
CITIZEN PETITION BEFORE
THE UNITED STATES
FOOD AND DRUG ADMINISTRATION

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, Maryland 20857

HUMANE FARMING ASSOCIATION,
Post Office Box 3577,
San Rafael, CA 94912-8902,

et al.

Petitioners,

vs.

JANE HENNEY,
in her official capacity as,
Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71

Rockville, MD 20857

Defendants.

PETITION SEEKING IMMEDIATE ACTION BY THE FDA
TO COMBAT THE SPREAD
OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)
IN THE UNITED STATES

Petition Requesting Immediate Action by the
Food & Drug Administration to
Combat Transmissible Spongiform Encephalopathies

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9. Introduction

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution, the Administrative Procedure Act, and the Food and Drug Administration's (FDA) implementing regulations, the undersigned submits this citizen petition for rulemaking and collateral relief and respectfully requests the Commissioner to establish regulations that protect the public from Transmissible Spongiform Encephalopathies (TSEs) by amending animal feed regulations.

10. Petitioners

This petition is submitted on behalf of the following petitioners:

1. **The Humane Farming Association**, an I.R.S. Code 501(c)3 not for profit organization, with its principle offices located in the State of California and its mailing address at Post Office Box 3577, San Rafael, California 94912-8902, (415) 485-1495;

2. **The Center for Food Safety**, a project of the International Center for Technology Assessment, an I.R.S. Code 501(c)3 not for profit organization with its principle offices located in the District of Columbia at 310 D Street, N.E., Washington, D.C. 20002-5722; (202) 547-9359;
3. **Center for Media & Democracy, Inc.**, an I.R.S. Code 501(c)3 not for profit organization, with its principle offices located in the State of Wisconsin at 3318 Gregory St., Madison, Wisconsin 53711-1725; (608) 233-3346;
4. **R. Douglas and Tracie L. McEwen**, 4 East 270 South, Kaysville, Utah, 84037; Mrs. McEwen's husband is R. Douglas McEwen, 30, a territory manager for a brokerage company until August of 1998, is presently terminally ill with CJD. It is an extremely agonizing decline for him, her, and their two young daughters, ages 3 and 8. He was diagnosed on Nov. 25, 1998 at the University of Utah Hospital in Salt Lake City, Utah, after a brain biopsy.
5. **Patricia C. Ewanitz**, 46 03 216th Street, Bayside, New York 11361; Ms. Ewanitz' husband, Andrew P. Ewanitz, Jr., a engineer and plant facilities manager, died of Creutzfeldt-Jacob Disease (CJD) at Jacob Perlow Hospice, 1st Avenue and 16th Street, New York City on April 9, 1997 after his initial diagnosis was a mild stroke;
6. **Elizabeth A. Armstrong**, 205 S. Cherry Street, Lebanon, Illinois, 62254; Ms. Armstrong's father, Charles O. Butcher, a law enforcement officer, died of CJD on May 6, 1996, at Veterans Administration Medical Center, Richmond, Virginia, after an initial diagnosis of COPD then Parkinson's Disease;
7. **Melvin J. Steiger**, 5582 Cora Way, Salt Lake City, Utah 84118-2316; Mr. Steiger's wife, Eleanor M. Steiger, 57, an accounting clerk, was initially diagnosed with depression. Symptoms began in 1996 with severe leg muscle cramps. Symptoms eventually included changes in personality where she become less patient and more argumentative, loss of coordination, memory and ability to function. Admitted to the hospital for a possible stroke, Mrs. Steiger was positively diagnosed with CJD on the 19th of February, 1998. On February 23, 1998, a biopsy, an EEG and examination confirmed that diagnosis. She passed away at home on March 19, 1998;
8. **Beverly Wilson Goodman**, 7308 Moody Court, Fort Worth, Texas 76180-6107; Ms. Goodman's father, Perry Marlin Wilson, died of CJD at Zale Lipshey a division of Parkland Hospital, Dallas, Texas, with a diagnosis of "unknown" on May 18, 1997;
9. **Mildred B. Campbell**, 2229 Hwy. 601-S, Mocksville, North Carolina; Ms. Campbell's husband, John D. Campbell, a retired law enforcement officer, died of CJD at Forsyth Memorial Hospital, Winston-Salem, North Carolina on March 18, 1997, with

an original diagnosis of stroke and peripheral neuropathy; CJD was later confirmed by a brain biopsy;

10. **Dorothy E. Kraemer**, 901 S. Stanley Street, Stillwater, Oklahoma 74074; Ms. Kraemer's mother cause of death from CJD was confirmed through a brain autopsy after her death at Stillwater Nursing Home on May 16, 1996; the original diagnosis was rapid onset Alzheimer's Disease;
11. **Cecile L. Sardo**, 17065 N.W. 22nd Street, Pembroke Pines, Florida 33028; Ms. Sardo's husband, Joseph Sardo, died of CJD;
12. **Jim and Rebecca Goodman**, of E103 County Q, Wonewoc, Wisconsin 53968, who make their living by farming in the State of Wisconsin;
13. **Bruce and Shelley Krug**, of Box 84 West Road, Constanceville, New York 13325; the Krugs are dairy farmers.

11. Statement of The Facts

Transmissible Spongiform Encephalopathy (TSE) is a mysterious class of diseases that are called by different names in different species. For instance some identified types of TSE are Creutzfeldt-Jakob Disease (CJD) in humans, scrapie in sheep, bovine spongiform encephalopathy (BSE) in British cattle, transmissible mink encephalopathy (TME) in mink in North America, and chronic wasting disease (CWD) in deer and elk in North America. There may be different strains of TSE within species, and new strains may be produced when TSEs move from one animal species to another.

There is vigorous scientific debate as to exactly what the TSE agent is, since it has never been completely isolated, but the leading theory seems to be that it is a mutant or infectious form of a naturally present protein probably present in all mammalian species called a prion protein; the name prion was created by Dr. Stanley Prusiner whose scientific work was awarded a Nobel Prize in 1997.

The common characteristics of TSE diseases are that they are invariably fatal. They can be transmitted through iatrogenic or physician induced exposure, such as corneal transplants, use of dura mater during surgery, contaminated human growth hormones, contaminated probes or possibly even blood. Additionally, infection may occur through exposure of infected material to mucous membranes or open cuts, and apparently in some cases, such as with British BSE-nvCJD, through the ingestion of the infectious agent. The agent does not trigger an immune response, and the infected animal or human appears perfectly normal until at some point in life (usually the sixth decade in humans who develop sporadic CJD) the

disease emerges as holes and amyloid plaque material spreading in the brain, causing symptoms of dementia, similar to Alzheimer's disease, physical failure and death.

TSEs can be difficult to diagnose during life; confirmation of TSE disease is usually made post-mortem through autopsy analysis, or through a newly-developed spinal fluid test and case study, and can be confirmed by passaging the infectious agent from the deceased specimen into the brain of a laboratory animal. (For instance, Dr. Richard Marsh of the University of Wisconsin passaged TME from mink that had fed on 'downer' dairy cattle into two Holstein bull calves via injection in the mid 1980s. The disease that resulted killed the calves, but they did not develop the 'madness' symptoms which led British BSE to be labeled 'mad cow disease.' Instead, the two bull calves suffered 'downer' cattle syndrome and TSE was confirmed as the cause of death in post-mortem examination. This provided further evidence of a theory first expressed in 1964 at a conference organized by Gajdusek and Gibbs that the source of TME might actually be a BSE in U.S. cattle.)

Prior to the outbreak of BSE in British cattle in the mid 1980s, and its spread to the human population as nvCJD which has claimed to date 35 lives, the best known TSE was sheep scrapie. It appeared in Spanish sheep in the 18th century, and has since appeared in most countries that raise sheep. Sheep scrapie appeared in U.S. sheep in the late 1940s, via Canadian sheep of British origins. After the failure of U.S. eradication efforts, sheep scrapie has spread across the United States and its actual occurrence is unknown.

Prior to the appearance of nvCJD in Britain, the best known occurrence of a TSE in humans was the disease kuru, a TSE that appeared in the Fore tribe in New Guinea in the early 20th century, spread by cannibalistic rituals until the recognition of that fact in work by Dr. Daniel Carleton Gajdusek and Dr. Clarence Joseph Gibbs of the U.S. National Institutes of Health. For this work Gajdusek received the first Nobel Prize awarded for TSE research.

When British BSE, dubbed 'mad cow disease', appeared in the mid 1980s, it stood out because of the madness symptoms of the animals in a rabies-free nation. From just a few animals the disease rapidly spread to infect hundreds of thousands. By 1988 epidemiology demonstrated that the disease was in fact being spread by the feeding of rendered animal byproducts as a protein and fat feed supplement. British cattle were consuming the remains unfit for human consumption of sheep, cattle and other animals. While the high prevalence of sheep scrapie in Britain has led to presumptions that British BSE is sheep scrapie in cattle, there is no proof of this. Others suspect that BSE may have emerged from the feeding

of a small number of BSE infected cattle back cannibalistically; in any case, the feeding of infected cattle back to healthy cattle clearly amplified and spread BSE within British cattle, whatever the origins of the TSE agent.

The practice of feeding rendered animal byproducts back to livestock began in very small ways in the 19th century, but became a large widespread practice involving billions of pounds of rendered animal fat and protein from the 1960s to the present. The practice continues today, although with some recent restrictions due to the spread of BSE and the emergence of nvCJD.

Despite the British outbreak, the practice of feeding rendered livestock meat and bonemeal back to livestock has been most widely practiced in the United States, where no meaningful restrictions were even attempted until August, 1997. Today, the U.S. lags behind Britain and Europe in implementing safeguards in the feeding of animals, and allows practices that should be banned, such as feeding pigs to pigs, pigs to cattle, and cattle blood protein to calves. These practices are allowed despite evidence that TSE disease may already infect pigs and cattle in the U.S., and despite the existence of proven TSEs in U.S. sheep, deer, elk and mink.

Indeed, Dr. Clarence Joseph Gibbs theorizes that every mammalian species is likely to have individuals with a TSE disease at some low level, perhaps one in a million. Therefore, any cannibalistic feeding practices might amplify and spread the disease, as in Britain, possibly creating a TSE that can jump from one species to another, as has apparently happened in the

U.K. with the spread of BSE into humans as nvCJD. While 35 deaths to date seems a small number, the British government admits that the virtually invisible disease nvCJD may have an incubation period measured in decades, and therefore it will require the passage of many additional years to determine the extent of the disease and to predict the eventual death toll.

Estimates have ranged from scores to hundreds of thousands eventual deaths from nvCJD in Britain.

CJD exists in the United States, but it is unclear at what level. Most CJD in the U.S. is considered 'sporadic' with an unknown cause. A smaller percentage appears to have a genetic factor.

The U.S. has a large population of persons with various dementia diseases, the most often diagnosed being Alzheimer's (four million cases). There is

no routine postmortem diagnosis of dementia deaths, although autopsy is the only sure way to determine what type of dementia a patient had. It appears that one of four dementia diagnoses made during life are actually incorrect, with another type of dementia causing the death.

Studies of people in the U.S. who have died of dementia suggest much higher levels of CJD than commonly suspected, with proven levels of anywhere from 1 to 13% of dementia victims. Individuals whose family members have died of CJD report great difficulties in receiving a correct diagnosis. Their recent activism through grassroots organizations such as CJD Voice, and the recognition that CJD seems much more common than thought, has led some states (Texas, Utah, Kentucky and Ohio) to begin making mandatory the reporting of CJD. Without specific new programs to investigate and identify CJD cases, the true number cases and whether they are increasing will remain difficult to document.

Given what is now known about the ability of TSE diseases to move between species and infect humans, the existence of animal TSEs in the United States, and the long and invisible incubation period during which a human or animal CJD strain might become epidemic, it is imperative that state and federal agencies implement programs for accurately determining and monitoring the number of TSE cases in humans and animals in the United States.

On December 16, 1998, press in Utah reported the case of a thirty year old man who is terminally ill due to diagnosed CJD. R. Douglas McEwen, is now a petitioner in this action. Mr. McEwen's young age makes this an extremely unusual occurrence; British nvCJD came to public attention because of the similarly young age of its victims. Mr. McEwen was a reportedly avid consumer of deer and elk meat, and some areas of the western U.S., including the area where Mr. McEwen hunted, have been shown to have very high levels (1% to 6% in tested individuals) of chronic wasting disease (CWD) in deer and elk, a TSE apparently unique to North America.

It is possible that Mr. McEwen has CWD contracted through contact with or consumption of infectious deer or elk. Whether or not this is the case, his CJD emphasizes the critical importance of taking all prudent steps to prevent the spread of TSEs in animals and people, and in determining and monitoring the existence of these diseases in the United States.

Human health concerns are amplified by the many unknowns surrounding CJD, including the invisibility of the agent and its infectious routes. For instance, contaminated medical instruments are impossible to adequately disinfect and have spread TSEs to healthy patients, as have cadaver-source tissue and organs. In laboratory tests blood can transmit TSEs, and in

Britain the use of British plasma has been curtailed because of concerns that it might spread nvCJD. Incidentally, Mr. McEwen, the Utah CJD patient, was reportedly a regular, dedicated plasma donor.

In summary, the emergence of infectious TSEs that can move between species is a new and unanticipated public and animal health threat that is being inadequately studied and addressed in the United States. This petition seeks to remedy those failures.

12. Procedural History

In light of the new scientific understanding, new studies and new evidence presented in this petition, the petitioners now request the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) take the following immediate actions to prevent the potential spread of transmissible spongiform encephalopathy including bovine spongiform encephalopathy (BSE), also known as "Mad Cow Disease," Chronic Wasting Disease (CWD), and Creutzfeldt-Jacob Disease (CJD):

1a Amend 21 C.F.R. § 589.2000 ("Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" finalized at 62 Federal Register 30,936 (June 5, 1997)) as follows:

- ai Amend the rule so that blood and blood products are not fed to animals;
- bi Amend the rule so that gelatin and gelatin products are not fed to animals;
- ci Amend the rule so that pig and porcine materials are not fed to animals;
- di Amend the rule so that animal feed labeling requirements include other species beside ruminant species, since TSE is not only a ruminant disease and other animals beside ruminants are infected and pass along TSEs;
- ei Amend the rule to state that no part of any TSE contaminated animal can be fed to animals or humans and that such contaminated material cannot be used as fertilizer, cosmetics, or other products; and
- fi Expand therecord keeping requirements from one year to ten years.

2a 21 C.F.R. § 589.2000 "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" should read:

(i) Label the materials as follows: "Do not feed to any **animal.**"

(h) Inspection; records retention. (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of **10 years.**

(Requested changes indicated in bold.)

Petitioners incorporate by reference information submitted to the agency through previous petitions dated June 23, 1993, December 21, 1993, March 26, 1996, March 27, 1996, as well as a the petition to the Health and Human Services agency dated January 6, 1999 and copied to this agency which presented evidence and requested action to combat the development of TSEs in general, and BSEs in particular, in the United States. Petitioners also incorporate by reference agency actions requested in those previous petitions.

Petitioners also incorporate by reference information submitted to the agency in a previous petition dated March 27, 1997, by the Government Accountability Project which demanded that the laws and regulations that keeps pigs with nervous system disorders from entering the food supply be strengthened.

Petitioners further incorporate by reference information submitted to the agency in a previous petition dated March 4, 1998, by Farm Sanctuary and Michael Baur which requested that the FDA and the USDA immediately label all downed cattle as adulterated pursuant to 21 U.S.C. § 342 (a). Petitioners further incorporate by reference information submitted to the agency in a supplemental petition dated May 10, 1998, which amended the March 4, 1998, petition. That supplemental petition requested that the FDA and USDA immediately label all downed *livestock*, not just cattle, as adulterated pursuant to 21 U.S.C. § 342 (a) to protect the health of the nation by reducing the possibility of the spread of transmissible spongiform encephalopathy (TSE) and its derivations, bovine spongiform encephalopathy (BSE) also known as "Mad Cow Disease," and Creutzfeldt-Jakob Disease (CJD).

On June 23, 1993, petitioning attorneys submitted an "Amended Petition Requesting the Food and Drug Administration to Halt the Feeding of Ruminant Animal Protein to Ruminants" on behalf of several individuals and a non-profit organization. The petition requested the FDA and the USDA to undertake agency actions that would address the potential health threat posed to U.S. animal herds, especially cattle, from TSEs and the threat posed to U.S. meat consumers, especially beef consumers, through the zoonotic development of CJD as a result of eating TSE contaminated meat.

On December 21, 1993, petitioning attorneys submitted a "Supplemental Petition Requesting the Food and Drug Administration to Halt the Feeding of Ruminant Protein to Ruminants" on behalf of the same individuals and non profit organization. The supplemental petition was filed as result of, *inter alia*, the FDA to respond to the June 23, 1993, petition within the one hundred and eighty (180) days mandated by 21 C.F.R. 10.30(e)(2).

In a much belated response to the two petitions, the FDA issued a proposed rule in the Federal Register proposing that specified offal from adult sheep and goats (of more than 12 months of age) is not generally recognized as safe for use in ruminant feed and is an unapproved food additive when added to ruminant feed. In June 5, 1997, a limited rule was promulgated by the FDA providing that a few certain types of animal proteins would not be used as raw materials in the rendering industry.

This petition serves to notify the FDA that it acted arbitrary and capriciously by failing to promulgate a rule preventing the establishment and amplification of TSE, and its particular strains of the disease BSE, CJD, and nvCJD through animal feed.

VA Statement of the Law

A0 Food and Drug Administration, Compliance Policy Guide 7126.24 (10-1-80) states:

Rendered animal feed ingredients which contain harmful microorganisms, toxins or chemical substances may be considered adulterated under Sections 402(a)(1) or (2) of the Act. Where a rendering procedure itself raises a question of disease transmission, the ingredient made may be deemed adulterated under Section 402(a)(4).

B. Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 321(f) defines food as "articles used for food or drink for man or other animals" and "articles used for component of any such article."

C. Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 342, Adulterated Food.

A food shall be deemed to be adulterated –

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance ... or (4) if it has been prepared, packed, or

held under insanitary [sic] conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

D. Administrative Procedure Act, 5 U.S.C. Section 706, Scope of Review.

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning and applicability of the terms of an agency action. The reviewing court shall --

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings and conclusions found to be -- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

E. Food and Drug Administration, 21 C.F.R. § 589, Substances Prohibited From Use in Animal Food or Feed, Subpart A, General Provisions Sec. 589.1 Substances prohibited from use in animal food or feed.

(c) The Food and Drug Administration either on its own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this part on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, shall be the form set forth in Sec. 571.1 of this chapter, and will be published in the Federal Register for comment if it contains reasonable ground. [45 FR 2839, Apr. 29, 1980]

F. Food and Drug Administration, 21 C.F.R. § 10.30(e)(2). Citizen Petition.

The Commissioner shall furnish a response to each petitioner with 180 days of receipt of the petition.

VI. Argument

1. *Inadequate Regulations Violates FDAs Mandate to Protect Public Health*

According to the FDA, “[t]he Food and Drug Administration touches the lives of virtually every American every day.”

For it is FDA's job to see that the food we eat is safe and wholesome, [and] the cosmetics we use won't hurt us . . . Feed and drugs for pets and farm animals also come under FDA scrutiny. FDA also ensures that all of these products are labeled truthfully with the information that people need to use them properly.

As will be established *infra*, the FDA and the USDA have failed to adequately regulate the rendering industry in order to protect the public health. The agency's refusal to amend the regulation "Substances Prohibited from Use in Animal Food or Feed" on the basis of new scientific evaluation and information, as requested in this petition would be arbitrary and capricious.

An agency's action is reviewed by the judiciary under the arbitrary and capricious standards of law. Under this standard, an agency must show a "rational connection between the fact found and the choices made." In determining whether an agency decision was "arbitrary and capricious," a court must consider whether the decision was based on a reasoned evaluation of the relevant factors and whether there has been a clear error of judgment. An agency action is arbitrary and capricious when an agency:

has relied on factors which Congress has not intended it to consider,

entirely failed to consider an important aspect of the problem, offered

an explanation for its decision that runs counter to the evidence before

the agency or is so implausible that it could not be ascribed to a difference

in view or the product of agency expertise.

Many different experts have warned of the possible epidemic proportion of the health threat to the United States' public from TSEs. One expert explained:

[T]he British BSE disaster was not some throwback to antique conditions or mere bad luck. It followed in part from a pernicious anti-regulatory ideology that has taken hold in Britain *and the United States* in the last two decades. . . . [E]ggs and chicken meat contaminated with salmonella, hamburger and fresh cider poisoned

with deadly *E. Coli* and ***beef infected with BSE all evidence a failure of government inspection, supervision and policy.***

The FDA's promulgated rule has been described as "disturbing" in that "compromises [are] built into the FDA's . . . ban." As one expert on TSE states:

[The regulation] . . . prohibit[s] the use of tissue from cattle, sheep and goats in feed for those ruminants but ***would permit the continued feeding of ruminant blood, milk and gelatin*** [This is the continued feeding of ruminants to ruminants]. Ruminant tissue would continue to be processed into feed for chickens, pigs and pets despite the known susceptibility of pigs and cats to spongiform encephalopathy and the possible passage of the disease agent through chickens into their manure, which organic farmers use to fertilize vegetables. Nor do the ubiquitous contamination of U.S. poultry and eggs with salmonella and the continuing outbreaks of human *E. coli* infection in government meat inspire confidence in government inspection. From the rendering industry's perspective, the ban turns a valuable asset into an expensive liability. That reversal in Britain led to widespread cheating. Without rigorous enforcement, U.S. consumers have reason to fear the same result.

Based upon the imminent human health hazard presented by TSEs, including BSE, the FDA must amend this regulations in order to protect human health. The FDA itself, by its very action in implementing animal feed regulations, demonstrates its understanding that animal feed practices that allow for high risk mammalian material to be fed to other mammals is a public health hazard. Allowing significant loopholes in the regulations, such as the feeding of cattle blood to cattle, shows a failure to consider important aspects of the health risk, and is clearly arbitrary and capricious.

2. Specific Regulatory Amendments Requested and Supporting Information

1. Blood and Blood Products Must Not Be Used In Animal Feed Since Blood and Blood Products Carries TSEs

Blood and blood products are listed as exceptions to the list of prohibited substances in the current regulations. Petitioners request that the regulations be amended as follows:

(a) Definitions (1) 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.

This current exception allows the producers and the rendering industry to continue the practice of feeding cattle blood and blood products to cows. This exception to the rule negates the very purpose of the rule. TSEs appear to be found in blood and blood products. Science shows that β (beta)-leucocytes, a component of blood, may propagate prions in blood and are needed for the TSE agent to spread throughout the body. Further, CJD and scrapie have been shown to be transmissible through blood components in rodent models. Because the blood itself is likely infectious, petitioners demand that the agencies stop feeding mammal blood to other animals.

In addition to the blood itself being infected, blood poses another risk in the transmission of TSEs. Blood flows and moves within the body to conduct and transport materials from one site to another site. Thus, simply as a fluid transporter, blood carries potentially high risk neurological material. That high risk neurological material is already banned from use in animal feeds, and thus blood must be banned as well.

In cows, high risk neurological material gets in the blood through the slaughtering process. Many cows are slaughtered via the use of pneumatic stun guns which inject air into the cows' brains destroying them. A cow's brain is literally "blown out" of the cranial cavity. Such force is used in this process that parts of the brain may travel throughout the cow's body. For instance, scientists have discovered chunks of brain throughout the lungs and the liver. Such high risk materials will be found in the blood

of the animals. Thus, merely as a transporter of high risk material, petitioner demand that blood no longer be allowed in animals' feed.

Although there is a risk of TSE contamination from slaughterhouse blood, an even more dangerous practice involves feeding blood directly to animals by adding the blood directly into animal feed.

Blood and blood products are used as animal feed in two ways. In the first practice, blood serum is used to a colostrum supplement for newborn calves. Colostrum is the first milk a calf would receive from its mother which is rich in antibodies and disease prohibiting agents. In modern factory farming practices, calves may be removed from their mothers immediately after birth. A colostrum replacer which might contain blood serum is then fed to the newborns. This practice is especially risky since calves are likely to be more vulnerable to transmission of infectious agents.

The second method of using blood as animal feed is the practice of spraying blood directly onto calf feed for weaned calves. A farm management article states that, "Hog producers have known for years that adding spray-dried plasma made from pigs' blood to their post-weaning starter rations could make money. . . Now there's a growing body of research that suggests spray-dried cows' plasma can make money for dairy producers, too." Since "[t]he method of spray drying helps maintain plasma protein structure and integrity" any infectious agent in the blood will remain potently infectious. Whereas in other animal feed processes, such as rendering, where animals' parts are heated or cooked, the level or titre of TSE infectious agent might be significantly reduced, the practice of spray-drying allows the infectious agent remains unreduced by heat or other processing. Thus, the plasma's protein structure, including the structure of the TSE prion, likely remains intact. The practice of feeding blood to animals is a high risk practice that is a health risk to the public. Based upon this information, the petitioners request the regulatory changes proposed above including the elimination

of blood and blood products from use in animal feed.

2. Gelatin and Gelatin By-Products Must Not Be Used In Animal Feed Since Gelatin and Gelatin By-Products Likely Carry TSEs

The current FDA regulation lists gelatin, *inter alia*, as an exception from prohibited animal feed substances. Petitioners therefore request the following regulatory changes:

(a) Definitions (1) 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.

Gelatine has been shown to be infected with TSE. During the European Commission controversial lifting of the embargo on gelatin in the UK in June, 1996, the Scientific Committee on Cosmetology, the Scientific Committee for Food and the European Medicine Evaluation Agency opposed the end of the embargo on gelatin as it might carry TSEs.

Furthermore, the World Health Organization has specifically recommended that in order to minimize the risk of the transmission of TSEs there should be special regulations for brain, spinal cord or related tissue. Those special regulations will keep high risk neurological tissue out of the food supply. However, high risk material can get into animal feed through gelatin. Gelatin is made from animals' bones. For instance, whole vertebra, the nerve tissues of which is designated high risk neurological material, is used to make gelatin. Thus, petitioners request that gelatin itself be a prohibited substance in animal feed. While England has stopped this mechanical recovery of meat or deboning, the United States continues engaging in this high risk practice. Thus, gelatin is not safe to be added to animal feed and should be prohibited under the regulations.

3. Record Keeping Requirements of One Year are Grossly Inadequate: Establishments and Individuals Responsible for Keeping Records Must Keep Files for Ten Years To Protect the Public Since BSE Incubation Periods Last from Two or Three to Eight Years

Currently the FDA requires cattle “establishments” and “individuals who are responsible for feeding ruminant animals to maintain records for one year of purchase invoices and labels of all their animal feed.” Petitioners request that this regulation be amended as follows:

(f) Requirements for establishments and individuals that are responsible for feeding ruminant animals. Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration; and

(h) Inspection; records retention. (1) Records that are to be made available for inspection any copying, as required by this section, shall be kept for a minimum of ~~1-year~~ 10 years.

Evidence of TSE incubation periods indicates that the FDA’s current record keeping requirement should be changed from one year to ten years for two reasons. First, a one-year record keeping requirement does not protect public health because animals do not show signs of TSE infection within one year. Second, the proposed changes will establish an adequate paper trail so that the agencies can trace back contaminated and infectious material.

The scientific evidence is clear that TSEs do not incubate in one year. According to APHIS’ *own publication*, BSEs are known to incubate for periods of two to eight years. Additionally, another two scientists have suggested that BSE may have an incubation period of between three and eight years. Based on the long incubation period, a one year record keeping requirement will not be adequate to detect the source of TSE. For example, a six year incubation period would mean a five-year gap in record keeping and thus no trace-back is possible to the source of contamination. Therefore, a ten year record keeping period will ensure the agency is reasonably prepared to prevent TSE outbreaks.

4. Pork and Pure Porcine Protein Must Not Be Used in Animal Feed Since Pigs are Susceptible to TSEs

Porcine and equine protein are referenced in the regulations, *inter alia*, as an exception to the definition of protein and thus allowed in animal feed. Petitioners request the following amendments to the regulation:

(a) Definitions (1) 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.~~

The current rule allows renderers to continue the practice of feeding animals to animals as long as that material comes from single species slaughterhouses, dubbed pure porcine or pure equine materials. Although FDA permits pig products in animal feed, the science shows that pigs are susceptible to TSEs. Due to this public health danger, other countries have proposed regulations banning the use of the remains of any mammals in pig feeds and banning the use of pig slaughterhouse waste and petfood waste as animal feed. Thus, FDA should prohibit the use of pig products or pure porcine protein in animal feed.

1. Case Studies Show that
People who Eat Pig Brains
Risk Infection of TSE

The greatest concern to human health involving infection from pigs comes from the ingestion of pig products as food. Epidemiologic evidence indicates that TSE victims are greater-than-average consumers of pig products. This concern comes from three case control studies. In the most recent and largest study, evidence shows that TSE in pork causes CJD in humans. This case control epidemiological study indicated a possible link between brain consumption and *sporadic*CJD, not *nv*CJD. In this study,

involving over four hundred CJD cases, researchers discovered a link between animal consumption and sporadic CJD. This link from animal consumption to sporadic CJD is worthy of notice because it has been presumed that only nvCJD, not *sporadic* CJD, was caused by animal consumption. The second study involved 38 CJD patients and showed that an unusually high number – a full one-third – ate brains as food. Indeed, those who ate brain tissue as food had a preference for hog brain. The third study involved 26 victims of CJD and showed that nine out of 45 food items were statistically related to the risk of CJD infection. *Six of nine* high risk food products came from pigs. The scientists who presented the evidence cautioned “[t]he present study indicate[s] that consumption of pork as well as its processed products (e.g., ham, scrapple) may be considered as risk factors in the development of Creutzfeldt-Jakob Disease.” “An increased consumption among [CJD] patients was found for roast pork, ham, hot dogs . . . , roast lamb, pork chops, smoke pork and scrapple.” In light of the risk of CJD from the consumption of pork and pig products, the agencies must protect the public from the risk of this disease by banning the use of all mammalian proteins, including swine, in the feed of all food animals.

2. FDA is Aware of the Evidence of Porcine TSEs

Evidence for the potential PSE (porcine spongiform encephalopathy) was gathered by an FSQS veterinarian, Dr. Masuo Doi. In 1979, Dr. Doi noticed some unusual central nervous system (CNS) symptoms in young (about 6 months old) hogs coming into a slaughter plant in Albany, New York. Dr. Doi decided to conduct a detailed study on central nervous system (CNS) symptoms/disease in young hogs which ran for 15 months (January 1979 to March 1980). The study consisted of extensive observations of animals, followed by pathological,

histopathological, and microbiological work on tissues from various organs of particular animals after slaughter.

The brains of 60 animals were examined. Examination was performed by Dr. Karl Langheinrich, Pathologist-In-Charge at USDA's Eastern Laboratory in Athens, Georgia. According to the USDA FSQS laboratory report, dated early November, 1979, Dr. Langheinrich noted similar brain defects between the pigs' brains and the brains of other animals infected with TSEs.

Indeed, the doctor's main diagnosis was encephalopathy and diffuse gliosis of undetermined etiology. Portions of the brains were sent for microbiological testing to a neurologist at the University of Georgia, where they came up negative for pseudo-rabies. The brain matter was unique enough that USDA scientists, Dr. Langheinrich and Dr. Doi, have mentioned it to students and scientific colleagues over the years.

Both the behavior of the pigs, as well as the histopathology on at least one pig, showed signs consistent with a porcine TSE. Behavioral changes can be seen in TSE-infected animals *before* any changes in brain morphology are visible. Dr. Clarence Joseph Gibbs, in testimony before a Congressional hearing on the TSE issue on January 29, 1997, made just this point

In the mid-1960s, we demonstrated with our French and English collaborators that *during the early incubation of the TSEs, when the virus titer in the brain was very low, there were already marked functional changes, even though no pathology was yet detectable, even ultrastructurally*. A month or two later, polynucleation of neurons appeared in spider monkeys, incubating kuru, and somewhat later, microvacuolation and membrane changes visible only by electron microscopy. *This preceded the first appearance of astrogliosis and spongiform change*. It was only much later that the classical scrapie-TSE pathology appeared with virus titers in brain of 10^{-5} or higher."

In November, 1996, USDA sent the single histopathology slide to Dr. William Hadlow, one of the foremost spongiform encephalopathy pathologists in the world. Dr. Hadlow reported:

I am impressed, though, with what seems to be an increase in the number of astrocytes in the section. Some astrocytes are in clusters, some are enlarged and vesicular. Where they are most numerous, a few rod cells (activated microglia) are seen. These findings suggest some perturbation of the nervous tissue. *Although such a glial response occurs in the transmissible spongiform encephalopathies, I do not know its significance in this case without examining other parts of the brain for changes characteristic of these diseases.* Thus, from looking at this one (1) section of brain, I cannot conclude that the pig was affected with a scrapie-like spongiform encephalopathy. (Emphasis added.)

In recounting the quality of the slide, Dr. Hadlow stated, "It was a bum slide. There was no evidence to make any diagnosis." Months later when Dr. Hadlow received additional slides he recalls that those slides were poorly prepared as well. Thus, Dr. Hadlow does not conclusively rule out a form of porcine spongiform encephalopathy, but rather this type of evidence suggests similarities to spongiform encephalopathies. England has developed more restrictions on what can be put into the rendering mix as science has learned more about how TSE can be transmitted. The United States however, continues to allow heads and backbones of cows, pigs and other animals. Considering the scientific evidence that pigs carry TSEs and further considering the risk to people who consume porcine products, Petitioners request that regulatory changes be made so that porcine protein material cannot be used in animal feed.

4. Animal Feed Labeling Requirements Must be Expanded to Include Other Species Beside Ruminant Species Since Other Species Get TSEs

Regulations addressing the labeling of animal feeds containing high risk TSE material should be amended as follows:

(I) Label the materials as follows: “Do not feed to ~~cattle or other ruminants~~ animals”

Labeling requirements must be changed to “Do not feed to animals” because the causative agent of TSE is unknown. The FDA’s regulation contains a loophole for the rendering industry allowing the selling of TSE contaminated material to other animal food producers, such as pet food manufacturers.

The theory behind a possible origin of TSEs is generally attributed to Dr. Clarence Joseph Gibbs, Jr. This “Gibbs Hypothesis” states that TSE occurs “spontaneously” as a natural mutation in mammals including humans. Usually, these odd, very rare, spontaneous cases would not be noticed or passed on. However, the ritual of butchering human bodies and cannibalism of the Fore People of New Guinea is a model for how a disease can spread when a species consumes its own members. This example shows why TSE infected material should not be fed to animals. The prion gene that causes TSEs has been found in all mammals studied so far. TSEs also have been found, or experimentally induced in many mammals including sheep, pigs, goats, cattle, deer, elk, mink, mice, hamsters, guinea pigs, domestic cats, puma, cheetah, eland, kudu, Arabian oryx, nyland, marmosets, macaques, chimpanzees and humans. Vulnerable species now include salmon and Drosophila (fruit flies). Considering the number of susceptible animals to TSEs, the agency should change its regulation to “Do not feed to animals” in order to ensure the TSEs do not affect public health and spread throughout all U.S. domesticated animals.

1. TSEs Infect Cats and Cat Food Must be Safe from TSE Contamination

In 1990, a cat named Max was the first feline to die of CJD in England. The chief veterinary officer stated that there was “[N]o cause for

alarm at all. . . . This is only one cat death out of 7 million cats in the U.K.” Over the course of only the next four years, sixty-six domestic cats would die before the government admitted that contaminated pet food probably killed them. “By 1 July 1998, 85 cats had succumbed to FSE in GB, 1 in Northern Ireland, 1 in Norway and 1 in Liechtenstein (both homebred cases). In light of the BSE epidemic in other countries, the FDA should change its rules to “Do not feed to animals.”

2. TSEs Likely Infects Dogs and Dog Food Must be Safe from TSE Contamination

In England, the pet food manufacturers voluntarily introduced a ban on all specified offal thought to be high risk for TSE in 1989. Later, in 1990, subsequent to the death of the first feline victim, “Max,” the government codified that ban. Since that time, 85 cases of cat TSE (Feline Spongiform Encephalopathy FSE) have been found. Over 400 hound dogs were examined in 1991, and although there were allegations that the British government covered up the findings, it appears that dogs do get TSE. Additionally, the Gibbs Hypothesis indicates that dogs’ brains will spontaneously mutate the disease at a rate of about one-in-a-million, and they are thus susceptible under the hypothesis. Consequently, dogs should be protected from contaminated food.

2. Some Animals Might be Carrier Species

In order to adequately protect public health, agencies must approach the disease as a uniform TSE disease rather than addressing subgroups or different strains of TSE. This disease is so dangerous because of its likely tendency to produce new strains or new variants in different species just as BSE is presumed to have led to nvCJD. Out of all the variations of differing strains entering differing animals, no one knows just which ones will infect and kill humans.

The agencies must also consider that some animals might merely be carrier species and not become ill themselves. When scientists injected scrapie into hamsters and then injected infectious agents from the hamsters' brains into mice, the mice did not get a TSE. Indeed, when those mice brains were injected into a second set of mice, the second set did not get scrapie, either. However, when the second set of mice brains were injected back into hamsters, the hamsters did indeed become infected with a TSE. In an analogy, the "British BSE-nvCJD" strain of TSE could be carried by pigs without the pigs showing symptoms of infection, yet later if the pigs parts were fed to cows in an animal feed supplement, the cows could become infected with that TSE which has infected and killed humans.

Scientific experts on medical properties of TSE have determined "that the results presented here would strongly favour a decision to stop feeding ruminant-derived products *to all animal species* especially domestic animals, poultry and animals raised to be consumed by humans since the poultry or domestic animals put into animal feed supplements could be carriers. Indeed, scientists have expressed their concern about this potential spread of the disease:

[F]arm animals that do not contract overt disease after consuming ruminant-derived meat and bone meal may, perhaps, develop a subclinical carrier state. Pigs and chickens that have been fed with cattle-derived meat and bone meal are thought to be safe to eat with respect to BSE, because these animals do not develop disease after oral exposure

to bovine prions. But, to the best of our knowledge, bovine prions from BSE-exposed pigs and poultry have never been assayed using calves as 'indicator' animals.

The FDA has been put on notice by scientists that it is not just cows that present the risk of spreading infectious TSEs. The agencies must consider a broader view of prohibiting mammals from being fed to other mammals.

Evidence shows that TSE has been experimentally induced in animals, and that "British BSE-nvCJD" has been likely transmitted from cows to people via ingestion of beef. Additionally, laboratory studies prove that some species can be carriers. Moreover, the "Gibbs Hypothesis" indicates that TSEs will occur at very low levels as a sporadic mutation rather than as a result from an infectious agent. Thus, there are many avenues of contagion and infection. Any feeding of any animal to any other animal will exponentially increase the spread of this deadly disease. The scientific evidence shows that variety of risks the rendering industry is subject to and the agencies must change the regulations to stop the feeding of TSE contaminated mammals or mammals parts to any other mammal.

5. Animal Feeds Must Not Contain Any Part of Any Animal Showing Signs of a TSE and Nor May Any Such Contaminated Material Be Used as Fertilizer, Cosmetics, or Other Products

The rules promulgated by the agencies to date have not adequately addressed the risk to human and animal health. The rules arbitrarily define protein to exclude hundreds of types of animal parts and proteins from different species. To address loopholes, petitioners request that the current regulations be amended as follows:

(a) Definitions (1) 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.~~

The current rule excludes a few types of protein from rendering while allowing many types of proteins from many species into animal feed. However, this rule is expected to “establish . . . a flexible system of controls and is designed to ensure that ruminant feed does not contain animal protein derived from mammalian tissues.” That goal is not being met by the current rules while animal parts which could carry TSEs are allowed to be used by the rendering industry. It only takes one contaminated animal part in a particular batch of bone meal or other animal food stuff to initiate a huge dispersal of infectious agent and spread the disease. This loophole must be closed by removing the exceptions to the definition of protein.

It is imperative that the United States agencies address the scope of the problem at hand. The appropriate response is for the agency to promulgate a precautionary rule addressing all TSEs. The Congressional Research Service of the Library of Congress has stated:

[A] case can be made that the scientific uncertainties suggest action to control feeding practices that may add to the possibility of cattle contracting BSE. Given the uncertainties, many believe it is safest to err on the side of caution until more of the questions on BSE and CJD are answered.

British beef laws have demanded that mammals no longer be fed to mammals. To comport its regulations with the those in other countries, the United States must acknowledge that animal parts which might carry TSE infection, not merely BSE infection, must not be used as fertilizer, cosmetics or other products. The WHO recommendations stated that no part or product of any animal which has shown signs of a TSE should enter the human or animal food chain. The WHO explains that many animals that are used as raw material for rendering have never been inspected and where inspected some parts of ruminants still make their way into animal feed. The recommendation requires all countries to ensure the killing and safe disposal of all parts of products of such animals so that TSE infectivity can not enter the food chain.

Meanwhile, the U.S. agencies optimistically overemphasize that “[British style] BSE has NOT been found in the United States.”

However, BSE is only one type of TSEs. As noted, there are many other diseases under the classification TSE, including, sheep scrapie, mink encephalopathy and a deer and elk disease called Chronic Wasting Disease (CWD). These TSEs have been known to exist in the United States for decades. The agencies must expand their rulemaking beyond British BSE-nvCJD, which is merely one facet of a disease that does not acknowledge a species barrier.

Moreover, the USDA overstates its case when it alleges that there is no BSE in the United States. It should be noted that one particular BSE positive cow from England was reported in Canada. Additionally, the FDA is aware that mink TSE has been transmitted to bulls which then showed symptoms of "downer cow syndrome" and died of TSE. There is scientific evidence that BSE will exist in cows at the same sporadic rate that it exists in humans, at about one in a million animals. Therefore, it is fallacious and misleading to contend that there is no BSE in the United States. Certainly, some BSE exists, at least in its sporadic variation or perhaps as "downer cow syndrome," even if not as "British BSE-nvCJD". Moreover, the question as to whether or not BSE exists in the United States is really a question of surveillance.

We've had one reported case of BSE in North America -- in Canada, in a cow imported from the United Kingdom. That cow was found by a rancher who had gone out on the range to feed his herd because of a severe snowstorm. If there had been no storm, the rancher would have stayed home, the cow would have gone down, a coyote would have eaten it, and no one would have been any the wiser.

These facts have led Dr. Clarence Joseph Gibbs, a TSE researcher, to query, "Do we have BSE in the United States? The real question is, if we do, will we find it?"

Furthermore, agencies' allegation that there is no BSE in the United States must be viewed in light of the fact that the number of BSE tests has been "phenomenally small." So far the USDA has only tested 2,000 animals out of 7,100 dead suspected cows.

Considering that other countries have banned feeding of any possible TSE carriers to other animals, and further considering that it is likely that at least sporadic BSE exists in the United States, as well as the fact that surveillance for "British BSE-nvCJD" is poor, the agencies must implement a rule keeping animals showing signs of TSEs from being used in products such as food additives, fertilizers, and cosmetics.

13. Environmental Impact & Certification

The enforcement actions here requested will not cause the release of any substance into the environment. They are categorically excluded from the requirement of environmental documentation under 21 C.F.R. 25.33(g).

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitions relies, and that it includes representative data known to the petitions which are unfavorable to the petition. Except as described above, petitioners know of no other similar issue, act, or transaction to this petition currently begin considered or investigated by any HHS office, other federal agency, department, or instrumentality, state municipal agency, court or any law enforcement agency consistent with FDA regulation 21 C.F.R. § 10.30(e)(2).

14. Agency Action Requested

Therefore, for the reasons cited in this petition, the reasons incorporated by reference in attorneys' earlier petitions, and because of the extraordinary health threat posed to both cattle and humans by the feeding of rendered animal protein to animals, especially ruminant animals, petitioners request that the FDA and USDA immediately make the following regulatory changes:

1. Amend 21 C.F.R. § 589.2000 ("Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" finalized at 62 Federal Register 30,936 (June 5, 1997)) as follows:

- a. Amend the rule so that blood and blood products are not fed to animals;
- b. Amend the rule so that gelatin and gelatin products are not fed to animals;
- c. Amend the rule so that pig and porcine materials are not fed to animals;
- d. Amend the rule so that animal feed labeling requirements include other species beside ruminant species, since TSE is not

only a ruminant disease and other animals beside ruminants are infected and pass along TSEs; and

e. Amend the rule to state that no part of any TSE contaminated animal can be fed to animals or humans and that such contaminated material cannot be used as fertilizer, cosmetics, or other products and further that contaminated material must be destroyed; and

f. Expand the record keeping requirements from one year to ten years.

2. 21 C.F.R. § 589.2000 "Substances Prohibited From use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" should read:

(i) Label the materials as follows: "Do not feed to any **animal.**"

(h) Inspection; records retention. (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of **10 years.**

Petitioners are requesting a response to this petition within one hundred eighty (180) calendar days. In the absence of an affirmative response, the Petitioners will be compelled to consider litigation in order to achieve the full and complete action required to address this violation of federal law.

Dated this 6th day of January, 1999.

On behalf of all petitioners,

Andrew Kimbrell

Executive Director

Joseph Mendelson, III

Legal Director

cc: Daniel Glickman, Secretary

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