

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND)	
UNITED STOCKGROWERS OF AMERICA)	
)	
Plaintiff,)	Cause No. CV-05-06-BLG-
)	RFC
)	
v.)	DECLARATION IN
)	SUPPORT OF
)	DEFENDANT'S
)	OPPOSITION
UNITED STATES DEPARTMENT)	TO PLAINTIFF S
OF AGRICULTURE,)	APPLICATION
ANIMAL AND PLANT HEALTH INSPECTION)	FOR PRELIMINARY
SERVICE, et al.)	INJUNCTION
)	
)	
Defendants.)	
)	

DECLARATION OF DANIEL L. ENGELJOHN

I, Daniel L. Engeljohn, declare and state the following:

1. I currently am serving, on a temporary basis, as the Acting Deputy Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA). FSIS is the food safety agency within USDA responsible for implementing and administering the nations meat, poultry and egg product inspection laws. My permanent position is in FSIS as the Deputy Assistant Administrator for the Office of Policy, Program and Employee Development. I have been employed by USDA for more than 24 years. My principal responsibilities throughout my service with FSIS have involved ensuring food safety, protecting the public health and managing public health risks associated with meat, poultry, and egg products. My educational background includes a Bachelor of Science degree in animal science

from the University of Illinois, a Master of Science degree in meat science/muscle biology from the University of Illinois, and a Ph.D. in human experimental nutrition from Howard University.

2. FSIS officials, food safety specialists and public health experts, myself included, work closely with the staffs of other United States government public health agencies including the Food and Drug Administration and the Center for Disease Control and Prevention of the Department of Health and Human Services. We work together to ensure the safety of the nation's food supply and public health.

3. Within FSIS, I have worked on the food safety issues posed by BSE since at least 1994, when I was the FSIS official responsible for policy development and risk management for what was then a relatively new technology for mechanically removing meat from bone. This technology is referred to as Advanced Meat Recovery (AMR) systems. Beef from AMR systems was a concern because of the scientific information developed in the United Kingdom pointing to an association between beef spinal cord material, a central nervous system (CNS) tissue, and BSE in cattle and the potential for vCJD in humans. Developing FSIS policy for dealing with the implications of BSE has remained a primary responsibility of mine to this day.

4. BSE is a type of transmissible spongiform encephalopathy (TSE), a group of animal and human diseases which include scrapie in sheep and goats, chronic wasting disease (CWD) in elk and deer, and the variant form of Creutzfeldt-Jakob disease (vCJD) in humans. The BSE agent in cattle has been shown to be linked to vCJD. In the United States, I have been involved with FSIS concern regarding CWD, because infected herds were being slaughtered in FSIS-inspected establishments and I led efforts in FSIS to address concerns with the possibility of cross-contamination of the CWD agent with equipment in the slaughter operation. Thus, my

responsibilities and experience at FSIS encompass the research and evaluation of not only BSE but the entire class of TSEs.

5. In 2002, I was responsible for the development of the FSIS rules to address AMR product. FSIS began collecting samples of beef from AMR systems in order to ascertain whether dorsal root ganglia (DRG), a CNS-type tissue, was present in AMR product. FSIS decided to engage in rulemaking on AMR, due in part to the 2001 scientific advisory committee report for the European Union which considered the amount and distribution of BSE infectivity in a typical case of BSE. The advisory committee estimated that, in an animal with clinical BSE disease, the brain contains approximately 64 percent of the total infectivity in the animal, and the spinal cord contains approximately 26 percent of the total infectivity. Thus the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90 percent of the total infectivity in the animal. The remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG, the trigeminal ganglia, the distal ileum, the spleen, and the eyes. I should point out that, in the study designed to identify the proportion of infectivity in cattle tissue, the scientists estimated the level of infectivity in the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle. In pathogenesis studies designed to ascertain when animals demonstrate clinical signs of BSE, as well as the distribution of infectivity in the animal's body, highest levels of infectivity were detected at the end stages of disease, as early as 35 months post oral exposure. Therefore, in older animals, FSIS concluded that the tissues known to demonstrate infectivity in cattle needed to be removed from the food supply.

6. At the same time, in experimentally infected cattle, BSE infectivity has been demonstrated in the distal ileum as early as 6 months post oral exposure to the BSE agent and in

the tonsils as early as 10 months post exposure. Thus, in younger cattle infected experimentally with BSE, the scientific data suggests that the distal ileum and the tonsils (included amongst the tissues termed specified risk materials) present the greatest risk of exposing humans to the BSE agent. In an experiment in which infected tonsil material was injected directly into the brains of BSE-free cattle, only one of five animals in the study developed clinical BSE at 45 months post-inoculation. The level of infectivity in the tonsils appears to be very low. Thus, while younger animals are not believed to have significant amounts of infectivity, if there is infectivity it is most likely to be found in the distal ileum and the tonsils.

7. In late 2003 and early 2004, I was responsible for the development of FSIS rules to minimize the exposure of humans to the BSE agent, known as the rules on Specified Risk Material (SRMs). These rules excluded the brain, trigeminal ganglia, skull (because remnants of the brain and trigeminal ganglia may not be completely removed), eyes, spinal cord, DRG, and vertebral column (except for those portions not containing remnants of the spinal cord and DRG) of cattle 30 months of age and older, and the distal ileum and tonsils of all cattle. These rules also expanded the prohibition on CNS tissues in AMR products, prohibited the slaughter of downer cattle and prohibited air injection stunning. The risk-based mitigations that FSIS prescribed in these rules were based upon the best available science, and what scientists and public health risk managers knew to be effective steps to minimize the risks to animal and public health. These rules, of course, were developed with due regard for the strong evidence that animal and human health protections had been in place in the United States, as well as in Canada, which included the import ban, feed ban, surveillance, and ante-mortem inspection of all cattle prior to slaughter.

8. I have worked with USDA colleagues, particularly with veterinarians and specialists at APHIS, on a variety of issues over many years. In this regard, I worked with APHIS in connection with the development of the Agency's response to the discovery of BSE in a cow in Canada in May, 2003. This interaction has continued with APHIS in regard to BSE concerns over almost two years. The assessment and evaluation of the BSE related issues are, of course, relevant to not only APHIS, but to FSIS and to all animal and public health agencies of the United States.

9. In working with APHIS in the development of the Minimal Risk Rule (MRR), I was able to bring my years of experience and expertise with FSIS food safety issues involving TSEs and, most particularly BSE, to bear in the development of the MRR docket. I also reviewed and evaluated the comments and attached material submitted by R-CALF USA, including materials submitted on December 9 and December 27, 2004. These materials submitted by R-CALF USA and the supporting documentation referenced in R-CALF USA's comments and by Dr. Louis Anthony Cox, Jr., encompass but a portion of the information, research and data reviewed and evaluated by FSIS and APHIS staffs and by our colleagues at sister animal and public health agencies. The developments in the science of BSE and TSEs and the epidemiological data contained in the R-CALF USA comments have been carefully followed and analyzed over the past several years and incorporated into the FSIS and APHIS policy development and rulemaking.

10. Also, I would note, specifically with regard to the materials submitted by R-CALF USA, this information and these studies, have been incorporated into the assumptions and design of the Harvard Risk Assessment, a study commissioned by USDA and performed by the Harvard

Center for Risk Analysis to evaluate the risk associated with BSE and to assess the need and effectiveness of an array of risk mitigation measures. In order to evaluate the effect of model assumptions on model results, Harvard conducted extensive sensitivity analyses as part of their original risk assessment for the introduction and establishment of BSE in the United States. FSIS risk assessors further worked with Harvard in order to further evaluate the estimated effects of the FSIS SRM mitigations contained in the January 2004 BSE-related rules.

11. As a matter of practice and routine policy, the food safety, animal health and public health officials within USDA, as well as our sister agencies with food safety, animal and public health responsibilities, keep current on new scientific developments involving TSE s and BSE, as they become available. All of these agencies, as a routine practice and policy, establish and maintain strong relationships, not only among the relevant agencies, but with scientists and subject matter experts in public and private universities, and with their counterparts in foreign governments and through WHO, CODEX and OIE. This ongoing interaction and exchange of information regarding food safety, animal health and public health is essential to our responsibilities and to our ability to carry out our missions.

12. At least since the 1990's there have been substantial advances in our scientific knowledge and understanding of BSE, and the broader class of TSE s generally. In fact, early in the study of BSE, mice models were mostly used, followed by cattle models in which a very small number of cattle received a large, uniform dose of the BSE agent at a very young age (4 months). New pathogenesis studies are currently underway that use a cattle bioassay in order to find low levels of infectivity that may not have been detected previously in the mouse bioassay. The cattle bioassay is expected to be several hundred-fold more sensitive in detecting BSE

infectivity than the mouse bioassay. However, this new work is not expected to be completed for several years. Meanwhile, using the current methods of detection of infectivity, we have been able to determine those tissues that cause infectivity in cattle and have a measurable effect on animal health, in particular. Primary factors known to influence whether animals or humans will become infected with the agents associated with TSEs are based upon animal model studies. These factors involve exposure of animals versus humans, exposure dose, strain variation, and route of administration.

13. While there is more to be learned, and research is ongoing, there is a solid scientific consensus as to our knowledge of the cattle tissues that contain BSE infectivity, as well as our knowledge of the modes of transmission of that infectivity. Thus, while it is likely that the ongoing research will enhance our knowledge of the disease agent and its modes of transmission, we are nonetheless confident that we have identified those modes of transmission that measurably affect animal and human health. This broad scientific consensus with respect to BSE infectivity and transmission supports the conclusion reached long ago in both the United States and Canada that a set of effective mitigation measures for BSE should be put in place sooner rather than later. As a result, both the United States and Canada established critical mitigations very early in the development of the science and epidemiology associated with BSE. These mitigations ensured that both countries are well protected from the primary pathways for BSE infectivity entering or spreading through the cattle populations. USDA's conclusion regarding the effectiveness of the mitigations in place in the United States and in Canada is still valid today, notwithstanding the recent discovery of BSE cows in Canada and in a cow of Canadian origin identified in the State of Washington. Our FSIS staff of food safety scientists and specialists

believe it is clear from the best available scientific evidence, confirmed by the various iterations and updates to the Harvard Risk Assessment, that prohibitions on the importation of live animals from the United Kingdom, and from other member states of the EU and elsewhere in the world, coupled with the early establishment of the ruminant feed ban, have been and will continue to be, very highly effective in preventing BSE from establishment and spread in the United States. As the science progresses, animal health, food safety, and public health scientists and specialists will without fail continue to participate in the research and the scientific discourse, domestically and internationally, and will develop and refine mitigation strategies as necessary and warranted.

14. Over the last two years, both the United States and Canada recognized the need to enhance their risk mitigations, particularly in light of the existence of a low number of BSE infected cattle in Canada, and the one animal of Canadian origin confirmed in Washington State. Accordingly, additional food safety mitigations were established to further reduce the exposure of animals and humans to the BSE agent. Canada established its additional mitigations in 2003, and the United States put additional measures into affect in 2004. With regard to the USDA s food safety rules issued in January 2004, our analysis concluded that the mitigation measures, specifically the SRM mitigations, would reduce the already extremely low risk of BSE exposure by at least 80 percent.

15. There is some research that suggests that sheep infected with scrapie have pathogenic prions in muscle tissue. Scientists also know, however, that the level of infectivity in these muscle tissues is several thousand times lower than that of other tissues of sheep. R-CALF USA has raised a concern, apparently based on this research, that beef muscle may behave similarly as to the effects of scrapie in sheep and, ultimately, demonstrate an ability to contain the BSE agent.

There is, however, very little, if any, scientific evidence to suggest that this would have an impact on animal or public health. For example, when BSE prions infect different species, such as mice in animal studies or vCJD infection in humans, the development of infection and disease is greatly limited by the recipient species. There is clearly a significant species barrier. The European scientists most heavily involved in dealing with the BSE outbreak and the subsequent BSE research have suggested that the level or amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. Accordingly, even if beef muscle tissue is at some point in the future shown to contain infectivity, the level of infectivity necessary to cause illness or disease would also have to be accounted for in determining what mitigation, if any, was necessary and warranted to protect animal and human health. At this time, however, this research does not suggest the need for further mitigations and does not alter the conclusion that the infective tissue that can carry levels of infectivity sufficient to cause animal or human illness are being removed from the animal and human food supply under our regulations, and the equivalent Canadian rules.

16. FSIS is also aware of, and has evaluated, the research suggesting that blood may be a potential source of BSE transmission. Ovine (sheep), mice, and hamster animal models studies have shown that there is an ability to transmit the BSE and scrapie agents from sheep to sheep through whole blood transfusion. There is however a continuing consensus among scientists involved in this work, particularly among the scientists within the European Commission Scientific Steering Committee (SSC), that the findings regarding the transmission of infectivity through the blood of sheep cannot be extrapolated to the transmission of BSE in cattle. This research nonetheless was considered by USDA in the preparation of the minimal risk region

rules, and there is no basis in the materials relied upon by R-CALF USA for modifications of those final rules.

17. R-CALF USA has also raised concerns about saliva. This is an area with which USDA scientists, its animal health and food safety officials, are familiar as well. It must be noted that the modes of transmission of TSE disease vary among species. For example, scrapie and CWD can spread through environmental contamination. Pastures in which sheep infected with scrapie and elk infected with CWD grazed were the source of infectivity for sheep and elk that grazed on the same pasture. The research relied upon by R-CALF USA is a recent article discussing prion infection of the tongue and the potential for sloughing of the prion agent into saliva, which may suggest that the exchange of saliva between host animals could play a role in environmental prion transmission. However, there is a much broader scientific view that if saliva were a primary factor for influencing BSE infectivity, horizontal transmission (cattle-to-cattle) would be observed. Careful observation and review of the outbreaks, and the epidemiological studies and reports, especially within infected herds of cattle during the United Kingdom epidemic, have not supported the thesis that saliva may be a mode of transmission. There is no new or compelling evidence in the material relied upon by R-CALF USA that would warrant a change in the final minimal risk region rules adopted by USDA.

18. In summary, USDA animal health and food safety experts developed and evaluated the minimal risk region rules in light of the best available scientific evidence and opinion. The information and materials provided to USDA by R-CALF USA were materials with which these experts are thoroughly familiar and this research, along with a very large body of additional research and studies, have been carefully considered in the development of the policies and rules

applicable to BSE. There is no basis in these materials for altering the established rules and mitigations which will provide sound, scientifically justified protections for both animal health and public health.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this __ day of February, 2005, in Washington, D.C.

Daniel L. Engeljohn