



Tommy Irvin
Commissioner

Georgia Department of Agriculture

Capitol Square • Atlanta, Georgia 30334-4201

MEMORANDUM

To: Division of Dockets Management (HRA-305)
Food and Drug Administration
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Rockville, MD 20852

From: Lee M. Myers, DVM, MPH, Dipl. ACVPM *Umm*
State Veterinarian and Assistant Commissioner
Georgia Department of Agriculture
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Date: December 20, 2005

Regarding: Docket No. 2002N-0273
Federal Register/Vol. 70, No. 193/October 6, 2005
Substances Prohibited From Use in Animal Food or Feed

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I would like to offer comments regarding the FDA proposed rule to remove additional animal tissues from all animal feed, specifically brain and spinal cord from cattle 30 months of age and older, and cattle not inspected and passed for human consumption (includes cattle not inspected and passed for human consumption by the appropriate regulatory authority, nonambulatory disabled cattle and fallen cattle).

The current FDA regulation, published as a final rule in 1997, (Substances Prohibited From Use in Animal Feed; Animal Proteins Prohibited in Ruminant Feed) prohibiting the use of certain proteins in ruminant feed established at Sec. 589.2000 (21 CFR 589.2000), contains the stated objective:

"To prevent the establishment and amplification of the agent(s) of Bovine Spongiform Encephalopathy (BSE) in the U.S. cattle herd through feed and thereby help minimize any risks from such agent(s) to animal or human health."

As you know, compliance with this rule by the affected industries is unprecedented at over 98%.

The Harvard Risk Assessment (published in 2001 and 2003) states: "Our analysis finds that the U.S. is highly resistant to an introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the U.S. Similarly, if the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in one to two cases per year with little spread".

The U.S. Department of Agriculture initiated a sampling program for BSE in 1990. Over the next 14 years, some 80,000 bovine brainstems were analyzed with an additional 550,000 samples analyzed since June 2004. All have been negative with the exception of one indigenous case of BSE, diagnosed in June of 2005.

The above facts present tangible and scientific evidence that the current programs are successful. There is no justification for additional regulations.

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EQUAL OPPORTUNITY EMPLOYER

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Georgia has a total bovine (beef and dairy) population of approximately two million head resulting in some 80 million pounds of dead animals per year, assuming a 4% annual mortality rate. Many of the dead stock currently pass through the rendering system, providing significant opportunity for animal disease surveillance and efficient disposal.

Our Department also licenses 169 slaughter and processing plants, most of which currently utilize rendering for disposal of inedible materials. Many of the landfills throughout the state have alerted our Department that they will not accept dead livestock or inedible material from food processing plants. Additionally, porous soils, high water tables, and limited land mass restrict environmentally responsible burial in many areas. If the FDA proposed rule is adopted as a final rule, there will be significantly limited disposal options for these biological wastes resulting in potentially serious environmental consequences.

Georgia has nine licensed rendering facilities. Representatives from the largest rendering companies have told me personally that the FDA proposed rule, if adopted, will force them to no longer accept offal from red meat slaughtering/processing facilities or dead or downer cattle.

The United States Animal Health Association (USAHA), of which I am President Elect, expressed similar concerns at the last annual meeting in November, 2005. The USAHA general membership adopted a resolution which states:

"The USAHA urges the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) to more thoroughly evaluate the unintended consequences of changes in the Ruminant Feed Rule so that reducing a very small risk from Bovine Spongiform Encephalopathy (BSE) does not lead to a carcass disposal crisis in many areas of the United States."

The resulting problem does not impact only bovine. Georgia is the largest poultry producing state in the nation. Representatives from large poultry renderers tell me that if the FDA proposed rule is adopted as a final rule, their customer base will soon mandate that poultry mortality be removed from their rendering process. This will amplify environmental issues and animal disease transmission risks. Removing rendering as a viable option invites inappropriate disposal methods with little to no control over these materials.

In summary, I urge FDA to not adopt the proposed rule as a final rule. The U.S. has existing firewalls and protections to prevent the transmission or amplification of BSE. No further regulations are scientifically, economically, or environmentally justified.

analyze the relevance of this proposal several fundamental questions must be asked:

1. What is the remaining BSE risk in the United States NOT already mitigated by existing regulations and enforcement put in place in 1989 and 1997, coupled with pre-1989 risk exposure and rendering and feeding practices pre-1997?
2. What information does the USDA expanded BSE surveillance program provide as evidence of the level of pre-1997 feed rule risks BSE risk?
3. How many animals born before the feed ban exist today, and how does this number alter risk analysis outcomes?
4. If the FDA seeks to further reduce any remaining risk of BSE infectivity in feed from specified risk materials (SRM) from cattle, which "classes" and ages of cattle would represent the majority of any residual BSE risk in the United States?

TCFA finds the FDA proposed rule lacking in many risk based details relative to these critical questions. Our comments are designed to shed light on these important areas and provide compelling evidence that the true risk of BSE in the United States is lower than many experts expected. Given the low risk of BSE in the United States it raises questions regarding the necessity of implementing the proposed rule as written. In fact, while we support all reasonable, science and risk based steps to prevent the amplification and spread of BSE, the proposed rule goes well beyond reasonable steps given the lack of risk of BSE in the United States. Last but not least, our analysis must be carefully considered by the FDA if we are to truly have a science and risk analysis based regulatory climate in the United States.

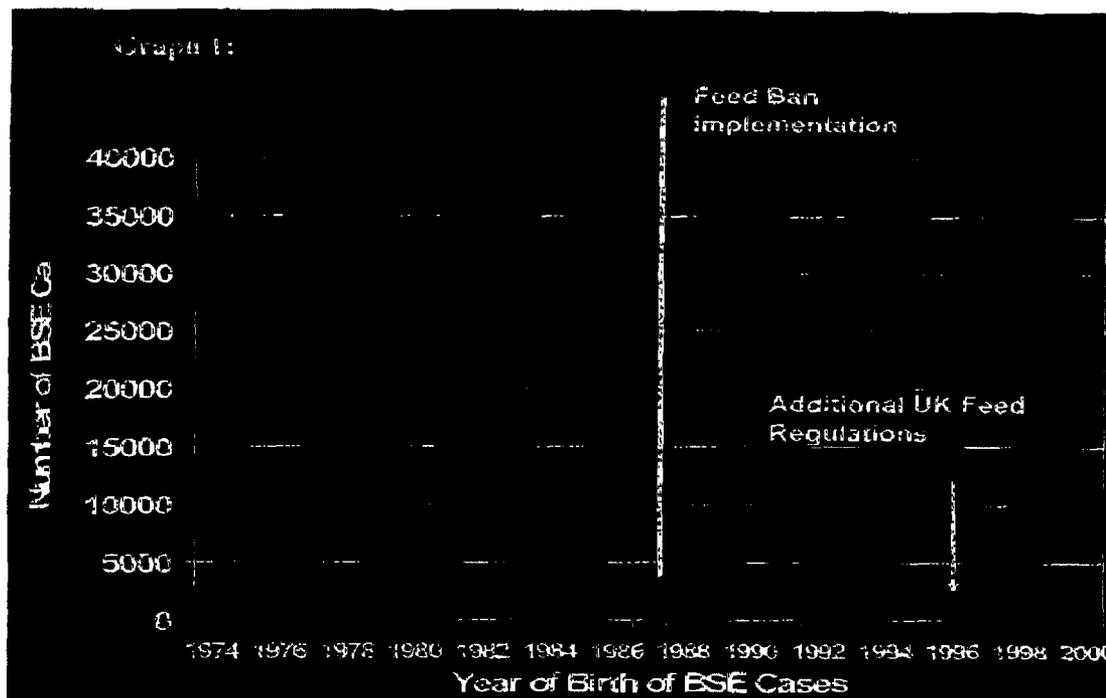
Issues Raised in the July 14, 2004 Advanced Notice of Proposed Rule-Making (ANPRM) (Docket No. 2004N-0264)

The rationale for publication of the ANPRM was primarily the identification of a BSE cow of Canadian origin in Washington State, along with the USDA's International Review Team (IRT) role and recommendations in the process of reevaluating our BSE prevention measures. However, the additional BSE prevention measures recommended by the USDA IRT do not appear to be based upon science but rather the members opinions that BSE risk in the United States was higher than analysis would indicate and/or that compliance with our feed restrictions was sufficiently lacking allowing amplification and spread of BSE. This opinion was illustrated by the following statement from the IRT report: *"While the science would support the feed bans limited to the prohibition of ruminant derived [meat and bone meal] MBM in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions."*

We believe that the opinion of the IRT and other critics of the United States BSE prevention efforts are based on a European bias. In addition, critics also point to the BSE situation in Japan as "evidence" that we should do more to prevent BSE. The facts are, if one reviews the attached **Global BSE Regulatory Timeline**, it is clear why the situation in the United States is different. We remain the first country in the world to take steps to prevent BSE before we had our first case.

Data from the United Kingdom (UK) (Graph 1) illustrate how dramatic an impact even a "simple" ruminant to ruminant feed ban had on the termination of the BSE epidemic. The graph depicts the date of birth of the cases of BSE identified and how the feed ban that went into effect in the fall of 1988 precipitated a dramatic reduction in cases. By 1996 when the relationship to variant CJD was identified, the epidemic was already well under control. The confusion in the UK in 1996 was due to the fact that animals infected with the BSE agent as late as the summer of 1988 were being identified as BSE cases in 1996, 8 years after the feed ban went in place. Thus the "epidemic" of cases identified in 1996 occurred 8 or more years AFTER exposure to

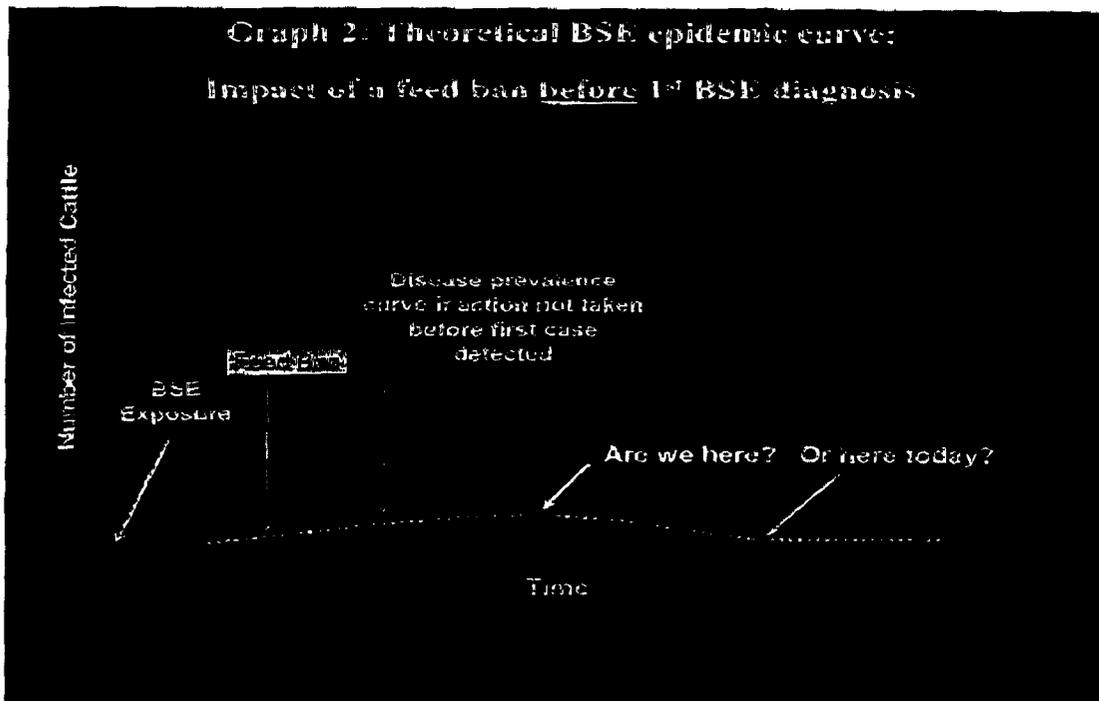
the agent. These cases in no way reflect what was occurring in 1996 in the UK in terms of amplification and spread of the disease. This point is especially relevant to the situation in the United States where one case of BSE in an animal born well before the feed ban has been misconstrued as a failure of the system when it is not.



The data analysis depicted in Graph 1 illustrates that while the 1988 feed ban was effectively preventing the amplification and spread of BSE there was still a perceived need to do even more when the zoonotic potential of BSE was implicated in 1996. However, the fact remains the feed ban was working even in the face of a very large dose of infectivity in the UK feed supply, a dose sufficient to have caused over 184,000 identified cases. Calls to do more in the United States after finding one case raise questions about the scientific and risk analysis basis for such demands.

Graph 2 illustrates the conceptual view of what the United States BSE prevalence would likely be if we had not taken steps in 1989 (14 years before our first BSE case) and 1997 (6 years before our first BSE case) and the likely BSE disease prevalence curve. Conversely, the graph depicts our most likely "actual" BSE prevalence curve. The United States single case realistically represents the prevalence at or slightly after the peak of our BSE cases.

This is completely consistent with estimates of risk calculated by the Harvard Center for Risk Analysis. Harvard conducted model simulations built upon assumptions ranging from the initial prevalence of BSE in the U.S. prior to the 1997 FDA feed ban coupled with the effect of the FDA feed ban, including an assumption of less than 100 % compliance. Harvard reports that in every scenario, there is too little BSE infectivity in the U.S. cattle system, coupled with a solid history of FDA feed ban compliance to perpetuate the disease. Harvard determined the U.S. was not only extremely resistant to the disease but if it had been introduced, it was on a steady path of eradication as a result of the feed bans.



In other words, the analysis indicates that the apparent underlying assumptions for the FDA proposed rule are not valid. Those assumptions are:

1. BSE risk in the United States is higher than originally predicted and analyzed in the Harvard Risk Analysis, and,
2. Compliance with the existing feed restrictions is insufficient to prevent the amplification and spread of BSE.

Risk Analysis and Reduction Measures Taken in the U.S. since 1989

The primary risk of BSE introduction into the United States relates to the importation of cattle from the UK prior to 1989. Animal and Plant Health Inspection Service (APHIS) records indicate they conducted a trace back effort to locate each of the 496 UK and Irish cattle that were imported into this country between January 1981 and July 1989. In 1996, personal communications with APHIS staff indicated that few of these animals came from farms in the UK that had cases of BSE. Thus the risk that these imported cattle were exposed to BSE was determined to be low.

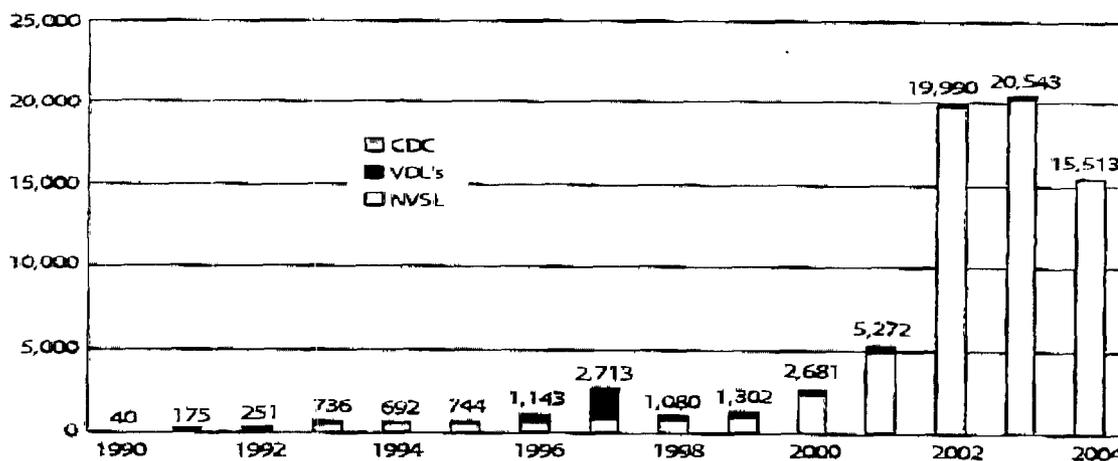
At the same time, it was estimated that perhaps as few as two of these imported animals might present a BSE risk. An effort was made in 1996 and 1997 to depopulate all remaining UK cattle and to test them for BSE. None of these animals were found to have BSE as a result of this testing program. The USDA also traced the location of any other cattle imported into the U.S., from other countries that subsequently had cases of BSE. Five head of cattle imported from other countries in Europe in 1996–1997 remained and were placed under quarantine and eventually depopulated and tested. None were found to have BSE. In December 1997, the USDA expanded the list of countries identified as having or at risk of BSE including virtually all of Europe.

In 1990, a BSE surveillance program was implemented in the U.S., initially using samples of brain tissue provided from rabies suspect cattle. The population of rabies suspect cattle over 30 months of age continues to be an important contributor of samples for the BSE Surveillance program.

The BSE surveillance program in the United States exceeded the minimum standards for BSE surveillance set by the International Office of Epizootics (OIE) which estimated the U.S. need only sample between 400-500 animals to provide a valid estimate of BSE prevalence. In 1999 an effort was made to increase the surveillance program to provide a higher level of confidence in our assumptions that even if the BSE agent had been introduced into the U.S. the prevalence of the disease was very low and the FDA feed bans put in place in 1997 would effectively reduce the risk of amplification and spread of BSE.

An assumption was made to design a surveillance program capable of identifying the disease if it existed at a level of 1 case per million cattle over 30 months of age. Assuming most of these cattle would be in the population of cattle that were disabled, diseased or dead, it was assumed that 45 cases of BSE (1 case per million, with 45 million cattle over 30 months of age) would be found in a population of 195,000 cattle as estimated by a survey conducted by the American Association of Bovine Practitioners. The USDA applied Cannon and Roe's formula to determine the sample size needed to be tested to detect disease at the estimated prevalence, indicating that nationally, a sample size of 12,500 was needed. USDA data illustrate that in 2002, 2003 and until June 2004, an average of nearly 20,000 cattle in the higher risk, targeted population had been sampled.

BSE Surveillance – May 1990 – FY2004 (through 4/30/2004)



(Source USDA Animal and Plant Health Inspection Service)

On June 1, 2004, the USDA began an expanded BSE surveillance program designed to test at least 200,000 cattle in the higher risk, targeted population as recommend by the IRT. As of December 16, 2005 the expanded program has actually tested over 556,143 cattle. With a sample size of 200,000 the program is reported to have been capable of detecting BSE if the prevalence rate was at or above 1 case per 10 million head of cattle over 30 months of age with 95% confidence. With over 548,786 samples tested what does this surveillance program tell us about BSE prevalence?

Table 1 illustrates how our observed BSE prevalence relates to prevalence in Europe and what it estimates the prevalence may be in the healthy cattle population in the United States.

Table 1: BSE Surveillance Comparisons

EU experience: positives/tests run versus U.S. Situation 2004/05

Year	2001	2002	U.S. Estimates
Clinical suspects	1 / 3.3	1 / 3.8	0/4600 (1990-2005)
Fallen stock & emerg slaughter	1 / 1,037	1 / 1,099	1/548,786 (Expanded Surveillance 2004/05)
Healthy slaughter	1 / 27,492	1 / 31,696	<1/15,200,000 (Estimated Maximum in over 30 month cattle)

Summary of Data and Analysis 1990-2005

Since 1990, the U.S. targeted surveillance program has sampled more than 600,000 animals and identified one indigenous case of BSE, a 12-year old cow, born before the 1997 feed ban went in place. Even though the rate of BSE in cattle with central nervous system symptoms has been found to be nearly 1 out of 3 in the EU, the United States tests over 300 such cases for BSE annually and over 4600 since 1990 without finding a single case of BSE. This data provides us confidence that if the disease is present at all, it is at a very low prevalence. This is important since a low estimate of BSE prevalence in the United States is one of the critical assumptions within the Harvard Center for Risk Analysis study. The Harvard study predicted that even if BSE had been introduced into the United States, the risks were low and prompt action has already pushed the disease toward eradication.

From this large data set we can safely draw a number of conclusions, including:

1. The expanded surveillance program provides a solid estimate of BSE prevalence pre-1997 FDA feed ban. The data indicate the lowest range of risks in the Harvard model accurately reflect the situation in the United States.
2. The BSE prevalence rates in the highest risk cattle population in the U.S. are at least 500 fold lower than in the EU, demonstrating the vastly different risk profile in the U.S. The risks in the United States are thus much lower than in Europe or Japan.

3. The BSE prevalence in healthy cattle going to market in the United States, over 30 months of age, must be less than 1 case per 15.4 million cattle. This is significant for many reasons:
 - a. It is estimated that there are less than 12 million cattle in the United States that were born before the 1997 feed ban.
 - b. We market 6.5 million cattle over 30 months in the United States annually.
 - c. With a BSE prevalence rate of less than 1 case per 15.4 million healthy cattle coupled with SRM removal from animals entering the human food supply, BSE is not a public health issue.
 - d. The prevalence of BSE in the SRM material from healthy cattle in the United States is extremely low, as overall disease prevalence is extremely low. Research also has documented that BSE infectivity in the SRM of clinically healthy cattle, even if they have BSE, is extremely low prior to the onset of disease symptoms, thus further reducing the risk in the SRM materials from healthy cattle in the U.S.
 - e. The United States is rapidly nearing eradication of any BSE that was introduced prior to the 1997 feed restrictions.

Implications of FDA Feed Ban Structure and Compliance Data

To prevent the establishment and amplification of BSE through animal feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, which became effective on August 4, 1997 involves inspections of renderers, feed mills, ruminant feeders, protein blenders, pet food manufacturers, pet food salvagers, animal feed distributors and transporters, ruminant feeders and other entities. Documents posted at the FDA web site illustrate the status of thousands of inspections of facilities that have occurred since the rules were established.

Since the rules went into effect, it is clear that the firms have committed to implementing the regulation, and due to re-inspections, there are ever higher levels of compliance at the time of the follow-up inspection. Thus the risk of BSE amplification continues to be reduced, and no evidence exists that the disease prevalence exceeds the range of options evaluated in the Harvard study. These facts continue to point toward the effectiveness of the U.S. system and refute the need for additional BSE prevention measures to protect cattle health and consequently public health.

FDA 2004 Compliance Data

The FDA's CVM has assembled data from the inspections that have been conducted and whose final inspection report has been recorded in the FDA's inspection database as of April 17, 2004. By that date, FDA had received over 29,000 inspection reports. The majority of these inspections (around 70%) were conducted by State officials under contract with FDA, with the remainder conducted by FDA officials.

It is important to note that the FDA has clarified the nature of compliance issues to more effectively put in perspective the "risk" posed by a compliance problem identified during an inspection. Some problems are merely a paperwork issue rather than actual violations in the production of feed ingredients or feeding of prohibited materials to cattle. Inspections conducted by FDA or State investigators are classified to reflect the compliance status at the time of the inspection based upon the objectionable conditions documented. These inspection conclusions are reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

The level of compliance demonstrated in these FDA reports is outstanding and well within the range of assumptions utilized by the Harvard Center for Risk Analysis, which determined the U.S. is extremely resistant to BSE and if present it is being eradicated as a result of the current feed restrictions. As is evident, the rate of OAI inspection violations is extremely low and declining (an OAI violation classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation).

On January 26, 2004 FDA Commissioner Mark B. McClellan, M.D., Ph.D. stated "FDA's vigorous inspection and enforcement program has helped us achieve a compliance rate of more than 99% with the feed ban rule, and we intend to increase our enforcement efforts to assure compliance with our enhanced regulations. Finally, we are continuing to assist in the development of new technologies that will help us in the future improve even further these BSE protections. With today's actions, FDA will be doing more than ever before to protect the public against BSE by eliminating additional potential sources of BSE exposure." (Source: FDA website.) Also posted on the FDA website are feed ban enforcement actions. When the FDA has identified a firm in violation of the FDA feed ban, actions have been taken as evidenced by the following statement provided by the FDA.

Department of Health and Human Services - FDA 2005 Budget Request

The validity of staying on the 100% feed ban compliance course was clearly articulated in the Fiscal 2005 FDA Justification of Estimates for Appropriations Committees. In this document the FDA outlines its intentions to use the requested budget of over \$8 million to "undertake a trilateral approach (to BSE prevention) of increased inspections, enforcement activities and education. These are all areas we fully support and believe will be adequate to prevent the amplification and spread of BSE in the U.S. All evidence points to the fact that in 2005, compliance with the FDA BSE prevention regulations was even higher than in the previous years.

BSE Risk Reduction

The USDA and FDA have taken numerous steps since 1989 to prevent the amplification and spread of BSE.

First, compliance with the existing feed bans has been outstanding. Data from the UK document the enormous risk reduction provided by a simple ruminant to ruminant feed ban.

Second, BSE expanded surveillance data compared to EU BSE data illustrates that the U.S. BSE risk is more than 500 fold less. The surveillance data also illustrate that if BSE is present in a cattle population, the vast majority of cases would be in the population of cattle in the "4-D" category of animals (known as disabled, down, diseased or dead), a classification of cattle prohibited from entering the human food supply. In addition, a smaller subset of these cattle would carry the vast majority of any BSE risk, notably, animals born before 1998. The number of cattle in this classification is less than 12 million head and declining.

In the U.S. as a result, the estimated prevalence of BSE in healthy cattle going to market is likely less than 1 case per 15.4 million head. Only cattle over 30 months would be at risk of BSE and we market 6.5 million head of cattle over 30 months annually in the United States. There is no scientific or other evidence to support taking further steps to reduce the risk of BSE in the U.S. The BSE risk in the United States is extremely small and getting smaller.

Conclusions

- BSE risk in the United States is extremely low due to steps taken since 1989 which are very different than those of other countries.
- BSE Surveillance data collected since 1990, including the expanded BSE surveillance program implemented in June of 2004, has demonstrated BSE risks are as low as the lowest estimate in the Harvard Risk Analysis -- likely less than 1 case per 15.4 million head of cattle over 30 months. Since there are less than 12 million head of cattle born before 1998 remaining in the herd, this further reduces the already low risk.
- From a truly science and risk based perspective, with the FDA feed ban compliance exceeding 99%, there is no need for additional BSE risk reduction steps.
- There is little net BSE risk reduction provided by removing brain and spinal cord from healthy cattle over 30 months that pass inspection, since there is likely a BSE prevalence in this class of cattle of less than 1 case per 15.4 million and within that, LD-50 levels in these tissues would be very low if not undetectable.
- There is virtually no BSE risk reduction from removing dead stock under 30 months from the animal feed supply. If FDA does not provide an exemption for this class of cattle, many of these cattle will no longer be utilized by the rendering industry and disposal costs will escalate. There is absolutely no reason to take this step from a BSE risk reduction perspective.

TCFA remains dedicated to following a science and risk-based program to prevent the introduction, amplification and spread of BSE. However, at this time, more than 15 years of action, information and analysis, especially data from the expanded BSE surveillance program, indicate that no scientific evidence exists to support FDA altering the existing feed regulations.

Since the vast majority of BSE LD-50 doses in any cattle population would be found in brain and spinal cord of animals in the 4-D category over 30 months of age, there is no defensible reason to look beyond removing them from the animal feed supply as a BSE risk reduction step. However, if FDA-CVM finds that the science based on an updated risk assessment supports taking the proposed additional measure of removing brain and spinal cord from these cattle we would accept that position.

There is no data to support removing SRM material from healthy cattle over 30 months that pass inspection and we also can not support removal of cattle under 30 months of age from entering the rendering and animal feed supply.

TCFA continues to fully support actions taken in January 2004 by the USDA to protect public health and also those announced by the FDA on July 9, 2004 to prohibit the use of cattle-derived materials that can carry the BSE-infectious agent in human foods, including certain meat-based products and dietary supplements, and in cosmetics.

Any questions can be directed to Richard McDonald or Ross Wilson at (806) 358-3681.

Sincerely,



Ross Wilson
Vice President