. Another comment noted that the specifications for tallow allowed for the presence of a small amount of protein and the possibility of a protein-associated infectivity.⁵⁵ Consider the following comments in favoring a more restrictive rule.⁵⁶

Dr. Michael of the Consumers Union commends the FDA for considering steps to prevent the possible occurrence and spread of the TSEs in ruminants. However, we feel that the current proposed action, which is prohibiting the use of ruminant or mink

~ Id.

~ Id at 30938.

⁵⁶ See Note 36 at 16. Comments made during the forum's open comment period.

Id at 16.

proteins in ruminant feed, is not sufficiently protective of the public health. In fact, we don't feel that any of the six options are currently protective of public health.

Because TSEs may occur in pigs and chickens as well as ruminants and because TSEs are believed to be transmissible to humans and because of the severity of the risk, FDA should take a more prudent approach. To fully protect public health, we are urging the FDA to basically do what was done in Britain, and that is to prohibit the use of any mammalian animal protein in food or any food animal. That's what they are doing in Britain and our basic concern are, leading us to think why we should be banning all mammalian protein in use of animal feed...⁵⁷

Caroline Smith DeWaal, Center for Science in the Public Interest stated, When the first case of BSE is documented in this country, the failure to act by this agency, by USDA, and any other agency with involvement here will be catastrophic. It'll be catastrophic to the cattle industry. It'll be catastrophic to American consumers. We saw the impact in Great Britain. We can learn from that example.

Cost benefit analysis should not be used to weaken the public's health protections which are needed to address this problem. The benefit to consumers of avoiding a fatal brain disease is not quantifiable and they are willing to take whatever steps, to see the agencies take whatever steps so they can avoid that risk. Were lucky because we're dealing with a situation where we think it hasn't been found yet in this country. We can almost entirely avoid the risk if we take the proper prophylactic steps right now, and its up to the government agencies involved to take those steps.

⁵⁸ Id at 18.

We believe the risks to American consumers have not been adequately assessed. We've heard numbers, 5,100 brains have been examined since 1990 or maybe 1989, who knows. The bottom line is, that's not really enough to give us tremendous confidence that it doesn't exist. In addition, we do know that CJD, the TSE most commonly found or associated with humans, does arise spontaneously and so it is likely that it does exist in low levels in this country.

Therefore, we urge the agency to take prophylactic protection and we support nothing less protective than the ruminant-to-ruminant feed ban which you have proposed. In addition, we think that Consumers Union's proposal for a mammal-to-all-farm animal ban should be carefully considered by the agency and should be adopted if it is, in fact, more protective of public health.

I also have to note that the absence of inspection of feed mills is troubling. I don't see how you can enforce this rule without inspections, and simply having a paperwork inspection system, as we know because of the work on HACCP, isn't going to be enough to satisfy American consumers that enforcement is really occurring. So I think you need to look at the issue of whether you have adequate inspection frequency of these plants and how you plan to enforce it. That isn't really adequately addressed in the rule.⁵⁸

Ms. Linda Golodner of the National Consumers League took the position that the National Consumers League supports the Food and Drug Administration proposal to prohibit using tissue from ruminants, from cows, sheep, goats, and other animals in the

manufacture of ruminant feed, and we would urge you to seriously consider the comments of Consumers Union to expand precautionary measures to assure safety.

The American public depends on its government regulatory agencies to take all reasonable precautions to prevent BSE from arriving at our shores. Our nation has a history of taking measures of protecting its citizens from questionable foods, animal and plant diseases, and viruses. Consumers traveling across the borders and sometimes from state to state recognize and accept the strict rules that are meant to protect us from human infection and infections of our animal and plant life. This is why we applaud the actions of the FDA and we recognize the safeguard to ensure that the spread of BSE is highly restricted. While the FDA is protecting our animal population with a potential of protecting the public from the possibility of CJD, the United States Department of Agriculture has not yet acted to assure the American public that meat does not contain spinal cord and other nerve tissues. I recognize that the FDA called this public meeting, but the American public considers the government the government and that the FDA and the USDA work together.

There is evidence that there is spinal cord tissue and brain stem tissue in product derived from advanced meat recovery (AMR) systems used by major processors in the US. This so-called meat has been analyzed by experts at the University of Nebraska in 1995 and they found spinal cord presence. The FSIS veterinary pathologists in Athens, Georgia, the regional laboratory of the Agricultural Research Service, found spinal cord and brain stem tissue in AMR samples. And while the FDA is taking precautionary measures to assure that animals are safe, the USDA has not responded to this evidence of spinal cord in our meat supply. There is also evidence of marrow in the AMR product.

Id at 19.

We urge the FDA to work with the USDA to assure that all these products are safe. It is irresponsible and dangerous to delay actions and the FSIS should ban the use of neck and backbones in the AMR system. We applaud the FDA for its proposed regulation to protect animals and we urge you to get the USDA to follow your lead.⁵⁹

Richard Wood of the Food Animal Concerns Trust (FACT) reflected the position of FACT in saying that FACT is a nonprofit organization that advocates better farming practices to improve the safety of meat, milk and eggs. We have participated in the FDA and USDA steps responding to concerns about BSE and TSE to the best of our ability...

We support the implementation of the proposed rule prohibiting the use of ruminant-derived protein in feed for ruminants. We believe this rule addresses the wellbeing of both the public and the well-being of the food animal industry. Without this prohibition, the public is at risk to a disease that is fatal if contracted. Without this prohibition, the industry is vulnerable, as we have seen, to the same devastating consequences experienced in England. And since we are dealing with a disease that has an extremely long incubation period and currently there is no adequate diagnostic test to determine its presence in animals, furthermore, it appears to be linked to a fatal human illness, in this circumstance, both the public and the industry should welcome new regulations. We would expect that any opposition to the regulation will be short-lived.

Nothing less than a prohibition on using ruminant-derived protein to feed ruminants is acceptable to us. The alternative proposals offered by the rule allow for too great a risk regarding undetected TSE in tissues or in other animals in the herd or flock. On the other hand, FACT is not opposed to a more stringent ban than what has been

proposed, such as a mammal-to-ruminant prohibition, particularly if it simplifies the regulation's enforcement and compliance.

The proposed regulatory requirements need to be strengthened, though, where both ruminant and non-ruminant materials are handled by a firm. The rule requires that firms establish separate equipment and facilities or clean-up procedures to prevent cross-contamination. The only verification regarding the integrity of this process in our records are written procedures to be maintained by the firm. FACT wants on-site inspection by the FDA to visually determine that ruminant and non-ruminant materials can be handled separately throughout the processing and shipping. This inspection could be facilitated if there were tests to determine the presence of BSE or test to distinguish between ruminant and non-ruminant proteins, and, of course, these tests do not exist. FACT calls on the FDA to encourage the development of such tests.⁶⁰

Other comments supported a minimalist approach. For example, a significant number of comments pointed out that BSE has not been diagnosed in the United States despite a most exhaustive surveillance effort by Federal and State veterinary laboratory diagnosticians, veterinarians accredited by the USDA, and veterinary practitioners who have been specifically trained to diagnose the early clinical signs of BSE in cattle. The USDA, through statutes administered by the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS), has taken actions to ensure that the border defenses against importing the BSE agent are as secure as possible. FDA has advised manufacturers of human and animal drugs and devices, human biologics, dietary supplements, and cosmetics to obtain bovine derived ingredients from countries

which are free of BSE. Some comments stated that the adoption by industry of voluntary measures to avoid the rendering of fallen sheep or sale of sheep proteins for use in ruminant rations, or to stop the feeding of ruminant proteins to ruminants are sufficient, and no regulation is warranted. Other comments reminded the agency of its public statements that the risk of BSE occurring in the United States is low and getting lower. A comment from a foreign regulatory official observed that zero risk cannot be achieved and that the calculation of risk through a mathematical model is essential; this comment also expressed the view that the agency's proposed regulatory approach exceeded the risk of BSE in the United States.⁶¹

Final Rule: FDA continues to believe, as it stated in the preamble to the proposed rule, that it is prudent to take action prohibiting the use of certain animal protein products in ruminant feed even though BSE has not been diagnosed in the United States and there is scientific uncertainty as to its origin, transmissibility, etc.⁶²

On June 5, 1997 the FDA announced that it was amending its regulations to provide that animal protein derived from mammalian tissues for use in ruminant feed is a food additive subject to certain provisions in the Federal Food, Drug, and Cosmetic Act (The Act).⁶³ The Act defines a food additive as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . if such substance is not generally recognized, among experts qualified by scientific training and

~ Id at 19-20.

⁶¹ See Note 40 at 30938.

⁶² Federal Register: June 5, 1997 (Volume 62, Number 108). Rules and Regulations page 30936.

⁶³ Id.

experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.⁶⁴

Expert opinion that the tissues are GRAS would need to be supported by scientific literature, and other sources of data and information, establishing that there is a reasonable certainty that the material is not harmful under the intended conditions of use. Expert opinion would need to address topics such as whether it is reasonably certain that BSE does not, or will not occur in the US; whether it is reasonably certain that the BSE agent will not be transmitted through animal feed, i.e., that the processed tissues are not infected by the agent, are deactivated by the rendering process or are not transmitted orally; and whether it is reasonably certain that the agent will not be transmitted to humans through consumption of ruminant products. General recognition cannot be based on an absence of studies that demonstrate that a substance is unsafe; there must be studies to establish that the substance is safe. Also, the burden of establishing that a substance is GRAS is on the proponent of the substance.⁶⁵

The final rule also establishes a flexible system of controls designed to ensure that ruminant feed does not contain animal protein derived from mammalian tissues and to encourage innovation in such controls. Thus, under the Agency's authority in section 701(a) of the Act⁶⁶ to issue regulations for the efficient enforcement of the Act, this final rule places three general requirements on persons that manufacture, blend, process,

See Section 201(s) of the Act (21 U.S.C. 321(s)).

⁶⁵ See *U.S. v. An Article of Food *** Coco Rico*, 752 F.2d 11(1st Cir. 1985).

distribute or use products that contain or may contain protein derived from mammalian tissues, and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by the FDA.⁶⁷

The second requirement is for the above mentioned establishments to maintain and make available to FDA records that are sufficient to track any material that contains any protein derived from mammalian tissues⁶⁸ throughout the material's receipt, processing and distribution. Based on available information, FDA believes that maintenance of such records is a usual and customary part of normal business activities for such firms. Therefore, this recordkeeping requirement creates no paperwork burden.⁶⁹

The third requirement is that individuals or firms that manufacture, blend, process or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping requirement is provided below.⁷⁰ During the 45-day comment period provided by the proposed rule, FDA received no comments regarding the requirement that individuals or firms that must maintain written procedures to prevent commingling and cross-contamination. Thus, the FDA received no comments that

⁶⁷ 21 USC 371(a)

⁶⁸ See 21 CFR Part 589.2000(c)(1)(i); (d)(4); (e)(1)(i) and (f).

⁶⁹ As defined in Section 589.2000(a)(1), which reads as follows: Protein derived from mammalian tissues

means any-protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food

and further heat processed for feed (such as plate waste and used cellulosic food casings); milk

products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

⁷⁰ 6962 FR 108 at 30975.

⁷¹ Id.

Id.

72 62 FR 552 at 568.

suggested that the recordkeeping requirements were overly burdensome or did not maximize utility.

The final rule is intended to prevent the establishment and amplification of BSE in the United States through feed and thereby minimize any risk to animals and humans. This final rule becomes effective on August 4, 1997.⁷¹

With regard to the scope of the final rule, protein derived from mammalian tissues includes both ruminant and nonruminant tissues. FDA's basis for its nonGRAS determination for ruminant and mink tissue is discussed extensively in the preamble to the proposed rule and no information was submitted to refute that determination. With regard to nonruminant tissue besides milk, such tissues may include animals such as cats, dogs, horses, swine, etc. As the preamble to the proposed rule discussed concerning a mammalian-to-ruminant prohibition,⁷² industry comments indicated that the usual practice at feed mills and rendering facilities is to commingle ruminant and nonruminant protein products. FDA indicated that regular commingling could provide a basis to determine that protein from mammalian tissues is not GRAS for use in ruminant feed. The description of industry practice received in comments on the proposed rule again indicated that the practice is to commingle ruminant and nonruminant protein.⁷³

Because of the potential TSE infectivity caused by mixing tissues from ruminant and mink and other mammalian tissues, FDA has determined that protein derived from mammalian tissues (with, certain exceptions) is not GRAS for use in ruminant feed. FDA notes that the ruminant-to-ruminant prohibition in the proposed rule also would

have prohibited the use in ruminant feed of this commingled tissue because the definition of protein derived from ruminant and mink tissue would apply to pure ruminant or mink tissue as well as other mammalian tissue that could contain ruminant or mink protein due to commingling. The final rule also reduces the risk of cattle and other ruminants being exposed to an agent that causes feline spongiform encephalopathy and acknowledges that feline protein could be a commingled component of mammalian protein products.⁷⁴

VI. Recommendations / Conclusion

The final rule⁷⁵ restricts the use of protein derived from mammalian tissues, with certain exceptions, in ruminant feed. Thus the final rule represents a regulatory approach that covers more material and is easier to implement than the proposed restriction on the use of ruminant protein in ruminant feed, but is more flexible and better suited to current industry practices than the alternative restriction of all mammalian protein in ruminant feed. Yet, while the United States has taken several important affirmative steps to minimize the threat of BSE and CJD in the US, additional actions could be taken by various governmental agencies which would increase the effectiveness of the current regulatory regime.

First, much additional research needs to be performed in this area. Our statutory regime is currently based on highly speculative and controversial information. Scientists know precious little about Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease. The existence of prions is also a relatively new discovery, hence scientists do

~ 62 FR 108 at 30937.

~ Id.

not fully understand how they transmit diseases or how they can be destroyed once infected. Additional research and surveillance needs to be conducted both separately and jointly by several governmental agencies. The National Institute of Health, CVM Office of Science, USDA and CDC all need to continue their research into BSE and CJD. An increased understanding of these fatal diseases will facilitate the promulgation of future regulations that will more effectively and efficiently minimize the threat of a future outbreak in the United States.

Additionally, The FDA should expand its record keeping requirements for cattle ranchers. British legislation requires cattle ranchers to maintain extensive breeding, feed, immunization, health and auction records for their herds. The maintenance of such records will allow authorities to more accurately trace the origins and cause of a future outbreak of BSE or CJD. If an outbreak of either of these diseases does occur in the future, insight into rancher's breeding and feeding patterns could prove invaluable in preventing additional occurrences. Furthermore, the marginal cost of maintaining such records would prove to be quite low in that many cattle ranchers already maintain extensive records to satisfy their own informational needs.

British legislation also prohibits the use of mammalian tissues in fertilizers that are to be applied to agricultural land.⁷⁶ The FDA should consider a similar prohibition until scientists are better able to identify how BSE and CJD are transmitted. Scientists are not currently able to rule out the possibility that these diseases may be transmitted through crops which are exposed to fertilizer contaminated with BSE.

~~21 CFR Part 589

76 See Number 11 at page 26.

The FDA also needs to consider implementing on-site inspections to ensure the integrity of slaughterhouse and rendering facility procedures mandated by the final rule. Currently the integrity of the system is verified only through written records maintained on-site by the private firms. While the industry's voluntary ban signifies the industry's willingness to adhere to the regulations, even a minimal level of on-site inspections would surely increase compliance and promote consumer confidence in rendering facility and slaughterhouse processes.

Finally, as suggested by Linda Goldoner of the National Consumers League,⁷⁷ the USDA could greatly reduce the threat of BSE and CJD by further regulating facilities which employ advanced mechanical meat recovery processes. Such facilities should be banned from recovering meat from the neck and vertebral column of cattle. Such safeguards would help reduce the presence of spinal tissue in our nation's meat supply, which would in turn reduce the likelihood of transmission of CJD to consumers of meat infected with BSE. Plants using such advanced recovery methods would be required to register with the USDA, and the USDA would employ some minimal level of on-site inspections to ensure compliance.

While the US government has taken important steps to minimize the threat of a future outbreak of BSE and CJD in the United States, employment of the additional actions recommended above would greatly strengthen the current regulatory regime. Additionally, the above recommendations would increase the effectiveness of our statutory framework to a level parallel to those recommended by the WHO and employed by the United Kingdom. Only once all available preventive measures are taken will our

statutory framework be complete, and only then will American consumers be able to regain confidence that their food supply is the safest in the world.

See Linda Golodner's comment at page 34.