

December 20, 2005

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20852

1170 5 10 23 10 AM

RE: Docket No. 2002N-0273 "Substances Prohibited From Use in Animal Food or Feed"
RIN: 0910-AF46

The National Cattlemen's Beef Association (NCBA) has carefully reviewed the Proposed Rule (Docket No. 2002N-0273) regarding "Substances Prohibited from Use in Animal Food or Feed."

The National Cattlemen's Beef Association (NCBA) is the largest organization representing America's cattle industry. Initiated in 1898, the NCBA is the industry leader in providing education and in influencing the development and implementation of science and risk analysis-based public policy to protect the health of the U.S. cattle population, provide safe and wholesome food and improve producer profitability. In this regard, the NCBA also strives to preserve the industry's heritage and ensure our future.

We appreciate this opportunity to share with the FDA our perspectives on the proposed rule to further reduce the already extremely-low risk of BSE amplification and spread in the United States.

In addition, as indicated by the FDA, the proposed rule would reduce "residual" BSE risk, i.e. that remaining risk not already mitigated by the efforts taken in 1989, 1997 and intensive feed ban enforcement since that time, to prevent the amplification and spread of BSE by 90 percent. Arguably, the BSE expanded surveillance data would indicate the BSE risk in the United States is already extremely small. To more completely analyze the relevance of this proposal several fundamental questions must be inserted into the analysis process, including:

1. What is the remaining BSE risk in the United States NOT already mitigated by existing regulations put in place in 1989 and 1997 and enforcement 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 BSE risk?
3. How many animals born before the feed ban exist today and does this number alter risk analysis outcomes?
4. If the FDA seeks to further reduce the remaining risk of BSE infectivity in feed from Specified Risk Materials (SRM) defined in the proposed rule as brain and spinal cord from cattle (brain and spinal cord that are documented to represent nearly 90 percent of potential BSE infectivity), which "classes" of cattle and ages would represent the majority of any residual BSE risk in the United States?

Prior to publication of the proposed rule by the FDA, Canada proposed to remove a far more extensive list of specified risk materials and to take many other control measures to address BSE

02N-0273

C 500

risks in Canada. Our analysis of BSE risk in both Canada and the United States most certainly leads to opposition to such drastic measures. In addition, relative to an analysis of BSE risk in the United States, the NCBA finds the FDA proposed rule lacks some important elements of risk analysis that we will include in our comments.

Our comments are designed to shed light on important areas of the science of BSE, risk analysis and surveillance data. This analysis provides compelling evidence that the true risk of BSE in the United States is lower than many experts expected. The low risk of BSE in the United States raises questions regarding the necessity of implementing all of the components in the proposed rule as written. In fact, while we support all reasonable, science and risk analysis based steps to prevent the amplification and spread of BSE, the proposed rule goes well beyond reasonable steps given the apparent real BSE risks in the United States. Our comments will, as a result, recommend FDA consider a narrower set of risk reduction steps that will mitigate virtually all remaining BSE amplification and spread risk 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 July 14, 2004 Advanced Notice of Proposed Rule-Making (ANPRM) (Docket No. 2004N-0264)

Consistent with the requirement that regulations be developed based upon science and risk analysis, we raised the following concern in the comments we submitted regarding the Advanced Notice of Proposed Rule-Making (ANPRM) (Docket No. 2004N-0264) published on July 14, 2004. "It is important to mention that the NCBA is very concerned that the FDA *'has tentatively concluded that it should propose to remove SRMs from all animal feed and is currently working on a proposal to accomplish this goal.'*" Our concerns in this regard are amplified based upon the results of the USDA expanded BSE surveillance program.

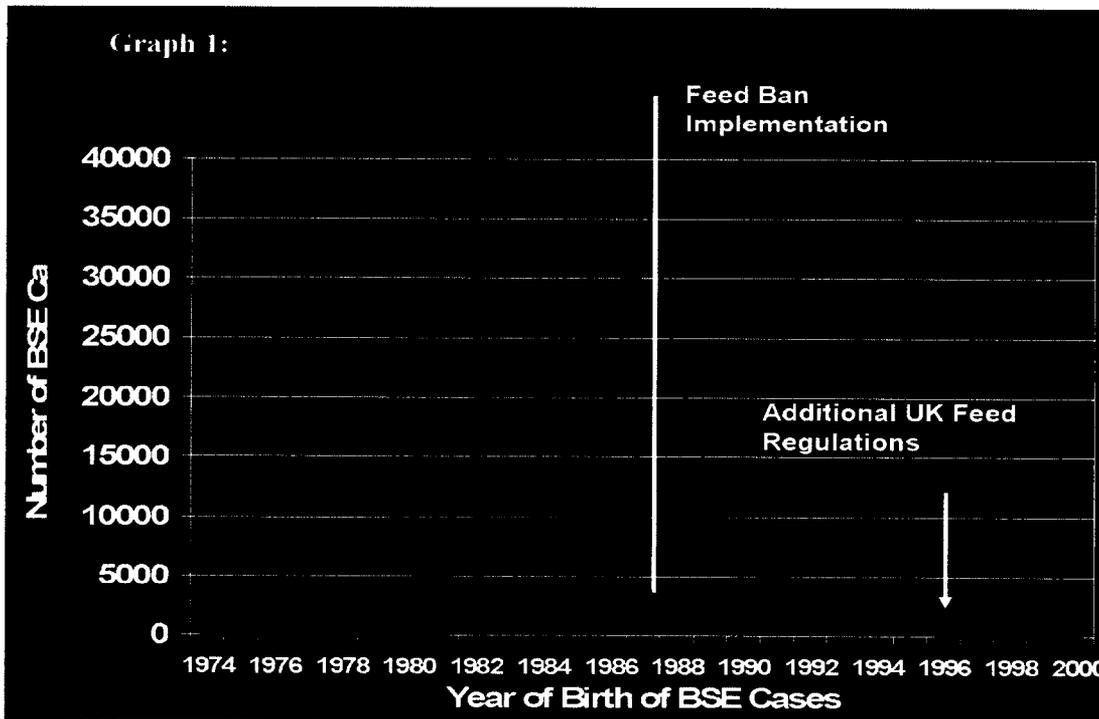
In our comments, submitted in response the ANPRM, we included an analysis of data and risk analysis efforts to make the case that the risk of the amplification and spread of BSE in the United States had been effectively and sufficiently addressed and that the disease, if present, was on the way to being eradicated.

The rationale for publication of the ANPRM was primarily the identification of a BSE cow of Canadian origin in Washington State. However the USDA's International Review Team (IRT) recommendations have also played a role in the process of reevaluating our BSE prevention measures. The additional BSE prevention measures recommended by the USDA International Review Team's (IRT) report do not appear to be based upon science but rather the team 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 Eurocentric bias. In addition, critics also point to the BSE situation in Japan as “evidence” we should do more to prevent BSE. The facts are, if one reviews the attached **Global BSE Regulatory Timeline**, 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 even had a domestic case.

Data from the United Kingdom (UK) (Graph 1) illustrate how dramatically even a “simple” ruminant to ruminant feed ban resulted in the termination of the BSE epidemic. The graph depicts the date of birth of the cases of BSE identified and how the fall 1988 feed ban 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; eight years after the feed ban went in place. Thus the “epidemic” of cases identified in 1996 is eight 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 relevant to the situation in the United States, where cases of BSE in cattle born well before the feed ban are misconstrued as failures of the system when they are not.

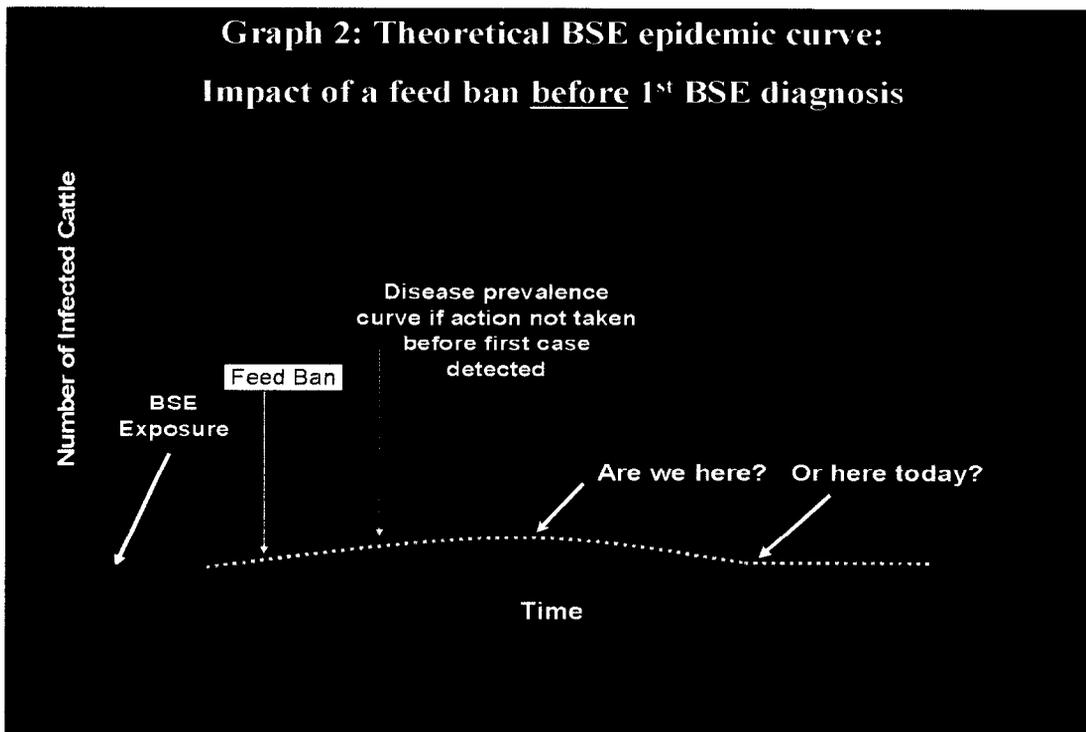


The data analysis depicted in Graph 1 illustrates that while the 1988 feed ban was effectively preventing the amplification and spread of BSE there was still a perceived need to do even more when the zoonotic potential of BSE was implicated in 1996. However, the fact remains the feed ban was working 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 a single case raise questions about the scientific and risk analysis basis for such demands.

The graph below (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 (1, 5, 10, 20, 50, 200 or 500) 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, our analysis indicates that 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. The Animal and Plant Health Inspection Service (APHIS) records indicated they conducted a trace-back effort to locate each of the 496 UK and Irish cattle that were imported into this country between January 1 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 analyzed 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 1996–97 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.

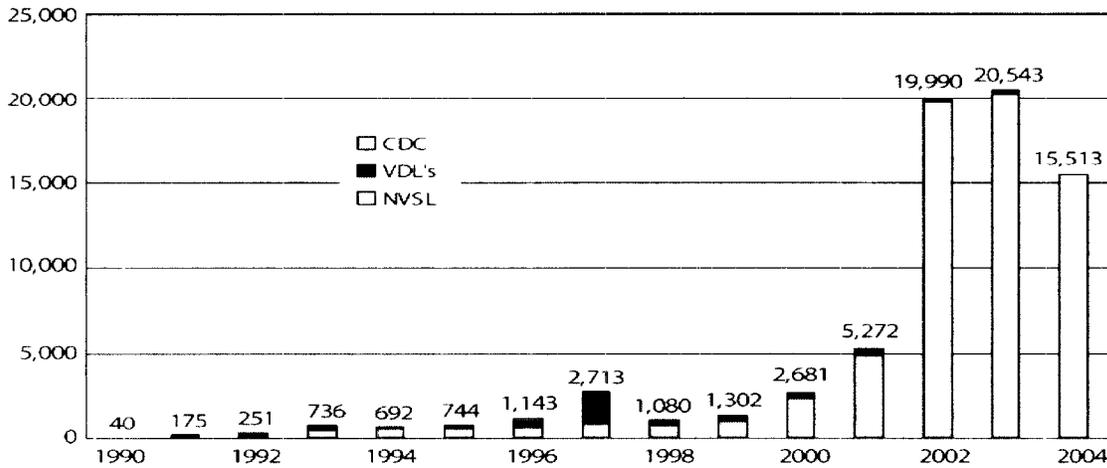
In 1990, a BSE surveillance program was implemented in the U.S., initially using samples of brain tissue provided from rabies suspect cattle. The population of rabies suspect cattle over 30 months of age continues to be an important contributor of samples for the BSE Surveillance program.

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 be reducing 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/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/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 18, 2005 the expanded program has actually tested over 556,143 cattle. At a sampling rate of 200,000 the program is reported to have been capable of detecting BSE if the prevalence rate was at or above 1/10 million head of cattle over 30 months of age with 95% confidence.

With over 556,143 high risk cattle samples tested, what does this surveillance program tell us about BSE prevalence in the United States?

The chart below (Table 1) illustrates how our observed BSE prevalence relates to Europe and what it tells us 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	1/556,143 (Expanded Surveillance 2004/05)
Healthy slaughter	1 / 27,492	1 / 31,696	<1/15,400,000 (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 an extremely low prevalence. This is important as a low BSE prevalence estimate 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 that 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 520 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 cattle¹. 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 1/15.4 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 if an animal has been exposed to an infectious dose of BSE early in life, the subsequent potential level of BSE infectivity in the SRM of these otherwise healthy cattle is extremely low, virtually undetectable. Thus even in a worst case scenario, the SRM materials from these healthy cattle in the U.S. represent virtually no BSE risk. The enclosed **Global BSE Regulatory Timeline provides a reference point useful in comparing BSE risk in the United States to that in the EU or Japan.** The United States 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, 21 CFR Part 589.2000 of the Code of Federal Regulations, became effective on August 4, 1997. The enforcement of the rule entails 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. The FDA has routinely posted all results in a database accessible at:

www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm

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 BSE amplification risks have continued to be reduced and no evidence exists that the disease prevalence exceeds the range of options evaluated in the Harvard

¹ In another analysis published by the EU in 2005 (Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in the EU in 2004, European Commission, July 13, 2005) BSE in was found in 0.018 cattle per 10,000 tests on high risk animals and for healthy slaughter animals over 30 months of age the risk was 23 times less that of the risk in high-risk animals. Extrapolation of these estimates to U.S. data would place our healthy cattle risk as less than 1/13 million healthy animals.

study. These facts continue to point toward the effectiveness of the U.S. system and refute the need for additional BSE prevention measures..

It is important to review the FDA's Center for Veterinary Medicine (CVM) compliance data that has been assembled and reported. One means of documenting the high level of compliance and how it has consistently increased over time is to use the data as of June 12, 2001 and compare it to the data posted July 29, 2004.

The CVM reported that by June 12, 2001 they had received inspection reports covering inspections (both initial inspections and re-inspections) of 9,867 different firms. The majority of these inspections (around 80%) were conducted by State officials under contract with FDA and the remainder by FDA officials.

Various segments of the feed industry had different levels of compliance with this feed ban regulation. The results to date are reported here both by "segment of industry" and "in total".

FEED MILLS LICENSED BY FDA:

By June 12, 2001 of the 435 licensed feed mills handling prohibited materials, at their most recent inspection (either an initial or a follow-up inspection):

- 47 (11%) had products that were not labeled as required
- 45 (10%) did not have adequate systems to prevent co-mingling
- 8 (2%) did not adequately follow record keeping regulations
- 76 (17%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FEED MILLS NOT LICENSED BY FDA:

Of the 1,580 feed mills not licensed by FDA which handle prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):

- 312 (20%) had products that were not labeled as required
- 169 (11%) did not have adequate systems to prevent co-mingling
- 85 (5%) did not adequately follow record keeping regulations
- 421 (27%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

OTHER FIRMS INSPECTED:

- 84 (14%) had products that were not labeled as required
- 25 (4%) did not have adequate systems to prevent co-mingling
- 29 (5%) did not adequately follow record keeping regulations
- 110 (18%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

TOTALS (by June 12, 2001):

Of the 2,653 firms handling prohibited materials, at their most recent inspection (either an initial or a follow-up inspection):

- 431 (16%) had products that were not labeled as required
- 222 (8%) did not have adequate systems to prevent co-mingling
- 112 (4%) did not adequately follow record keeping regulations
- 591 (22%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule. These 591 firms will be re-inspected in the near future.)

Re-inspections:

When firms are found to be out of compliance with the feed ban rule, FDA lists them for a re-inspection. By June 12, 2001, reports of 1,251 re-inspections have been submitted to CVM. On re-inspection of these 1,251 firms, 106 (8%) were found still to be out of compliance with this rule. Firms previously found to be not in compliance have corrected problems through a variety of ways, including further training of employees about the rule, developing systems to prevent co-mingling, re-labeling their products properly, and adhering to record keeping regulations. Other firms have achieved compliance by eliminating prohibited materials from their operations.

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, not 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**).

An **OAI** inspection 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. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be

promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented

A **VAI** inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the Ruminant Feed Ban. These include provisions such as minor recordkeeping lapses and conditions involving non-ruminant feeds.

An **NAI** inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable were not relevant.

RENDERERS

Of the 159 active firms handling prohibited materials, their most recent inspection revealed that:

0 firms (0%) were classified as OAI; 2 firms (1.3%) were classified as VAI

LICENSED FEED MILLS

FDA licenses these feed mills to produce medicated feed products. The license is required to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time. This licensing has nothing to do with handling prohibited materials under the feed ban regulation. A medicated feed license from FDA is not required to handle materials prohibited under the Ruminant Feed Ban.

Of the 338 active firms handling prohibited materials, their most recent inspection revealed that:

1 firm (0.3%) was classified as OAI; 7 firms (2.2%) were classified as VAI

FEED MILLS NOT LICENSED BY FDA

These feed mills (approximately 1,000 inspected in conjunction with other FDA actions on farms) are not licensed by the FDA to produce medicated feeds.

6 firms (0.5%) were classified as OAI; 36 firms (3.2%) were classified as VAI

PROTEIN BLENDERS

These firms blend rendered animal protein for the purpose of producing quality feed ingredients that will be used by feed mills.

Of the 67 active firms handling prohibited materials, their most recent inspection revealed that:

1 firm (1.5%) was classified as OAI; 2 firms (3.0%) were classified as VAI

RENDERERS, FEED MILLS, AND PROTEIN BLENDERS

This category includes any firm that is represented by any of the above four categories, but includes only those firms that manufacture, process, or blend animal feed or feed ingredients utilizing prohibited materials.

Of the 542 of active renderers, feed mills, and protein blenders processing with prohibited materials, their most recent inspection revealed that:

7 firms (1.3%) were classified as OAI; 19 firms (3.5%) were classified as VAI

OTHER FIRMS INSPECTED

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters.

- Number of active firms whose initial inspection has been reported to FDA – 10,393
- Number of active firms handling materials prohibited from use in ruminant feed – 1,842 (18% of those active firms inspected)
- Of the 1,842 active firms handling prohibited materials, their most recent inspection revealed that:

11 firms (0.6%) were classified as OAI; 68 firms (3.7%) were classified as VAI

TOTAL FIRMS

Note that a single firm can be reported under more than one firm category; therefore, the summation of the individual OAI/VAI firm categories will be more than the actual total number of OAI/VAI firms, as presented below.

- Number of active firms whose initial inspection has been reported to FDA – 14,037
- Number of active firms handling materials prohibited from use in ruminant feed – 2,474 (18% of those active firms inspected)
- Of the 2,474 active firms handling prohibited materials, their most recent inspection revealed that:

11 firms (0.4%) classified as OAI; 80 firms (3.2%) were classified as VAI

On July 29, 2004 the FDA-CVM published additional data documenting compliance with the feed ban as of July 17, 2004 having received over 31,000 inspection reports. The majority of these inspections (around 70%) were conducted by State officials under contract to FDA.

RENDERERS

These firms are the first to handle and process (i.e., render) animal proteins and to send these processed materials to feed mills and/or protein blenders for use as a feed ingredient.

- Number of active firms whose initial inspection has been reported to FDA – 244
- Number of active firms handling materials prohibited from use in ruminant feed – 161 (66% of those active firms inspected)
- Of the 161 active firms handling prohibited materials, their most recent inspection revealed that:
 - 0 firms (0%) classified as OAI; 4 firms (2.5%) were classified as VAI

LICENSED FEED MILLS

FDA licenses these feed mills to produce medicated feed products. The license is required to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time. This licensing has nothing to do with handling prohibited materials under the feed ban regulation. A medicated feed license from FDA is not required to handle materials prohibited under the Ruminant Feed Ban.

- Number of active firms whose initial inspection has been reported to FDA – 1,081
- Number of active firms handling materials prohibited from use in ruminant feed – 367 (34% of those active firms inspected)
- Of the 367 active firms handling prohibited materials, their most recent inspection revealed that:
 - 3 firms (0.8%) classified as OAI; 5 firms (1.4%) were classified as VAI

FEED MILLS NOT LICENSED BY FDA

These feed mills are not licensed by the FDA to produce medicated feeds.

- Number of active firms whose initial inspection has been reported to FDA – 5,059
- Number of active firms handling materials prohibited from use in ruminant feed – 1,358 (27% of those active firms inspected)
- Of the 1,358 active firms handling prohibited materials, their most recent inspection revealed that:
 - 6 firms (0.4%) classified as OAI; 36 firms (2.7%) were classified as VAI

PROTEIN BLENDERS

These firms blend rendered animal protein for the purpose of producing quality feed ingredients that will be used by feed mills.

- Number of active firms whose initial inspection has been reported to FDA -- 267
- Number of active firms handling materials prohibited from use in ruminant feed -- 67 (25% of those active firms inspected)

- Of the 67 active firms handling prohibited materials, their most recent inspection revealed that:
 - 1 firm (1.5%) classified as OAI; 2 firms (3.0%) were classified as VAI

RENDERERS, FEED MILLS, AND PROTEIN BLENDERS

This category includes any firm that is represented by any of the above four categories, but includes only those firms that manufacture, process, or blend animal feed or feed ingredients utilizing prohibited materials.

- Number of active renderers, feed mills, and protein blenders whose initial inspection has been reported to FDA – 6,452
- Number of active renderers, feed mills, and protein blenders processing with prohibited materials – 556 (8.6% of those active firms inspected)
- Of the 556 of active renderers, feed mills, and protein blenders processing with prohibited materials, their most recent inspection revealed that:
 - 8 firms (1.4%) classified as OAI; 19 firms (3.4%) were classified as VAI

OTHER FIRMS INSPECTED

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters.

- Number of active firms whose initial inspection has been reported to FDA – 10,915
- Number of active firms handling materials prohibited from use in ruminant feed – 2,205 (20% of those active firms inspected)
- Of the 2,205 active firms handling prohibited materials, their most recent inspection revealed that:
 - 16 firms (0.7%) classified as OAI; 76 firms (3.4%) were classified as VAI

TOTAL FIRMS

Note that a single firm can be reported under more than one firm category; therefore, the summation of the individual OAI/VAI firm categories will be more than the actual total number of OAI/VAI firms, as presented below.

- Number of active firms whose initial inspection has been reported to FDA – 14,355
- Number of active firms handling materials prohibited from use in ruminant feed – 2,901 (20% of those active firms inspected)
- Of the 2,901 active firms handling prohibited materials, their most recent inspection revealed that:
 - 17 firms (0.6%) classified as OAI; 86 firms (3.0%) were classified as VAI

The level of compliance demonstrated in these FDA reports is **outstanding and well within the range** of the set of assumptions utilized by the **Harvard Center for Risk Analysis** that 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 percent** 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.

"The Department of Justice, Civil Division, Office of Consumer Litigation and the United States Attorney's Office of the Western District of Washington filed the Consent Decree in the United States District Court of the Western District in Tacoma, Washington. It permanently enjoins X-Cel from manufacturing animal feeds in violation of the Food Drug and Cosmetic Act and requires the firm, its officers, and employees to take specific steps to avoid future violations including, implementing clean-out procedures, obtaining protein supplier certifications and implementing standard operating procedures for compliance until it satisfies FDA that it has corrected its problems."

This is additional evidence that FDA compliance is outstanding and that failures to comply are dealt with aggressively.

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: Options and Costs

The USDA and FDA have taken numerous steps since 1989 to prevent the amplification and spread of BSE. 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. BSE expanded surveillance data compared to EU BSE data illustrates that the U.S. BSE risk is more than 500 fold less. These surveillance data sets also illustrate that if BSE is present in a cattle population, the vast majority of cases would be in the population 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 1/15.4 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.

As we stated in our comments to the July 2004 ANPRM there is really no scientific or other evidence to support taking steps to reduce the risk of BSE further in the U.S. The BSE risk in the United States is extremely small. However, if the FDA wants to remove the vast majority of any remaining BSE risk, i.e. the risk remaining after over 95 percent compliance with the 1997 feed ban, and in light of surveillance estimates that place the BSE prevalence at less than 1/15.4 million cattle over 30 months, then a far narrower set of steps than offered in the proposed rule should be seriously considered.

FDA Proposed Rule Science and Risk-Based Recommendations

Risk Associated with 4-D Cattle

At the most extreme, the FDA proposed rule should focus on removal of SRM materials from 4-D cattle over 30 months and those over 30 months failing antemortem inspections (or removal of the cattle themselves if SRM removal is not practical). USDA expanded surveillance program estimates would place the BSE prevalence in this cattle population at 1 case out of the total population of animals annually in this category (approximately 650,000 cattle over 30 months die annually in the United States, most of these animals are dairy and beef cows, 62.4% and 20% of cattle in these categories would be rendered annually² &³ In this regard it is also important to note that there are likely no more than 12 million cattle in the United States born before the 1997 feed restrictions went into place. Removing either the SRM material from the 4-D cattle over 30 months in the United States or the cattle themselves, would remove the estimated 2 cases of BSE that would exist in the United States cattle population from the animal food and feed supply. In

² Based upon review and analysis of USDA-APHIS National Animal Health Reporting Service data and...

³ Analysis by Informa Economics, Inc. An Economic and Environmental Assessment of Elimination of Specified Risk Materials and Cattle Mortalities From Existing Markets, 2004.

terms of percentage reductions this step would remove 82% of the residual BSE Lethal Doses (LD-50 is the dose needed to infect 50% of animals exposed) in the total United States cattle population. It conceivable there may only be 2 additional cases of BSE in the United states as estimated by the expanded USDA BSE surveillance program. This single step would virtually push the real risk of the amplification and spread of BSE in the United States to essentially zero.

We estimate the cost of this approach (removal of deadstock over 30 months from animal and pet food) to be between \$64 and \$76 million based upon some industry estimates. There are concerns regarding potential other disposal costs and related expenses not covered in these estimates.

Risk Associated With Healthy Over 30 Months Cattle Passing Inspection

Cattle passing inspection in the United States pose little net BSE risk to the human food or animal feed supply. Expanded BSE surveillance data illustrate that the likely maximum prevalence of BSE in health cattle marketed in the United States would be less than 1/15.4 million head. Only 12 million head of cattle in the United States were born before the 1997 feed bans were put in place. Even if an animal over 30 months is incubating BSE, the BSE infectivity (LD-50) level in the SRM materials from these animals that appear healthy is hundreds if not thousands of times lower than in 4-D animals. In most cases the disease agent levels are so low as to be undetectable by even the most sensitive screening tests.

Consequently, the proposal to remove the SRM materials from the 6.5 million cattle over 30 months that are marketed annually in the United States would offer virtually no level of BSE risk reduction while costing the industry, and consumers as a consequence, between 1.4 and 1.7 million dollars per year.

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 (see enclosed **Global BSE Regulatory Timelines**).
- 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 estimated in the Harvard Risk Analysis, likely less than 1/15.4 million head of cattle over 30 months. Less than 12 million head of cattle born before 1998 are still in the herd, further reducing the already low risk.
- Based upon the science and risk known to-date and with FDA feed ban compliance over 95-99% there is no need for additional BSE risk reduction steps.
- If additional BSE risk reduction measures are to be implemented the vast majority of BSE risk (which is already extremely low in the United States) would be reduced by removal of 4-D cattle and antemortem condemned cattle over 30 months or their brain and spinal cords from the animal feed supply.
- There is little net BSE risk reduction provided by removing brain and spinal cord from healthy cattle over 30 months that pass inspection as there is likely a BSE prevalence in this class of cattle of less than 1/15.4 million and within that, LD-50 levels in these

tissues would be very low if not undetectable. However, if the FDA-CVM finds that the science and an updated risk analysis supports taking the proposed additional measure of removing brain and spinal cord from these cattle we would accept that decision.

- There is virtually no BSE risk reduction from removing dead stock under 30 months from the animal feed supply. FDA must allow for exemptions for this class of cattle. In addition, disposal costs will escalate if such exemptions are not granted, with no net BSE risk reduction.

Summary

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

The NCBA 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.

If the FDA has questions regarding our comments they can be directed to Dr. Gary Weber, Executive Director Regulatory Affairs at gwweber@bccf.org or by phone (202) 347-0228.

Respectfully submitted by:



Jim McAdams
President, National Cattlemen's Beef Association

Enclosure: Global BSE Timeline

Timeline of BSE Measures

1986

1988 USDA establishes BSE working group

1989 U.S. bans imports of cattle and cattle products like MBM¹ from countries with BSE

1990 U.S. begins formal BSE testing program

1993 U.S. testing program expanded to include "downers"

1996 U.S. beef industry calls for voluntary MBM¹ cattle feeding ban

1997 U.S. gov't bans ruminant MBM¹ in cattle feed import ban expanded to all of EU

2000 U.S. bans import of all rendered animal protein from Europe regardless of species

2001 Harvard Center for Risk Analysis says U.S. is robust against the spread of BSE if introduced

2002 FDA responds to GAO⁴ report with increased feed ban enforcement. Now >99% compliance

2003 U.S. finds first BSE case in imported Canadian cow

2004 U.S. steps up BSE testing to sample as many high-risk cattle as possible

2005 U.S. surveillance finds first domestic BSE case



United States



Canada

1990 Canada bans imports of cattle from UK

1992 Canada starts BSE testing program

1993 Canada finds first case of BSE in imported cow

1994 Canada's import ban expanded to any countries with domestic BSE cases

1997 Canada bans feeding ruminant MBM¹ to cattle

2000 Canada bans imports of all rendered animal protein from countries with BSE

2003 First domestic BSE case in Canada



United Kingdom

1986 UK finds first BSE cases

1988 UK bans ruminant MBM¹ in cattle feed and starts passive BSE testing

1993 UK BSE epidemic peaks at 1,000 cases per week

1994 UK bans all mammalian protein in ruminant feed due to cross contamination

1996 UK starts feed sampling program to test feed ban compliance

2001 UK starts active BSE surveillance program



European Union

1989 Republic of Ireland reports first BSE case outside the UK

1994 Ban on feeding ruminant MBM¹ to cattle instituted for all EU countries

1996 EU commission bans cattle and feed imports from UK to EU member countries

2000 FVO³ study reports EU member states not adequately enforcing feed ban

2001 EU states required to start BSE testing and ban feeding any animal protein to livestock



Germany

1992 Germany's first imported BSE case

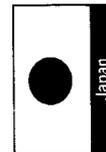
1994 Germany bans feeding ruminant MBM¹ to cattle

1996 Germany supports EU wide ban on cattle and feed imports from UK

1997 Germany diagnoses five more BSE cases in imported animals through 1997

2000 FVO³ study finds Germany not enforcing feed ban. Germany finds first domestic BSE case

2001 Germany begins active BSE testing program and finds 125 BSE cases



Japan

1996 Japan starts testing 200-400 BSE samples per year through 2001

1997 Japan bans live cattle and MBM¹ imports from UK

2001 Japan finds first BSE case. Starts 100% testing, bans MBM¹ live-cattle imports from BSE countries and expands feed ban

Developments since December 23, 2003



January 12, 2004 U.S. Department of Agriculture's Food Safety and Inspection Services (USDA FSIS) finalizes regulations which

- Prohibit "downer" cattle and the tissues that can carry BSE infectively (specified risk materials or SRMs) from the food supply
- Require additional process controls for establishments using advanced meat recovery (AMR)
- Prohibit air-injection stunning
- Require meat from cattle targeted for BSE surveillance to be held until test results are confirmed negative

February 4, 2004 Review panel of international experts releases report on BSE investigation that commends USDA's efforts and makes recommendations for further ensuring elimination of the disease in the United States

February 9, 2004 USDA completes BSE field investigation for Dec. 23 case, which involved tracking 51 herds with more than 75,000 cattle. No new cases were identified within the 225 animals that were depopulated and tested for BSE

June 1, 2004 Following the recommendation of the international review panel, USDA implements its enhanced BSE surveillance program targeting the highest-risk cattle. The experts at Harvard's Center for Risk Analysis support the program

July 9, 2004 The Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) jointly announce new rules to strengthen existing BSE firewalls banning certain bovine material from human food, dietary supplements and cosmetics

June 24, 2005 USDA announces diagnosis of the first indigenous BSE case in the United States. The animal never entered the human food or animal feed supply

August 30, 2005 USDA and FDA jointly release the results of their epidemiological investigation into the herd mates and feed history surrounding the first domestic BSE case, concluding the index cow was infected prior to the 1997 feed ban

Week of November 7, 2005 More than half a million of the cattle at greatest risk for BSE have been tested with only one additional case identified -- proving that this disease is very rare in the United States

Early 2006 Animal identification program spearheaded by producers becomes fully operational

- Meat and bone meal (MBM) from BSE-infected cattle used as a protein supplement in cattle feed is believed to cause the spread of BSE
- MBM imports from the UK were banned by Canada in 1978 for reasons other than BSE prevention
- The European Commission's Food and Veterinary Office (FVO)
- General Accounting Office 2002 report which identified potential steps for strengthening the U.S. feed ban firewall