NATIONAL CATTLEMEN'S BEEF ASSOCIATION

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January 17, 2008

Ms. Susan Dudley, Administrator
Office of Information and Regulatory Affairs
The Office of Management and Budget
EEOB Room 262
Washington, D.C. 20503

Dear Ms. Dudley,

The National Cattlemen's Beef Association appreciates the opportunity to meet with you and other OMB staff this afternoon. We have compiled a packet of information to leave with you after this meeting. Included in the packet are the following:

- Official comments submitted by the National Cattlemen's Beef Association on December 20, 2005 regarding the proposed rule regarding "Substances Prohibited from use in Animal Food or Feed"
- Timeline of BSE Measures that was submitted as part of NCBA's 2005 comments
- Informa Economics study on the Economic Impacts of Proposed Changes to Livestock Feed Regulations, prepared for the National Renderers Association
- January 2008 follow-up letter to USTR from the National Renderers Association
- January 2008 follow-up letter to OMB from the National Renderers Association
- OIE information on BSE cases worldwide

Once again, we thank you for your time and look forward to working with you on this and on other issues in the future.

Sincerely,

Jay H. Truitt
Vice President, Government Affairs
National Cattlemen's Beef Association

December 20, 2005

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

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

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.

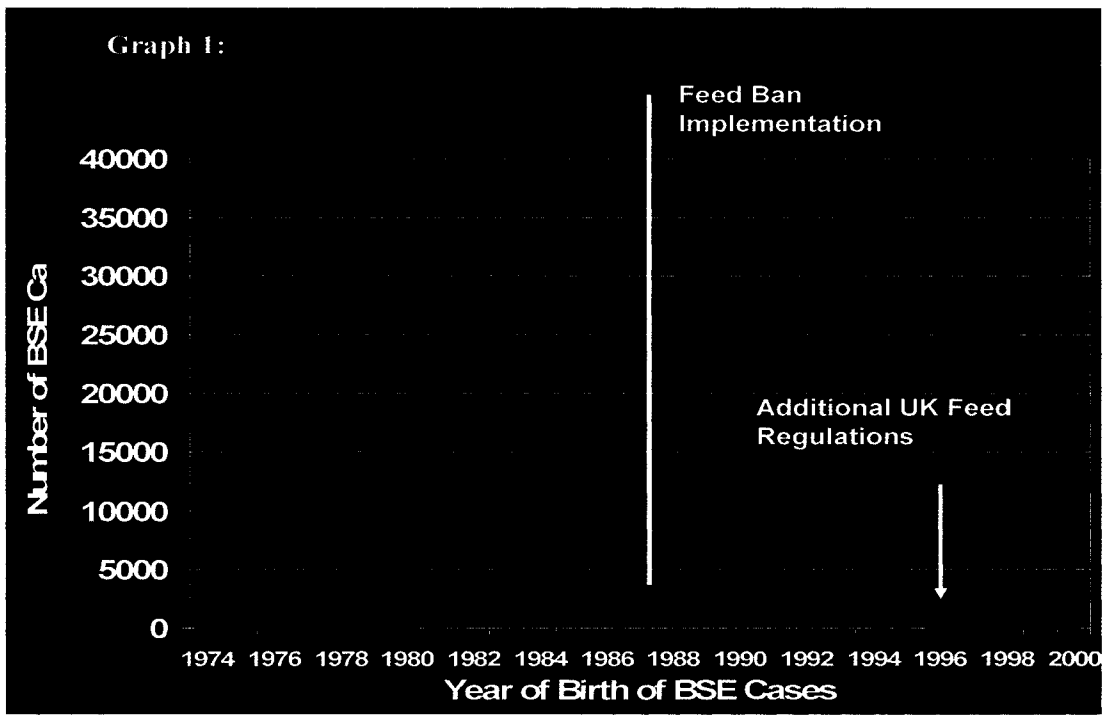
In our comments, submitted in response the ANPRM, we included an analysis of data and risk analysis efforts to make the case that the risk of the amplification and spread of BSE in the United States had been effectively and sufficiently addressed and that the disease, if present, was on the way to being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

The rational 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 than 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.

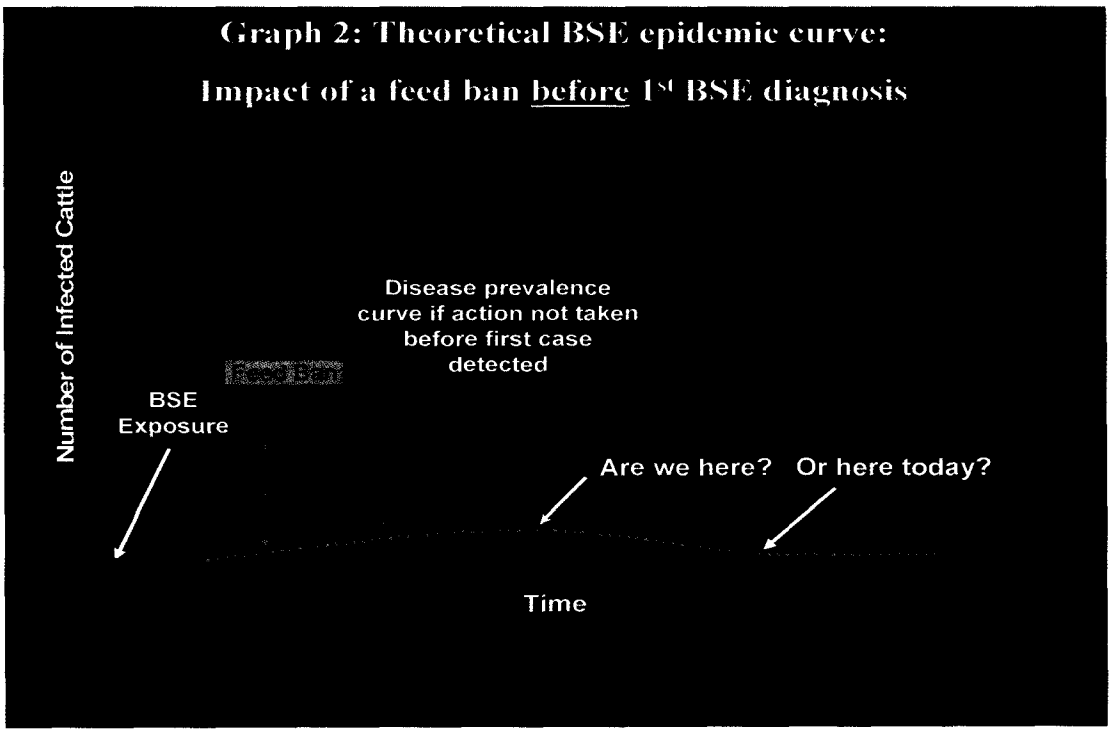


The data analysis depicted in Graph 1 illustrates that while the 1988 feed ban was effectively preventing the amplification and spread of BSE there was still a perceived need to do even more when the zoonotic potential of BSE was implicated in 1996. However, the fact remains the feed ban was working 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 place 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.

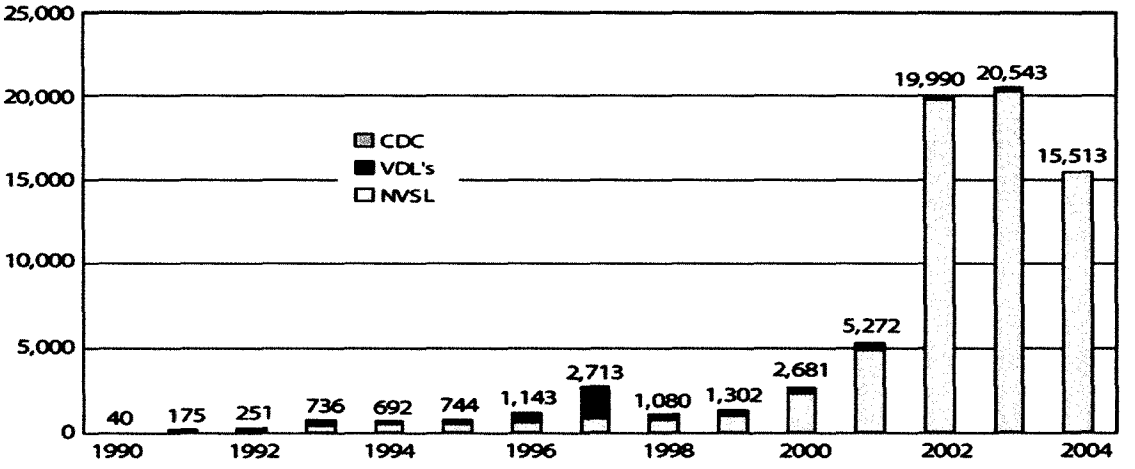
In 1990, a BSE surveillance program was implemented in the U.S., initially using samples of brain tissue provided from rabies suspect cattle. The population of rabies suspect cattle over 30 months of age continues to be an important contributor of samples for the BSE Surveillance program.

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 cattle[1]. 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 Unites 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 annually[2 & 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

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[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 gweber@beef.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 →

United States

1988: USDA establishes BSE working group.

1989: U.S. bans imports of cattle and cattle products like MBM[1] 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 MBM[1] cattle feeding ban.

1997: U.S. govt. bans ruminant MBM[1] 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 GAO[4] 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.

Canada

1990: Canada bans imports of cattle from UK.[2]

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 MBM[1] 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 MBM[1] 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 MBM[1] to cattle instituted for all EU countries.

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

2000: FVO[3] 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 MBM[1] 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: FVO[3] 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 MBM[1] imports from UK.

2001: Japan finds first BSE case, starts 100% testing, bans MBM[1]/ 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 infectivity (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 Heath 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.

1. 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.
2. MBM imports from the UK were banned by Canada in 1978 for reasons other than BSE prevention.
3. The European Commission's Food and Veterinary Office (FVO).
4. General Accounting Office 2002 report, which identified potential steps for strengthening the U.S. feed ban firewall.

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Economic Impacts of Proposed Changes to Livestock Feed Regulations

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Economic Impacts of Proposed Changes to Livestock Feed Regulations

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Economic Impacts of Proposed Changes to Livestock Feed Regulations

In response to the discovery of two isolated cases of bovine spongiform encephalopathy (BSE) in the United States, a series of regulatory actions and policy changes were undertaken to strengthen protections against the spread of BSE in US cattle. In addition to greatly increasing BSE surveillance and testing on the US herd—which continues to find no threat to human health associated with domestic beef—several regulations were modified or expanded to further strengthen the "firewalls" already in place designed to prevent consumer exposure to the agent believed responsible for BSE. Among the measures adopted was prohibiting the sale of certain cattle products (brains, spinal cords, and other material through to potentially harbor the prion responsible for BSE) for use as human food, and the elimination of certain techniques used in slaughter houses and meatpacking facilities, particularly the mechanical separation of beef for human food.

While there was some debate over whether even these regulatory changes were necessary given the strength and apparent success of the protections already in place (both cattle that tested positive for the disease were born prior to the existing rules that prohibit feeding ruminant protein to cattle and calves, and one was originally from Canada), they nevertheless increase the confidence in the safety of our food supply and were instituted at *relatively* low cost to the sector, requiring no fundamental change in the way cattle are raised, or beef is processed, in the United States.

In an effort to enhance BSE safeguards even further, the Food and Drug Administration (FDA) has recently proposed changing existing feed regulations to eliminate certain cattle material from any and all types of livestock feed. The proposed rule is intended to reduce the already extremely low potential for BSE to spread or infectivity to be amplified through the feeding of animal proteins to ruminants, particularly from cross-contamination of ruminant feed with protein material derived from ruminant species. However, unlike the protections already in place, this new rule will create entirely new challenges regarding the handling and disposal of material eliminated from existing markets, including the potential for serious, adverse environmental consequences. These challenges are in addition to the significant economic burden that will be faced by renderers, livestock producers and meatpackers as a result of lost raw material for valuable livestock feed and higher costs to dispose of byproducts that become worthless.

Materials Potentially Affected

FDA's proposed regulatory option (the proposed rule) would prohibit certain cattle materials from any animal food or feed. The rule defines prohibited cattle material (PCM) as *the brain and spinal cord* of:

(1) All slaughter cattle greater than 30 months of age
(2) All non-ambulatory cattle (i.e. "downers")
(3) All cattle that died other than by slaughter

(4) Any cattle to be processed using mechanical separation, unless the brain and spinal cord have been removed prior to separation.

The rule also places certain limits on the tallow derived from PCM material.

Under these proposed restrictions, slaughterers and renderers would be required to separate the PCM from existing processes and arrange for its disposal. All of this material is already banned from use in human food. Slaughterers would be expected to modify their animal killing operations to separate brains and spinal cords from other offal and arrange for delivery to an approved site or facility to dispose of this material. Currently, this material is mixed with all other offal and is used by renderers to produce meat and bone meal (MBM) and tallow for feed and industrial applications. Renderers would be required to add new procedures to their processes for handling cattle and calf mortalities and downers to remove brains and spinal cords from these animals. Currently, the entire carcass of such animals can be rendered.

Expected Impact of New Feed Restrictions

Since 1997, FDA has prohibited the use of all mammalian protein products, with the exception of pure pork and pure equine protein from single species processing plants, in animal feeds given to cattle and other ruminants (21 CFR 589.2000). This restriction, along with other measures in place including import restrictions of ruminants and ruminant products from countries infected with BSE, is widely viewed as providing effective protection against the spread of BSE in the United States. Importantly, the current feed restrictions operate by *diverting* ruminant-based feed ingredients away from ruminant feed and to feed used for other species. Hence, although this rule has undoubtedly affected the market price of certain ruminant-based feed ingredients, it maintains existing channels for disposing of slaughter by-products and livestock mortalities through the rendering sector, minimizing the need for alternative disposal options.

The feed rule recently proposed would not maintain existing channels for disposing of the material restricted from livestock feed. By eliminating the material defined as PCM from use in *any* livestock feed, these restrictions would necessitate disposal of this material by methods other than rendering. The following are key points to consider:

- The rendering industry generates its revenue from the sale of feed, food and industrial products manufactured from slaughter by-products and other material (such as livestock mortalities) that is either not suitable or widely used for human food. The primary product market is animal feed. Restricting any of this material from feed markets will reduce its economic value to a point below the cost of handling, transport and processing, so economics dictates that it will not be renderered—or collected by renderers—unless fees are levied to cover the expectedly high costs of disposal by alternative means. And, *no appropriate alternative means of handling and disposal have been identified.*

- Facing unfavorable market conditions for rendered feed ingredients, renderers routinely charge collection fees for processing livestock mortalities and/or slaughter byproducts. Removing PCM from dead and downer cattle and calves will directly increase the cost of processing these animals, reduce the volume of material available for sale in existing markets, and increase the volume of material requiring disposal by alternative means. The result will be a sharp increase in the fees required to collect these animals, and a likely decision by many renderers to discontinue this service.

- It has been suggested that renderers could continue to collect, process and dispose of PCM—including cattle mortalities—by charging a fee sufficient to cover the revenue lost from the sales of rendered product. However, the rendering industry is not uniformly equipped for dedicated processing of this material, and constructing the necessary infrastructure would take considerable time and expense.

- The collection fee that renderers would be required to charge slaughter facilities and livestock producers to make the collection of restricted material economically viable given lost product markets and the need to retool facilities and materials handling procedures would far exceed any fees currently being levied across the industry. Absent specific regulation of disposal methods, producers of restricted material—especially cattle and calves that dies on the farm—will search for alternative means of disposal—including perhaps less costly but much more environmentally damaging methods such as burial and landfilling—that will directly compete with rendering.

- While rendering restricted material would reduce the volume that requires disposal, it remains unclear how even this rendered material would be disposed of in the US. Unlike in Europe, the US does not have significant capacity to incinerate this material, and landfilling could require exorbitant transportation or other costs.

- Removing brains and spinal cords from cattle and calves that die prior to slaughter (assuming such a practice is even operationally feasible) would greatly increase renderers' cost of collecting mortalities, requiring an increase in collection fees of a magnitude that would likely force producers to employ alternative mortality disposal methods, often at significant risk to the environment. Therefore, we believe that PCM removal from dead livestock is not a viable option.

- The proposed restrictions on feed ingredients would cause the immediate loss of the current market revenue renderers generate from the sale of meat and bonemeal (MBM), tallow, and all other products currently derived from the restricted material. These losses will be felt not only by the rendering industry, but will also be reflected in higher livestock feed costs (from a reduction in feed ingredient supply) and higher costs of slaughtering cattle (from the need for meatpackers to incur additional costs of PCM segregation and disposal).

- The environmental impact of alternative disposal methods for slaughter byproducts and cattle/calf mortalities must be carefully considered, especially in the absence of

strict regulatory oversight of alternative disposal methods such as on-farm burial and composting of dead livestock.

Prior to announcing its proposed rule, FDA solicited the assistance of the Eastern Research Group (ERG) to estimate the potential economic impact of the rule across the livestock sector, including potential lost revenues by renderers and higher costs faced renderers and slaughter facilities. While their analysis suggested an economic impact approaching $16 million in increased costs and lost revenues, we believe this grossly underestimates the actual impact on the sector, including the total costs of product disposal, revenue losses by renderers, and adverse environmental impacts.

Much of the difficulty in estimating these costs reflects the limited amount of reliable information readily available concerning the structure and operation of the rendering industry. As a result, much of the ERG analysis relies on results provided in previous research and assumptions drawn from limited interviews of select industry participants and observers. Recognizing the need for more detailed, current and complete information on which to estimate the potential cost and industry impacts of this rule, Informa Economics solicited the participation of the entire rendering industry in a detailed survey of their current operating characteristics and expected efforts and operational changes necessary to comply with this rule. The results of this survey form the basis of our cost analysis presented in this report.

Rendering Industry Survey

A copy of the survey sent to renderers is provided in Appendix I, and Appendix II provides a compilation of written comment received. The survey was mailed during the week of October 24 to all 52 rendering firms that are current members of the National Renderers Association (NRA), and the 22 members of the Animal Protein Producers Industry (APPI) that render animal materials. We believe this captures the vast majority of firms actively engaged in the US rendering industry, representing at least 99%—if not the entirety—of all US rendering volume. We asked each firm to return an individual, completed survey for each plant that they operate. As of December 1, 102 surveys were returned, the vast majority of which included all, or nearly all, of the information requested. Because the surveys were filled out and returned by individual plants, many of which operate under names different than that of the parent company, and lacking information on the number of plants operated by each firm, we do not know with precision the proportion of the industry represented by those that responded to our survey. However, we have confidence that our results capture the overwhelming majority of industry participants and nearly all of the volume of material processed by the industry, particularly the volume associated with ruminant material.

The total processing volume estimated for 2005 among the firms represented in our survey is 25.992 billion pounds[1] (excluding kitchen grease), with 72 plants indicating they process at least some ruminant material. The total annual reported volume of

[1] Ten plants did not report their annual volume, most of which we believe to process poultry material exclusively.

ruminant material processed by these plants is just over 13.3 billion pounds, but at least five plants that appear to process ruminant material (based on responses to other questions) did not report the proportion of their total volume this accounts for, suggesting the true volume of ruminant material accounted for in our survey is somewhat higher. Given that previous research estimates the total volume of ruminant material processed by renderers at between 15 and 16 billion pounds annually (see Sparks 2001), it is clear that our survey captures most if not all of the ruminant-based rendering industry.

Seventy-six plants, with a combined 2005 processing volume of 17.9 billion pounds, indicated that they were "independent" facilities, while 15 plants, with a combined 2005 processing volume of 7.2 billion pounds, reported that they are packer owned. The remaining 9 plants representing under 1 billion pounds in combined annual processing volume, did not report whether they were independent or packer owned. The 76 independent facilities together process at least 6.5 billion pounds of ruminant material, suggesting firms of this type account for roughly half of all such material processed.

Impact on Cattle and Calf Mortality Disposal

USDA estimates 1.7108 million cattle and 2.2924 million calves died prior to slaughter in 2004[2], for a total species count of just over 4.0 million deaths. Similar numbers of cattle mortalities were reported in all years since at least 2000, generally varying by under 100,000 head per year, with most of the variation found in the number of calf deaths. Renderers also process non-ambulatory cattle unapproved for human food use. Absent official statistics regarding the number of such cattle in the United States, we refer to a USDA estimate based on a survey of American Association of Bovine Practitioners members[3], which suggests approximately 200,000 per year. Hence, the total dead and non-ambulatory cattle population in the United States is estimated at roughly 4.2 million per year, plus or minus a few hundred thousand. This is consistent with estimates used throughout previous studies conducted by Informa Economics (formally Sparks Companies), the FDA and the Eastern Research Group (ERG).

Recent estimates of the percent of cattle mortalities processed by rendering firms range from 17% by ERG[4] to between 42% and 45% by Sparks Companies, Inc.[5,6] While these earlier estimates were necessarily based on the best information available from various USDA surveys of livestock disposal methods, industry interviews and other imperfect sources, Informa Economics has consistently believed that rendering remains a primary

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[2] USDA/NASS, *Meat Animals Production, Disposition, and Income 2004 Summary*, April 2005

[3] Hansen, Don and Bridges, Victoria. *A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herd in 38 states.* The Bovine Practitioner; 33(2); 179-187, 1999.

[4] Eastern Research Group, Inc, *Economic Impacts of Proposed FDA Regulatory Changes to Regulation of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy.* July 25, 2005

[5] Sparks Companies, Inc, *Livestock Mortalities: Methods of Disposal and Their Potential Costs*, March 2002.

[6] Informa Economics, Inc, *An Economic and Environmental Assessment of Eliminating Specified Risk Materials and Cattle Mortalities from Existing Markets*, August 2004

method of cattle deadstock disposal, accounting for much more than 17% of the total. This suspicion is confirmed by the information collected in our survey.

Of the 102 rendering plants that responded to our survey, 52 reported that they currently accept dead or disabled cattle and/or calves, with 45 of these firms reporting non-zero collections for 2005.[7] All of these firms are independent, i.e. not packer owned. The estimated total volume collected by these 45 plants in 2005 (annualized estimate for the entire year) is 864,827 calves and 1,004,943 adult cattle. Data provided for previous years (2000 and 2003) suggest that for these firms, the number of cattle mortalities collected in total has been relatively steady or has even increased slightly, contrary to some industry speculation that the role of the rendering industry in livestock disposal declining over time. Applying this data to the USDA estimates of annual cattle mortalities cited above, these firms alone process more than half of all adult cattle mortalities and nearly 40% of all calf mortalities, accounting for about 45% of all dead and downer cattle in the United States (Table 1).

Table 1: Estimated Quantities of Dead and Downer Cattle Rendered

	Cattle Mortalities[1,3]	Rendered	Percent Rendered
Calves	*1000 Head*	*1000 Head*	*Percent*
2000	2386.0	772.8	32.4
2003	2319.6	940.4	40.5
2004-05[2]	2292.4	864.8	37.7
Cattle[3]			
2000	1910.8	936.0	49.0
2003	1910.1	986.7	51.7
2004-05[2]	1910.8	1005.0	53.4
Total			
2000	4296.8	1708.8	39.8
2003	4229.7	1927.1	45.6
2004-05[2]	4203.2	1869.8	44.9

1. Source: USDA/NASS
2. Cattle mortalities reported for 2004 based on the most recent USDA/NASS estimates. Rendering volume reflects estimates provided by each responding plant of their total volume expected for 2005
3. 200,000 head added to USDA mortality estimates to account for non-ambulatory cattle

While previous estimates of the rendered volume of cattle mortalities made by Informa Economics and others attempted to identify cattle by type, i.e. beef cattle, dairy cattle, feedlot cattle and calves, the categories of information collected in our survey are slightly different. Since renderers generally do not track or identify the intended use (e.g. beef or dairy) of deadstock cattle processed by their plant, our categories instead include calves, feedlot mortalities, other cattle generally assumed to be over 30 months of age, and other

[7] In other words, 7 of the 52 firms that report a willingness to accept cattle and calf mortalities did not report any number or volume of these collections for 2005. This could either indicate that these firms had no or negligible volume of this type in 2005, or a decision by individual firms in this group to withhold this information.

cattle generally assumed to be under 30 months of age.[8] The estimated deadstock collection volume across these categories is presented in Table 2.

Table 2: Estimated Dead and Downer Cattle Rendered, by Type

Category	2000	2003	2005[1]
		1000 Head	
Calves	772.8	940.4	864.8
Feedlot Cattle	412.4	459.8	424.4
Other Over 30 Months	430.4	433.0	469.2
Other Under 30 Months	93.2	93.9	111.4
Total	1,708.8	1,927.1	1,869.8

1. Annualized estimate for the entire year

Comparison with Previous Estimates

Our survey results strongly support the results of previous Sparks/Informa Economics studies that found rendering to be a major disposal outlet for dead and disabled cattle. The finding that roughly 45% of all dead and downer cattle are processed by rendering plants is remarkably close to our previous estimates cited above which placed the total at between 42% and 45%. The fact that our previous estimates were derived using an entirely separate procedure and different sources of information only adds confidence to these findings. These estimates stand in sharp contrast to the findings by the Eastern Research Group conducted on behalf of the FDA, which found only 17% of the all dead and disabled cattle are processed by renderers.

Implications by type of cattle include[9]:

- **Calves:** Our finding that nearly 40% of dead calves are rendered far exceeds the ERG estimate provided to FDA that only 5% are currently rendered, and also exceeds our previous estimate (Sparks, 2004) of 27.4%, including 43.8% of dairy calves and 20% of beef calves. Since calves account for the majority of bovine mortalities in terms of number, any loss of this important disposal outlet or higher fees for collecting calf mortalities will have a significant negative impact on dairy and livestock producer costs. Our survey results do not permit us to determine the relative volume of dairy versus beef calf mortalities processed, but previous research and industry knowledge suggests that while beef calves account for the bulk (nearly 70%) of all calf mortalities, the fact that a larger proportion of dead dairy calves tend to be collected by renderers (more than 44% versus 20% of beef calves), makes dairy

[8] There can of course be some imprecision in the deadstock volume assigned to each category, but identifying calves is quite obvious, collections from feedlots are typically associated with high-volume suppliers often collected under contract, and the last two remaining categories will capture the remaining deadstock sources based on the typical size of the animal and the renderer's best judgment of its source.

[9] FDA and/or ERG estimates discussed below primarily refer to Table 2-5 of "*Economic Impacts of Proposed FDA Regulatory Changes to Regulation of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy*", July 25, 2005, unless otherwise noted.

and beef calf mortalities account for nearly equal proportions of all deadstock calves rendered (see Sparks 2004).

- **Feedlot Mortalities:** We find that more than 400,000 dead feedlot cattle are processed annually by renderers. All previous research found rendering to be the primary means of disposal of feedlot mortalities, ranging from 90% in the ERG/FDA study to 94.4% in the previous Sparks report (Sparks, 2004), and this survey supports that general finding and suggests that the true proportion could be even closer to 100%. However, previous studies also placed the total number of dead feedlot cattle at only about 300,000 per year, based on an industry average death rate loss and the average number of cattle placed in large feedlots. Our estimate of more than 400,000 dead feedlot cattle collected by renderers does not necessarily suggest a significantly higher feedlot death rate than the industry claims (although it does vary year-to-year); more likely this apparent discrepancy is the result of several factors that increase the apparent volume of dead cattle collected from feedlots beyond the level explained solely by an average death rate loss. These include:

    - Feedlot death estimates generally do not include downer cattle (which are alive but non-ambulatory), while material processed by renderers from feedlots does include such cattle. If even half of the estimated 200,000 downer cattle produced annually in the United States originate from feedlots, this alone could account for the increased volume of material from feedlots processed by renderers.
    - Some deadstock collections at feedlots can also include dead cattle that did not actually originate from a feedlot, perhaps including dead cattle picked up by the collector on the way to or from the feedlot, or that were delivered to a feedlot by another cattle producer for eventual pickup by the deadstock collector.
    - Some collections attributed to feedlots could in fact include collections from large, concentrated dairy operations, which often maintain similar contractual arrangements with renderers/deadstock collectors as do feedlots.

  The high volume of cattle mortalities attributed to feedlots supports the general conclusion from all previous research that renderers remain the most important deadstock disposal option for feedlot operators—collecting at or near 100% of mortalities—so that loss of this option or significantly higher collection fees will result in severe economic hardship for feedlot operators. And, given that feedlots tend to concentrate an enormous number of cattle on a relatively small land area, disposal by burial or even composting could be either infeasible or associated with severe risk to the environment.

- **Other Cattle:** Our survey indicates that in addition to calf and feedlot mortalities, renderers will process more than 469,000 other cattle mortalities believed to be over 30 months of age, and more than 111,000 other cattle believed to be under 30 months of age. Dead and downer cattle over 30 months of age would primarily include dairy

cows and bulls, along with beef replacement heifers and bulls. Other dead and downer cattle under 30 months of age would primarily include beef cows and steers intended for slaughter but that were not put in a feedlot. The ERG/FDA study estimates 1.4 million non-feedlot beef cattle mortalities and 400,000 dairy cattle mortalities, of which 10% and 60%, respectively, are rendered, implying that of the total of 1.8 million non-feedlot cattle mortalities, 380,000 (21%) are collected for rendering. Our survey shows that renderers process at least 580,600 non-feedlot adult cattle, which would constitute 32.2% of all non-feedlot cattle mortalities. However, if some proportion of total non-feedlot beef and cattle mortalities processed were actually counted by renderers as feedlot mortalities (as discussed above), the result would suggest an even higher proportion—perhaps 35% or more—of non-feedlot cattle mortalities processed by renderers. Regardless, our survey provides strong evidence that the ERG/FDA study sharply underestimates the proportion of non-feedlot cattle mortalities currently processed by renderers.

Our finding that the proportion of cattle and calf mortalities rendered has increased marginally especially since 2000 was unexpected, but not unreasonable. Although deadstock collection fees have almost certainly increased since 2000, continuing and well documented changes in the structure of the livestock industry—particularly dairy but also feedlot and cow-calf operations—toward much larger, specialized operations almost certainly limits the alternative disposal options for these producers. Since well-established livestock industry trends toward greater concentration of production are expected to continue, any loss of future rendering capacity to process these mortalities and/or significantly higher collection fees will magnify the potential environmental and economic impact of the proposed rule.

Impact on Deadstock Collections from FDA's Proposed Rule

There are at least two ways that FDA's proposed rule could impact the number of cattle and calf mortalities rendered. First, renderers will necessarily charge higher collection fees to cover the increased costs of material disposal and processing, and lost product revenues from reduced volumes of MBM and tallow available for sale. These higher fees, depending on their magnitude, will cause some cattle and dairy producers to find other ways to dispose of their mortalities. However, the costs and technical difficulties of complying with these regulations will also force some renderers to end the practice of collecting dead cattle altogether, particularly those renderers for whom deadstock collection accounts for a relatively small proportion of their total processing volume. Other renderers might scale-back their deadstock collection activities, focusing only on customers that generate sufficient volume and/or cattle and calves whose condition has not deteriorated to such a level that brains and spinal cords cannot be easily removed.

Our survey asked renderers to estimate the percent of their current annual cattle deadstock volume that, if the proposed FDA rule were enacted, they would: a. No Longer Accept; b. Accept and Remove the Brain and Spinal Cord; c. Accept and Remove the

Head and Spinal Column[10]; and Accept but not allow the material to be rendered for feed use. We also asked renderers to estimate, given the higher fees they would charge for options b, c and d, what the result would be on their expected cattle deadstock collection volume (i.e., the market impact of the higher collection fees).

Table 3 reports the number of plants currently accepting cattle mortalities that indicated they would *no longer accept* this material if FDA's proposed rule were enacted. These plants currently process in excess of 314,000 cattle and calf mortalities per year, accounting for nearly 17% of all cattle and calf deadstock rendered.

Table 3: Lost Deadstock Rendering Volume from Plants Indicating They Would Eliminate Deadstock Collections

Cattle Deadstock Category	No longer accept		Percent of Current Volume Lost
	Plants	*Head*	*Percent*
Calves	29	178,604	20.7
Feedlot	20	10,540	2.5
Other over 30 Months	27	100,986	21.5
Other Under 30 Months	26	24,583	22.1
Total		314,713	16.8

The largest number of plants (29) indicated that they would no longer accept calf mortalities. The result would be to eliminate the current disposal outlet for more than 178,000 dead calves, nearly 21% of the volume currently rendered. However, we believe this is an extremely conservative estimate of the number of plants that would no longer collect calf mortalities—implying that the actual volume impacted could be much higher—since several plants indicated that they are leaning strongly toward eliminating calf collections but have not yet made a formal decision to do so. Similar caveats apply to the other categories of deadstock collection, but they appear to be strongest for calves.

Non-feedlot beef and dairy mortalities would also lose access to rendering facilities that currently account for roughly 22% of all such cattle rendered. The fewest number of plants (20) indicated they would cease to accept deadstock from feedlots, but these 20 plants account for only 2.5% of current feedlot collections. These are clearly relatively small plants, or plants for which feedlot collections account for a small proportion of their deadstock and/or total processing volume. However, the loss of 20 plants that currently accept deadstock from feedlots would leave fewer than a dozen firms serving this need.

[10] This option was added to account for the fact that some cattle could be deteriorated to a point where removal of only the brain and spinal cord is technically infeasible, or for the possibility that some renderers might find removal of the entire head and spinal column to be an easier method of compliance with the proposed rule. The result of removing the head and spinal column would be a sharp increase in the volume of material removed from the rendering process compared with removal of only the brain and spinal column.

While some plants that continue accepting cattle and calf mortalities might gain some of the market abandoned by those renderers who exit the business, this is unlikely to capture a meaningful proportion of the lost deadstock rendering volume. Given the decline in the number of rendering plants over the past several decades, industry observers suggest that many areas the United States already do not have easy access to a rendering plant, so loss of 20 or more facilities accepting cattle mortalities will certainly leave vast portions of the country un-served.

Furthermore, several plants indicated that even if they continue to accept dead and disabled cattle and calves, there would still be some proportion of their existing volume that they would likely refuse to accept under the proposed FDA rule. Such refusals could be the result of an intention to no longer accept deadstock decomposed beyond a certain level (which complicates the removal of brains and spinal cords), an intention to continue the service only for particular customers (perhaps large volume costumers or those within a prescribed geographical area), or both. Given the higher collection fees expected to result from enactment of the proposed regulation, renderers also estimated the deadstock volume they would expect to lose through market forces. Table 4 presents the expected impact of the proposed FDA rule on deadstock collection volumes across the industry.

Table 4: Estimated Lost Deadstock Volume Under Proposed Rule

	No Longer Accept[1]		Lost to Higher Fees[2]		Total
	Head	*Percent*	*Head*	*Percent*	*Percent*
Calves	246,520	28.51	475,451	54.98	83.48
Feedlot	24,692	5.82	121,733	28.69	34.51
Other over 30 Months	136,643	29.12	153,472	32.71	61.84
Other Under 30 Months	36,485	32.75	51,584	46.30	79.05
Total	444,340	23.70	802,240	42.90	66.60

1. Includes firms that would refuse all deadstock from the particular category, plus the volume that remaining firms indicated they would refuse to accept under the FDA rule.
2. Estimated from the percent reduction in expected volume indicated by each plant, from the proportion of current volume each plant indicated it planned to continue to accept.

Our survey suggests that under the proposed rule, the number of cattle and calf mortalities processed by renderers would decline severely, including nearly 24% of current volume (across all categories) that would be no longer accepted by renderers, and an almost 43% loss in remaining volume due to higher collection fees. These estimates are in sharp contrast with those provided in the ERG/FDA study, where the authors predict a reduction of only 0.6% of the current number of cattle and calves rendered.

One source of discrepancy arises from the fact that the authors of the ERG/FDA study apparently did not seriously consider the likelihood that some renderers would cease collection of any or all cattle deadstock under the proposed FDA rule. This possibility alone is conservatively estimated by our survey to reduce collection volumes by nearly 445,000 head per year, accounting for 23.7% of current collections. The ERG/FDA study also predicts the market impacts of higher fees on collection volumes would be extremely minor, ranging from 0% for feedlot and dairy cattle to 1% for beef cattle

mortalities. Regardless of the data and methods used, we believe this severely underestimates the likely true market impact, with the renderers in our survey indicating that they would expect to see a decline in volume of close to 43% given the fees they anticipate to charge, with the largest percentage decline due to market forces (55%) affecting calf collections.

Not surprisingly, the smallest impact on collection volumes (though still severe) would affect feedlot mortalities, where renderer refusals and/or lost collections due to market forces would potentially eliminate 34.5% of current collections. Given that feedlots have few viable disposal alternatives and generate large volumes of mortalities for the renderers who serve them, rendering is likely to remain one of the most important disposal options, albeit at significantly higher costs to the feedlot operators.

It should also come as no surprise that the collection of deadstock calves would face the largest decline in volume—up to or exceeding a loss of 83.5% of current volume. Given that calves are light-weight animals—limiting the volume of material that can be rendered from each—but still must undergo the same procedure for brain and spinal cord removal as do the much larger adult cattle, simple economics dictates high unit costs for calf collection and much less renderer incentive to do so. As noted above, survey comments and renderer discussions indicate that many plants are still considering whether to eliminate calf collections altogether under the proposed rule, suggesting that our estimate of a nearly 29% reduction in calf volume due to renderer refusals is extremely conservative, and likely to be much higher. And, given the fees that must be charged for this service to cover the higher unit costs, tremendous additional volume will be lost to market forces.

Feasibility of Removing Brains and Spinal Cords from Dead Cattle

One of the critical issues in complying with the proposed FDA rule is the practical and economic feasibility of removing brains and spinal cords from dead cattle and calves prior to rendering. While equipment exists to facilitate this task, the fact remains that carcass decomposition can severely hamper these efforts if deadstock is not promptly collected. Cattle that die particularly in the hot summer months can decompose rapidly, and the rate of death loss also tends to increase with heat stress, which further complicates efforts by renderers and deadstock collectors to collect all deadstock prior to significant caracass deterioration.

Faced with cattle mortalities for which decomposition makes brain and spinal cord removal complicated or infeasible, renderers would either be forced to remove substantially more material than only the brain and spinal cord, such as the entire head and spinal column (impacting both the economics of deadstock collection and the amount of material requiring disposal by some other means), or simply refuse to collect the decomposed carcass. The complications of complying with this rule under conditions where significant amounts of cattle could be severely decomposed prior to collection likely plays an important role in leading many renderers to suggest they will no longer collect deadstock under any circumstances if this proposed rule is enacted.

Our survey asked individual plants to report, in a "typical" year, the estimated percent of their deadstock collections that are in condition good enough to remove the brain and spinal cord prior to rendering. Estimates ranged from a high of 98% to a low of 23%, with many renderers pointing out that there is significant seasonal variation within these averages as well as year-to-year variation based on weather conditions. Across the 49 plants that responded to the question, the average percent of cattle believed to be in good enough condition to remove the brain and spinal cord is 54.4%. When the responses are weighted by the volume of deadstock collected by each plant, the result is nearly identical, at 54.8%.

Some renderers also commented that since removal of brains and spinal cords from dead cattle is a new procedure that has not been routinely applied previously, its feasibility and/or success rate is still unknown. Particularly on large animals where the back might be broken during collection or transport, efforts to remove the spinal cord can fail using equipment and procedures currently available, especially if this procedure is applied on site as opposed to at the plant. The result is that a significant portion of the spinal cord can remain inside the animal. At a minimum this suggests that the time and effort required for this procedure—and therefore costs—could exceed expectations, but it also raises some doubt as to its overall feasibility.

These findings have important, practical implications for compliance with FDA's proposed rule, which the ERG/FDA study appears to overlook. With nearly half of all current deadstock collected by renderers estimated to be deteriorated to the point where brain and spinal cord removal is infeasible or impractical, and the possibility that even non-deteriorated cattle could have a limited success rate for spinal cord removal, industry compliance would require either the removal of a significantly greater volume of material from each dead cattle and calf collected, or renderer refusal to collect a significant proportion of the current volume of cattle and calves processed by renderers. Either way, the volume of material requiring disposal by alternative means and the potential losses to the rendering industry, increases greatly beyond the best-case scenario.

Impact on Disposal Fees

Renderers routinely charge a fee for deadstock collection services. These fees can vary tremendously across plants, and even among individual producers served by particular plants depending on the volume collected and the distance required for collection. Fees charged by individual firms are considered proprietary, and official information regarding these fees does not exist.

Our survey asked each respondent to indicate the fees they currently levy for this service and the fees they would anticipate to charge in order to comply with the proposed FDA rule. Nearly all firms that currently collect deadstock provided information on their current fees, and most offered estimates of the fee likely required to comply with the FDA rule by either removing the brains and spinal cords from all deadstock, removing

the head and spinal column, and/or collecting deadstock but keeping all material separate from feed markets. Table 5 presents averages across all firms.

Table 5: Average Deadstock Collection Fees Currently Charged, and Estimated Fees to Comply with the Proposed FDA Rule

	Current Fee[1]		Estimated Fee Under FDA Rule
	$/head	*$/cwt*[2]	*$/cwt*
Calves	$44.78	$17.91	$38.75 - $41.44/cwt
Feedlot	$15.80	$1.76	$6.08 - $10.40/cwt
Other Over 30 Months	$43.57	$3.35	$6.16 - $12.46/cwt
Other Under 30 Months	$22.58	$2.51	$6.97 - $11.17/cwt

1. Average reported collection fee weighted by the volume collected by each renderer
2. Estimated based on an assumed average weights as follows: calves, 250 lbs; feedlot cattle, 900 lbs; other cattle over 30 months, 1300 lbs; other cattle under 30 months, 900 lbs.
3. Range represents an average across all renderers (weighted by deadstock volume) that provided fee estimates for any or all of the collection options discussed, including removal of the brain and spinal cord, removal of the head and spinal column, or collecting deadstock but not rendering the material for feed use. Individual fee estimates for each option are not provided to avoid disclosure of information on the intentions by individual firms or plants.

The highest current collection fees were found for calves, averaging close to $45 per head—much higher than previous estimates have suggested—while collection fees for feedlot mortalities and other cattle under 30 months of age are within range of previous estimates.[11] The average fees for other cattle over 30 months of age, assumed to be heavily weighted toward dairy cattle, are also somewhat higher than previously anticipated at $43.57 per head. However, in each case the range of reported fees is quite wide, with several firms charging no collection fee (particularly for feedlot collections) and others charging in excess of $75 per head, regardless of the type of cattle/calf or its source. On a per hundredweight basis, current fees range from $1.76/cwt for feedlot cattle to $17.91/cwt per calf.

The surprisingly high fees charged for collecting calves likely reflects the limited volume of marketable material (e.g. meat and bonemeal and tallow) renderers can recover from dead calves (given their small size), but the fixed transportation costs that are still incurred for collection. And, since most dead calves originate from operations where production is not highly concentrated, such as small dairies and cow-calf operations (as opposed to feedlots that generate steady and significant quantities of deadstock), these fixed transportation costs for irregular or infrequent collections could be quite high on a per-unit basis. Furthermore, as noted above, the current fees reported are not necessarily applied to all operators or collections, so that calf mortalities generated by operations that also generate significant adult cattle mortalities, for instance, likely face much lower collection fees.

[11] A previous report by Informa Economics, *An Economic and Environmental Assessment of Eliminating Specified Risk Materials and Cattle Mortalities from Existing Markets*, August 2004, assumed deadstock collection fees of $10/head for calves and $25/head for mature cattle, based on discussions with individual firms.

However, this finding does have important implications for calf collections under FDA's proposed rule. The limited amount of raw material available for processing in each calf also makes it even less economically viable to remove the brain and spinal cord prior to rendering. Therefore, it is not surprising that the largest number of renderers suggested that they will either refuse to accept calves altogether or sharply curtail their calf collection efforts (see Table 4). Unlike the ERG/FDA study which predicts only a 0.5% reduction in the volume of calf mortalities renderered, our findings suggest a decline of nearly 84%, including a 29% reduction in the number of calves accepted by renderers, and a 55% reduction in volume due to significantly higher collection fees.

Under the proposed FDA rule, renderers indicating they plan to continue accepting cattle and calf deadstock reported they would likely charge fees ranging from $38.75/cwt to $41.44/cwt for calf mortalities, and between $6.08/cwt and $12.46/cwt for adult cattle. These ranges cover all collection options believed to be viable, including removal of the brain and spinal cord, removal of the head and spinal column, and rendering/disposing of the entire carcass but keeping all material separate from existing feed markets. However, estimates of expected fee structures are difficult since renderers have a lack of knowledge on specifics on how the rule is likely to be applied and its implications.

Reduced Revenues from Lost Deadstock Volume

Across all renderers that report some collections of cattle and calf mortalities in 2005, the average proportion of their total raw material volume accounted for by this material is 19%, ranging from under 2% for some renderers to more than 45% for a few others. Loss of any significant volume of this material for processing will have a dramatic effect on the revenue potential for some renderers, all of which according to our survey are independent renderers.

For this analysis we focus on lost product revenues from the sale of MBM and tallow derived from deadstock that is expected to no longer be collected if FDA's proposed rule is enacted. While revenue associated with deadstock collection fees will also decline, we assume that these fees are primarily a means of covering processing and transportation costs under the relatively weak product market prices experienced in recent years, and not generally viewed as a profit center by individual firms. Our focus is also on the volume of deadstock that renderers themselves estimate they will no longer accept under the proposed rule. As noted in Table 4, a significant additional volume of deadstock material is expected to be lost as livestock producers face higher collection fees and search for alternative means of disposal. However, given the difficulty in predicting these market impacts and the likelihood that some renderers could capture additional volume—at significantly higher collection fees—from the deadstock refused by other renderers, we believe that focusing only on renderer deadstock refusals provides a reasonable—and quite conservative—economic impact estimate.

Table 6 shows the value of lost revenue from deads and downers as described above. Lost MBM sales are estimated at more than $7.1 million and lost tallow sales exceed $8.6 million, for a combined revenue loss of more than $15.7 million across the rendering

industry. This far exceeds the $1.0 million in lost revenue predicted by the ERG/FDA study, even without considering the potential for additional lost volume as livestock producers search for alternative disposal methods given the higher collection fees renderers are expected to charge for this service.

Table 6: Revenue Losses to Renderers From Lost Dead and Downer Collections

	Head no Longer Accepted[1]	Volume lost to Rendering[2]	MBM Yield[3]	Tallow Yield[3]
	Head	*Lbs*		
Calves	246,520	61,630,056	20%	18%
Feedlot	24,692	22,222,361	20%	20%
Other Over 30 months	136,643	177,635,990	30%	15%
Other Under 30 Months	36,485	32,836,241	28%	18%
Totals	444,340	294,324,649		
	Pounds MBM Lost	Pounds Tallow Lost	Value MBM Lost[4]	Value Tallow Lost[4]
Calves	12,326,011	11,093,410	$1,109,341	$1,996,814
Feedlot	4,444,472	4,444,472	$400,003	$800,005
Other Over 30 months	53,290,797	26,645,399	$4,796,172	$4,796,172
Other Under 30 Months	9,194,147	5,910,523	$827,473	$1,063,894
Totals	79,255,428	48,093,804	$7,132,989	$8,656,885

1. Reported in Table 4, column 2
2. Estimated based on an assumed average weights as follows: calves, 250 lbs; feedlot cattle, 900 lbs; other cattle over 30 months, 1300 lbs; other cattle under 30 months, 900 lbs.
3. Yields assigned to correspond with the July 2005 ERG/FDA report, Table 2-6
4. MBM valued at $0.09 and tallow valued at $0.18 for consistency with July 2005 ERG/FDA report, Table 2-6.

Increased Costs to Livestock Producers

Livestock producers will be forced to reconsider their livestock mortality disposal options as they face significantly higher collection fees from renderers and the likelihood that many renderers will cease ruminant deadstock collections altogether under FDA's proposed rule. Under the existing fee structure charged by renderers for deadstock collection, livestock producers presumably choose the disposal method that minimizes their total costs within the feasibility constraints of each option. For instance, while on-farm burial is a viable option for some producers and is assumed to account for the majority of dead cattle disposals that are not rendered, other producers can face severe constraints in their ability to use this method in an environmentally responsible way, given their existing land base in relation to the number of livestock mortalities they experience. This is especially the case with feedlots and large-scale dairy operations. Other producers might lack the necessary equipment (e.g. a backhoe) or labor necessary for burials, and would be willing to pay a relatively high fee to renderers simply to avoid the cost and logistical burden of performing this task themselves with rented or borrowed equipment. However, as the collection fee increases considerably, alternative options are likely to be considered much more seriously.

Table 7 shows the estimated disposal costs by burial for the more than 444,000 cattle and calves that renderers predict they will not longer accept under FDA's proposed rule. We use the identical methodology and cost factors applied in the ERG/FDA study, as originally presented in the Sparks (2002) report. However, since most renderers charge a fee for deadstock collection, we also estimate the current total expense paid to renderers to collect these cattle, which is also presented in Table 7. Given that producers face some cost under either option, they presumably choose the least costly one among all viable alternatives.

Table 7: Estimated Disposal Costs for Deadstock No Longer Collected by Renderers

Disposal Costs by Burial				
	Head no Longer Accepted[1]	Labor Disposal Costs[2]	Equipment cost of Disposal[2]	Total Disposal Cost
Calves	246,520	$734,630	$8,628,208	$9,362,838
Feedlot	24,692	$147,161	$864,203	$1,011,364
Other over 30 months	136,643	$814,393	$4,782,507	$5,596,900
Other Under 30 Months	36,485	$217,449	$1,276,965	$1,494,414
Totals	444,340	$1,913,633	$15,551,883	$17,465,516
Fees Currently Paid to Renderers				
	Head no Longer Accepted[1]	Average Reported Collection Fee ($/Head)[3]		Total Fee Currently Paid to Renderers
Calves	246,520	$44.78		$11,039,176
Feedlot	24,692	$15.80		$390,126
Other over 30 months	136,643	$43.57		$5,953,538
Other Under 30 Months	36,485	$22.58		$823,824
Totals	444,340			$18,206,665

1. Reported in Table 4, column 2
2. Assumes 10 minutes for animals under 500 lbs and 20 minutes for animal over 500 lbs, at $17.89 per hour. Equipment costs are estimated at $35/hour, with a minimum of one hour per each animal (as applied in the ERD/FDA study).
3. Reported in Table 5.

Total disposal costs by burial for the deads and downers refused by renderers are estimated at nearly $17.5 million, far exceeding the $1 million estimate presented in the ERG/FDA report. However, deadstock that is not collected by renderers is not subject to a deadstock collection fee, and based on average collection fees reported by our survey, this suggests a savings of $18.2 million in current fees paid, slightly higher than the costs associated with burial. This does not suggest that livestock producers are acting irrationally by paying renderers to collect their deadstock; rather it illustrates the difficulty in applying average cost estimates across broad categories of producers. For instance, the total renderer collection fees estimated above are likely somewhat overestimated since producers that generate large quantities of deadstock presumably pay

much lower fees, and perhaps no fees at all, which could sharply reduce the total fees faced by the industry.[12] Similarly, burial costs are likely underestimated, since the calculation assumes that this option is feasible for all deadstock—which certainly it is not, at least in an environmentally acceptable manner. In fact, many producers will face costs much higher, especially those that generate large volumes of mortalities and might be forced to turn to alternative disposal methods such as incineration or composting, both of which far exceed the expected cost of burial (see Sparks 2002). But given that our estimates of current collection fees charged by renderers versus disposal costs associated with burial are relatively close, this suggests that these options do compete at the margin, a result we would expect.

The greatest economic impact on livestock producers will occur as a result of higher fees charged by renderers if the FDA rule is enacted. As illustrated in Table 5 (above), renderers willing to estimate the fees they would likely charge under this rule suggested that on average collection fees could at least double, and in some cases might increase by a factor of six or more. We believe these estimates reflect the costs renderers could incur to remove the necessary quantity of material from dead and down cattle, and to handle, processes and dispose of the prohibited material in a manner consistent with the proposed rule. Hence, we do not attribute any of these fees to profit transfers across industry segments, only to a net increase in costs faced by the entire livestock sector, paid in this case by livestock producers. Given the uncertainty over appropriate disposal techniques and the very high costs likely associated with some options, it is not surprising that the fees proposed are high and cover a wide range.

As a conservative estimate of how this higher fee schedule could impact livestock producers, we applied the lower range of fees estimated in the last column of Table 5 to the current estimate of deadstock processed by renderers *minus* the amount of deadstock that renderers estimate they would no longer accept under the FDA rule. In other words, we assume that the total number of cattle and calf mortalities eligible for collection by renderers falls by 444,340 head due to refusals by renderers to accept this material, leaving 1.425 million deads and downers potentially eligible for rendering, at a collection fee at least double current levels. The estimated fees faced by livestock producers are presented in Table 8.

[12] Recall that the collection fees used here report averages across renderers, not average fees paid by producers. The collection fee reported by each renderer likely reflects a "posted" price which could be negotiated lower by individual livestock producers.

Table 8: Estimated Deadstock Collection Fees Paid by Livestock Producers Under Proposed Rule

	Head Eligible for Rendering[1]	Volume of Material[2]	Estimated Collection Fee[3]	Total Cost to Livestock Producers
		lbs	*$/cwt*	
Calves	618,307	154,576,727	$38.47	$59,465,667
Feedlot	399,684	359,715,243	$6.08	$21,870,687
Other Over 30 Months	332,533	432,293,490	$6.16	$26,629,279
Other Under 30 Months	74,924	67,431,582	$6.97	$4,699,981
Totals	1,425,448	1,014,017,041		$112,665,614

1. Current deadstock renderered minus Table 4, column 1 estimate of head no longer accepted.
2. Estimated based on an assumed average weights as follows: calves, 250 lbs; feedlot cattle, 900 lbs; other cattle over 30 months, 1300 lbs; other cattle under 30 months, 900 lbs.
3. Reported in Table 5, based on the bottom end of estimated range.

Our estimates above suggest that livestock producers that are able to send cattle and calf deadstock to renderers could face fees of over $112.6 million per year to do so, including an average fee of over $96 per calf, over $54 per feedlot cattle, $80 per other cattle over 30 months old, and nearly $63 for each other cattle under 30 months old. The average collection fee across all types and ages of cattle would be just under $80 per head. We emphasize again that these estimates are generated based on the *low* end of the fee ranges provided in Table 4.

The magnitude of these estimated livestock mortality disposal costs has important economic and environmental implications across the rendering and livestock sectors. First, at collection fees anywhere near $80 per head, producers will certainly consider alternative means of disposal. This has an immediate implication for the volume of material available for producing MBM and tallow. While Table 6 estimated the value of lost MBM and tallow production from that deadstock that renderers are expected to refuse at nearly $16 million per year, there will certainly be additional production lost as livestock producers explore alternative options for avoiding exorbitant collection fees. This again highlights the fact that our cost estimates to the rendering industry in Table 6 are extremely conservative, and raises the real possibility that nearly the entire current volume of deadstock cattle and calves rendered could be lost to alternative means of disposal, in stark contrast to the ERG/FDA study that found only minor impacts on the volume of dead and downer cattle rendered.

There are also environmental considerations. The large volume of deadstock currently processed by renderers despite relatively high collection fees—that in some cases might match or exceed the cost of on-farm burial—suggests a relatively inelastic demand for these services by many livestock producers. For many of these producers on-farm burial might not be feasible within existing environmental guidelines, and composting or incineration still remains prohibitively expensive and/or complicated, so rendering remains the best alternative despite the fees typically charged. But faced with deadstock collection fees that could double or triple overnight, even the best-intentioned livestock

producers will likely be tempted to overlook some environmental concerns in order to save thousands or tens of thousands of dollars per year in renderer collection fees. Absent any type enforceable regulation of mortality disposal, unapproved and dangerous methods could find widespread use, including burial without regard to environmental considerations or faulty and inadequate attempts at composting or incineration. It is not unreasonable to seriously question whether the potential for environmental damage and risk to human and livestock health from the improper disposal of dead livestock as an indirect result of the proposed FDA rule exceeds the reduction in risk to human health that these new regulations are intended to provide.

Disposal of PCM Generated by Packers and Renderers

Since FDA's proposed rule regarding the removal of brain and spinal cord material from feed channels applies not only to deads and downers but also to all cattle over 30 months of age, this rule will present new disposal and logistics challenges for packers that must separate this material on the kill floor and identify alternative methods for disposal.

Given that the brain and spinal cord represents a relatively modest proportion of the total volume of offal typically available for rendering (estimated by ERG/FDA and other sources at 1.3 pounds per animal slaughtered at federally inspected facilities and 16.5 pounds per animal at state inspected plants) it is tempting to assume that the disposal costs will be modest across the industry and appropriate means of disposal will emerge that keep this material from accumulating at packing plants or rendering facilities or inadvertently entering prohibited or dangerous disposal channels. However, in part because of the relatively small volumes of material targeted, unit costs of disposal could be extremely high, and there is no assurance that renderers or other potential outlets for disposal will accept this material in the first place.

The rule appears to allow that this material be processed by renderers to derive tallow (with specific impurity standards) for sale in existing markets. However, the fact that this process would require entirely separate and dedicated equipment means that substantial capital investments would first be required. Whether plants will make this investment depends on both the expected revenue generated by tallow in relation to the processing costs (which currently suggests limited or no incentive for such processing), and the relative impact that processing could have on the cost and ability to dispose of raw material versus the processed and segregated MBM. The capital investments associated with this decision are discussed in later section of this report.

Our survey asked each renderer whether it would be willing to accept brains and spinal cords from cattle over 30 months of age (i.e. Prohibited Cattle Material) if this material is properly removed by a packer, and if so, the expected fee they would likely charge to provide this service. Of the 102 plants that responded, 72 indicated that they currently process ruminant material, and of those, exactly half (36 plants) indicated they would **not** accept this prohibited cattle material for disposal (assuming they cannot be forced to do

so). This is not surprising, since this material has no marketable value and has very limited potential to be processed into any material saleable into existing markets.[13]

Several renderers also identified a general concern about their own potential liability related to handling this material under the proposed FDA rule. Since the rule as it applies to slaughter facilities focuses only on cattle over 30 months of age, there is always some possibility—intentional or not—that brains and spinal cords derived from these older cattle could be commingled with the slaughter byproducts of younger cattle not subject to this rule. This could occur as a result of the slaughter facility having inaccurate or incomplete information about the age of a specific animal, a mistake by the person that removes the brain and spinal cord from an animal over 30 months of age (i.e. simply putting the material in the wrong bin), or even an intentional effort by the slaughter facility to avoid the much higher disposal fees associated with brains and spinal cords from older animals. And, while there is some ability to identify the age of cattle prior to slaughter, there is no ability whatsoever for renderers to verify that the brains and spinal cords they collect and process are exclusively from cattle under 30 months of age. The fear is that if an inspection or follow-up investigation by the regulatory agency in charge of enforcing the rule finds that prohibited cattle material was commingled with other material processed by renderers, the burden of proof that this did **not** occur will fall at least partially on the renderer, who could be subject to product recalls at the cost of millions of dollars in addition to fines associated with rule violation. As result, some renderers have suggested they might refuse to handle brain and spinal cords from any cattle, simply to protect themselves from this potentially expensive liability.

Among those firms indicating they would accept this material, their estimated price to provide this service ranged from a minimum of $100 per ton up to $1000 per ton, with an average response of $230.28 per ton ($11.51/cwt).

Using the ERG/FDA estimates that brain and spinal cord material generated by packers totals 51.566 million pounds per year requiring disposal, the resulting disposal costs faced by packers would be just over $5.9 million per year at $11.51/cwt, but could be as high as $25.8 million per year if disposal costs approach the upper range of estimates provided.

Much of the difficulty in estimating the likely disposal costs derives from a lack of consensus or any industry guidance regarding exactly how this material will or should be disposed of. The ERG/FDA study suggests that $12/cwt for disposal is an "amply conservative" estimate used to avoid underestimating the costs, without forecasting exactly how this material will be disposed of. Our research indicates that this is a dangerous assumption. We find $11.51/cwt to be an average response provided by renderers that believe they can or would be willing to find a means of disposing of this material, suggesting it is not at all conservative and in fact could be much higher depending on the ultimate cost and feasibility of various disposal options.

[13] As noted above, renderers could process this material on separate lines and extract tallow for sale into existing markets, but given the small volume of material and the fact that the protein must still be disposed of by alternative means, this option is extremely cost prohibitive at current (or even historic) tallow prices.

Our survey finds that the potential cost of disposing of prohibited material—and its ultimate feasibility—hinges critically on the willingness and availability of landfills to accept this material for direct disposal. We asked renderers to rank, in terms of practical feasibility and economic viability, various means of prohibited material disposal that have been suggested in previous research. The options included direct landfilling, dedicated rendering, alkaline digesters, incineration and composting. Table 9 reports the number of renderers that identified the relative feasibility of each option provided.

Table 9: Feasibility of Disposal Options for Prohibited Material as Identified by Individual Rendering Plants

Disposal Option	Infeasible 1	2	3	4	Feasible 5	Total Responses
	Number of Responses					
Direct Landfilling of Prohibited Material	18	6	5	14	30	73
Rendering Prohibited Material (on dedicated lines/equipment) prior to landfilling[1]	21	12	22	9	10	74
Alkaline Hydrolysis Digesters	53	13	2	1	1	70
Incineration	46	17	6	3	3	75
Composting	44	13	3	11	0	71

1. Allows collection of tallow from prohibited material for sale into existing markets if it meets a 0.15% impurities specification

Direct landfilling of prohibited material was by far viewed as the most feasible option identified, with 44 of 73 respondents ranking this option as either a "4" or "5" on a 5-point feasibility scale (with 1 representing the lowest level of feasibility). On the other hand, the majority of renderers found composting, incineration and alkaline digestion to be almost entirely infeasible, while dedicated rendering received a wide range of responses along the feasibility scale (somewhat skewed toward the infeasible end, however) likely reflecting its technical feasibility but extremely high unit costs and necessary capital investment.

The apparently strong assumption that direct landfilling is a viable option for disposing of raw PCM material raises important questions about the ultimate cost of disposal and the ability for renderers (and slaughter facilities) to secure appropriate disposal outlets. As noted in the ERG/FDA study and elsewhere, state regulations, including in several Midwestern States, often prohibit disposal of unprocessed dead animal parts or carcasses in landfills. To the extent that renderers or meatpackers are unaware of these specific regulations or expect that they will not apply to them, the range of disposal options available could be sharply curtailed and costs therefore would increase tremendously. Furthermore, since most solid waste landfills are privately owned and operated, there is no assurance that they will accept this material even if current regulations do not specifically prohibit them from doing so. Since landfill operators must balance their revenue opportunities against public perceptions regarding the safety of their facility and environmental impact, it should by no means be taken for granted that this malodorous,

potentially infectious (with various animal diseases) and highly unstable material will be allowed to enter most landfills and any price.

Unfortunately, even rendering this material prior to disposal—at significantly higher costs to the sector—does not necessarily assure a viable and reliable disposal outlet. Because this protein material would be—by implication of this rule—considered potentially dangerous to human health and infectious to animal populations even after being processed into MBM, landfills could easily have reason to refuse accepting it. In fact, personal discussions with landfill operators and the trade group that represents them reveals a high degree of reluctance to commit to accepting prohibited material that has been deemed too dangerous for existing livestock feed channels, even if it has first been processed into MBM. Since prions are believed to be stable in the environment and not easily broken down by natural processes, even the chance that this material could be infectious could be reason enough for some landfills to refuse it. Some operators have suggested that this material might need to be handled in a manner similar to medical waste, greatly increasing the cost of disposal and reducing disposal options. Lacking formal guidelines that establish the safe handling of this material and proper disposal techniques, landfill operators and all material handlers will have to rely on their own perceptions, which can be easily influenced by public resistance and alarmist reports by the media.

Another option might be to incinerate the processed material. But tipping fees at waste incinerators tend to be close to double those at landfills, which would suggest much higher disposal costs for prohibited cattle material even after incurring the significant processing costs that would be required. And, with fewer than 145 municipal solid waste (MSW) incinerators operating in only 29 US states, versus 1,700 MSW landfills across all 50 states (according to the National Solid Waste Management Association), the result is likely to be higher transportation costs to ship this material to incinerators, and legitimate concern as to whether these existing facilities even possess the necessary capacity to incinerate the volume of material that will be generated.

The result is tremendous uncertainty in the actual method by which prohibited material—generated both by slaughter facilities and renderers that continue to accept deadstock cattle—would ultimately be disposed of if the FDA rule were enacted. While the ERG/FDA study simply assigns a cost of $12/cwt to dispose of all this material without investigating which means of disposal might even be feasible or appropriate, we believe that this does not adequately address the potential scope of disposal challenges the industry is likely to face. In fact, it is entirely possible that renderers and slaughter facilities could face daunting challenges to identify the appropriate disposal technique and outlets, at costs that far exceed even the most pessimistic levels suggested by our survey or the FDA. And, until that appropriate method is identified and widely adopted, this material could accumulate at the facilities where it is generated, at substantial storage cost and potential risk to human and environmental health.

It would, in our opinion, be highly irresponsible for FDA to enact this rule without first fully exploring the cost, feasibility, and environmental impact of alternative disposal

options for this newly prohibited cattle material, and simultaneously offering specific guidelines for the proper handling, transport and disposal of this material that minimizes both environmental risk and industry cost.

Capital Costs for Renderers and Slaughter Facilities

Compliance with FDA's proposed rule will require the purchase of new equipment, and the hiring of additional employees to operate that equipment, by rendering facilities that handle prohibited material (dead and downer cattle and/or brains and spinal cords from cattle over 30 months of age) and the cattle slaughter facilities that process any cattle over 30 months of age.

For renderers that plan to continue to handle dead and downer cattle, removing the brain and spinal cord from these cattle will require the purchase of equipment that no renderer in our survey has indicated they own. There is some uncertainty about the type of equipment that might be needed and its ultimate cost. The ERG/FDA study suggests that most renderers, particularly relatively small ones, will forgo the cost of specialized equipment for brain and spinal cord removal and instead purchase circular cutting saws and/or use existing knives to remove the entire head and spinal column. These saws, their installation, and disposal bins to collect this prohibited material could cost anywhere from $7,000 to $12,000 per plant, according to the ERG/FDA study and independent discussions with equipment suppliers to the rendering industry. However, plants that process significant numbers of deadstock could require larger saws capable of accommodating faster line speeds, which can easily exceed $35,000 or more.

Removal of brains and spinal cords (as opposed to the entire head and spinal column) at the rendering facility could be done with similar knives or saws, but will require either additional labor to split the entire carcass and skull to physically remove this material, or substantially more expensive specialized equipment such as the vacuum-type systems often used for brain removal in cattle slaughter facilities. Purchase and installation of this type of equipment can easily exceed $50,000 per plant.

Some renderers have suggested that regardless of the capital investment to remove brains and spinal cords at the plant, there will almost certainly be a significant reduction deadstock processing line speed. Depending on the type of equipment used, some renderers might need to split each carcass to access the vertebral column, a step that will add significant time necessary for processing each animal, possibly reducing line speeds by 35% to 50%. Even using equipment that does not requiring splitting the carcass—such as saws designed to cut into the spinal column to remove the spinal cord and vacuum pumps to remove the brain—could add three minutes or more of processing time to each carcass, directly limiting the total number of carcasses that can be processed on a single line in a given day. This reduced line speed will decrease processing efficiency—and increase operating costs—for all renderers, but will especially impact those for whom deadstock processing accounts for a significant proportion of their total volume. This could also impede the ability of some renderers to continue processing their current volume of deadstock, especially during periods of severe weather when cattle and calf

mortalities peak. The result could force stockpiling of carcass at the rendering plant awaiting processing or at farms awaiting pickup, again raising environmental considerations and providing even more incentive for livestock producers to find alternative methods of disposal.

And, adding saws to any processing operation where they were not required previously will increase the potential for and frequency of workplace injuries, including not only cuts and contusions (many of which can be severe) but also long-term damage associated with repetitive motion disorders. While we make no attempt to quantify the likely incidence of these injuries that might result, the meatpacking industry—from where much of the equipment that would be required to remove brains and spinal cords would be adopted—reports some of the highest injury rates of any profession, with worker injury rates for many operations requiring saws and knives estimated by the industry as high as 20% to 40% annually (AMI).

Segregated Processing

The ERG/FDA study suggests that a small number of renderers might add processing capacity (i.e. separate lines and processes) to process and handle prohibited cattle material in their facilities. While this step is not specifically required by the regulation, our findings above suggest that it might turn out to be the only practical option for handling this material given that evidence indicates a low likelihood that landfills will accept it especially in its raw form, and other disposal methods are widely viewed as infeasible (see Table 9). Even incineration—which might be considered the method with the fewest possible adverse side effects—would likely be most practical if applied to processed MBM as opposed to raw product.

However, processing this material prior to disposal will require an enormous fixed investment by renderers to purchase and install the necessary equipment, and even once this investment is made, the cost of operating this equipment will far exceed the potential value of the tallow likely recovered, adding considerably to the total costs of disposal.

Among the plants in our survey, 52 plants indicated they might consider installing separate lines to process this material and 25 indicated they would not, with the remainder offering no opinion. When asked the capital costs they would likely incur to install these dedicated lines and equipment, estimates ranged from $250,000 to $8 million, averaging $3.025 million across all responding firms. Operating cost estimates ranged from $100,000 per year to more than $4 million, averaging $1.088 million per year across all firms that responded. Capital and operating costs obviously increase with volume the plant expects to handle, with firms in our survey expecting to handle an average of 12,530 tons of prohibited material per year. This implies a fixed investment in plant and equipment of $241 per ton of prohibited material, and annual operating costs of $86.83 per ton to process this material.

Independent discussions with a leading provider of rendering industry equipment (Dupps Equipment) confirmed that the necessary equipment (installed in the existing plant) to

process approximately 12,000 tons of material a year would likely require a minimum $2-$3 million investment at each facility. And, while larger volumes would require a decreasing marginal investment (i.e. doubling the processing capacity would not require doubling the investment), given the already small volume that 12,530 tons represents for this industry, smaller volumes would not necessarily require a smaller capital investment.

If we assume that 26 firms actually install dedicated processing equipment (50% of those who indicated some interest in doing so), 20 of which invest what we believe would be the minimum necessary investment of $2.5 million, the other six each investing $5 million, the result would be an industry-wide capital investment of $80,000,000. Annualizing this over ten years at a 7% discount rate suggests annual capital expenditures of $11.3 million.[14] Based on the total volume of PCM of 64.3 million pounds estimated by ERG/FDA, the result is $16.10 per ton of raw material simply to cover investment costs.

While some value could be extracted from the tallow derived through this process, it would be insufficient to cover the expected operating costs given the volumes implied at current prices. Assuming a tallow yield of only about 7%, the average expected volume of prohibited material processed by each plant would generate 877 tons of tallow for sale, which if sold at a price of $360 per ton[15] would generate $315,756 in annual tallow revenue ($25.20 per ton of raw material), $772,244 dollars (71%) *less* than the cost of processing. As a result, for each ton of PCM processed on dedicated lines and equipment, there would be a net cost of $61.63 per ton in operating costs ($86.83 in operating costs less $25.20 in tallow revenue), in addition to whatever cost is required to dispose of the remaining protein material, and in addition to the annualized costs of the fixed investment in plant and equipment.

One of the greatest challenges in estimating the potential capital investment required by the rendering industry to handle and/or process prohibited cattle material is the uncertainty regarding the number of firms that would actually make the necessary investment in dedicated processing equipment. Based on the issues raised earlier regarding disposal of PCM, particularly the very low likelihood that this material would be accepted by landfills in its raw form, we believe strongly that compliance with the rule will ultimately require that all of the raw PCM material (generated at slaughter facilities as well as at renderers that continue to process deadstock) be processed prior to disposal.

However, the high fixed cost of dedicated processing equipment relative to the volume of material likely to be handled makes this is an extremely risky investment for any individual renderer. Profitability will require that the fees charged to process this material be large enough to cover the high fixed costs as well as the high per unit operating costs likely associated with operating a facility on such a small scale. But investment in PCM processing capacity by several firms—even at the minimum scale considered feasibility for most processing equipment—will almost certainly result in

[14] A 9% interest rate, which might be more realistic given the risk of the investment, results in annualized capital costs of $12.5 million per year.
[15] Consistent with estimates used in the ERG/FDA study.

industry-wide overcapacity, increasing the possibility that some renderers cannot generate sufficient volume to cover investment costs, and raising the risk of business failure.

Miscellaneous Impacts

The primary focus of this analysis is the economic impact of FDA's proposed rule on renderers, cattle producers, and meatpackers through changes in the way cattle and calf deadstock, and brains and spinal cords removed by slaughter facilities, are disposed of. But the actual impact will likely be broader than this, rippling into other categories of deadstock collection and also affecting hundreds of small meatpacking facilities that could find it impossible to continue operating at any level.

For many renderers, the decision to end or significantly scale back collection of dead cattle and calves could impact the economics of collecting other types of deadstock, including hogs and poultry. Renderers for whom cattle and calves currently comprise a significant portion of their total deadstock volume (across all species) will almost certainly experience higher unit costs of collecting other species if their current ruminant deadstock volume is sharply reduced—either by choice or market forces from higher fees. As a result, these renderers will necessarily have to reconsider the economics of all deadstock collection, possibly deciding to end this service for all species, or at least increasing collection fees for non-ruminant species.

Our survey found 15 plants that indicated they intend to end deadstock collection of all species if the proposed rule is enacted. The result would be lost processing volume of hog mortalities exceeding 80 million pounds per year, and poultry mortalities exceeding 49 million pounds per year. This will directly reduce MBM and tallow revenues for these renderers beyond the estimates provided in Table 6, and could also create additional disposal challenges for the producers of *non-ruminant* deadstock that these firms currently serve. In addition, at least 25 plants suggested they would increase collection fees for non-ruminant deadstock to cover the higher unit costs resulting from lost ruminant deadstock volume. Proposed fee increases for non-ruminant deadstock collection ranged from 5% to over 100% of current levels, averaging roughly 50% across all firms. Practically all firms indicated that higher non-ruminant deadstock collection fees would negatively impact the volume they expect to collect. Without prior knowledge of the fee structure for non-ruminant deadstock collections (information that was not collected by our survey), we cannot quantify the impact that these higher fees might have on non-ruminant livestock producers, but it is clear that a 50% increase in disposal fees would be significant.

Our survey also indicated a strong reluctance among renderers to continue collecting any material from non-federally inspected meatpacking plants or facilities. This is not surprising, since verification that all PCM material was properly removed and segregated would become the exclusive responsibility of the renderer—a responsibility that might not be worth the risk and effort given the small quantities of material these firms produce. Indeed, 35 plants suggested this rule could reduce their willingness to collect material

from state-inspected packing plants, 46 suggested it would impact their willingness to collect material from other non-inspected custom packing plants, and 57 indicated they would reconsider their willingness to collect material from any other non-federally inspected source. All of these categories of packing plants are overwhelmingly characterized as small, family-owned facilities, and the ability for these small businesses to remain operational would clearly be put in severe jeopardy if they were to lose any or all existing channels of by-product disposal.

Overview of Impacts

FDA's proposed rule that would prohibit most (if not all) cattle brains and spinal cords from all livestock feed markets will have immediate and profound impacts on the livestock sector, particularly on the rendering industry and livestock producers. The consequences will be both economic and environmental, reflecting lost product volume to the rendering industry and the high likelihood that much of this volume will be diverted to disposal channels that threaten the environment in numerous ways, including polluted groundwater and the potential to spread human and livestock diseases. While an economic analysis of this proposed rule conducted on behalf of the FDA by the ERG group predicted that the overall impact of this regulatory option on slaughtering and rendering processes would be "modest," our own analysis suggests a much larger impact, with the potential for severe economic distress among many renderers.

We find that direct economic impacts faced by the rendering industry and livestock producers—exclusively through the loss of existing channels for cattle and calf deadstock processing—are conservatively estimated at over $127.7 million per year. This is in addition to the costs that will be faced by slaughter facilities to handle and dispose of PCM and the significant capital investment that must be made throughout the sector (particularly by renderers) to handle, process and dispose of all material identified by this rule. **In total, the aggregate impact across the sector will almost certainly exceed $150 million per year, even under the most conservative assumptions**. Clearly, this is not a modest impact. Important conclusions from our analysis include:

The proportion of deadstock cattle and calves rendered in the United States far exceeds 17%. Our research, based on a large survey of the rendering industry, finds that this industry currently processes roughly 45% of all cattle and calves in the United States that die or are condemned prior to slaughter—consistent with previous estimates made by Sparks/Informa Economics using entirely different methodologies. We find that in 2005 this industry expects to process nearly 1.9 million cattle and calf mortalities of all types, accounting for over 1.3 billion pounds of raw material volume.

The proposed rule will severely reduce the number of dead/downer cattle and calves rendered in the United States. The requirement that brains and spinal cords be removed from all deadstock cattle and calves prior to rendering will create costly and complicated challenges for renderers, causing many to abandon this service and causing those that remain to substantially increase their collection fees. The result will be a sharp decline in the availability of this service, as well as a decline in the number of livestock

producers willing to pay renderers to the fee necessary to collect cattle and calf mortalities. Nearly 30 renderers reported that they intend to end collection of all deadstock cattle and calves under this new rule, with most of the remaining renderers suggesting they would refuse to collect at least some proportion of their current volume. The estimated impact of reduced availability of this service would be a 32.75% reduction in deadstock cattle and calves rendered, forcing producers of more than 444,000 cattle and calf mortalities each year to find alternative means of disposal. Higher collection fees will reduce this volume even further, possibly by more than 800,000 head per year, resulting in a total reduction of volume of more than 1.2 million head, or roughly 66% of the amount currently renderered (see Table 4).

The reduced availability of deadstock collection services by renderers and higher fees will create a high potential for adverse environmental consequences. The large volume of deadstock currently processed by renderers despite relatively high collection fees suggests a relatively inelastic demand for these services by many livestock producers. For many of these producers on-farm burial might not be feasible within existing environmental guidelines, and composting or incineration still remains prohibitively expensive and/or complicated, so rendering remains the best alternative despite the fees typically charged. But faced with deadstock collection fees that could double or triple overnight, even the best-intentioned livestock producers will likely be tempted to overlook some environmental concerns in order to save thousands or tens of thousands of dollars per year in renderer collection fees. Absent any type enforceable regulation of mortality disposal, unapproved and dangerous methods could find widespread use, including burial without regard to environmental considerations or faulty and inadequate attempts at composting or incineration. It is not unreasonable to seriously question whether the potential for environmental damage and risk to human and livestock health from the improper disposal of dead livestock as an indirect result of the proposed FDA rule exceeds the reduction in risk to human health that these new regulations are intended to provide.

Reduced sales of MBM and tallow from the loss of deadstock rendering volume will exceed $15.7 million per year, at least 15 times larger than suggested by the ERG/FDA study. Our estimate of reduced rendering industry revenue is based only on the sales that would be lost among those renderers expected to eliminate or curtail deadstock cattle collections, making it an extremely conservative estimate. Further reductions in volume resulting from higher collection fees will add to the revenue shortfall.

Costs of deadstock disposal faced by livestock producers could exceed $112 million per year under the proposed rule. Our estimates suggest that livestock producers that are able to send cattle and calf deadstock to renderers could face fees of over $112.6 million per year to do so, including an average fee of over $96 per calf, over $54 per feedlot cattle, $80 per other cattle over 30 months old, and nearly $63 for each other cattle under 30 months old. The average collection fee across all types and ages of cattle would approach $80 per head. We emphasize that these estimates are generated based on

the *low* end of the fee ranges suggested by renderers in our survey (provided in Table 4) and are therefore extremely conservative.

The capital investment required by renderers and meatpackers to comply with this rule will be significant. While the ERG/FDA study finds that capital costs by renderers just to install the necessary equipment for brain and spinal cords from deadstock cattle/calves will exceed $3.10 million, with the total costs (including annualized capital costs) of operating this equipment exceeding $1.88 million per year, we believe that given the disposal challenges associated with raw PCM, ultimately all of this material will require dedicated processing prior to disposal, significantly increasing the capital expenditures required by industry. If we assume that 26 firms actually install dedicated processing equipment (50% of those who indicated some interest in doing so), 20 of which invest what we believe would be the minimum necessary investment of $2.5 million, the other six each investing $5 million, the result would be an industry-wide capital investment of $80,000,000. Annualizing this over ten years at a 7% discount rate suggests annual capital expenditures of $11.3 million.[16]

Disposal of PCM generated by meatpackers and renderers will be costly, and no universally appropriate methods of handling and disposal have been identified. Among firms in our survey indicating they would accept this material, their estimated price to provide this service ranged from a minimum of $100 per ton up to $1000 per ton, with an average response of $230.28 per ton ($11.51/cwt). However, the potential cost of disposing of prohibited material—and its ultimate feasibility—hinges critically on the willingness and availability of landfills to accept this material for direct disposal, which is the method most renderers suggested was most feasible for their operations. But since state regulations often prohibit disposal of this type of material in landfills, and since many other landfills would likely refuse to accept it even if regulations allowed, there is a high likelihood that all of this material will ultimately need to be rendered prior to disposal, greatly increasing the overall cost of disposal even beyond the $12/cwt estimate that the ERG/FDA study suggests is "amply conservative."

[16] A 9% interest rate, which might be more realistic given the risk of the investment, results in annualized capital costs of $12.5 million per year.

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Appendix I: Renderer Survey

Following is a blank copy of the survey form sent to the rendering industry.

Firm Name _____ Contact name: _____

Plant Address* _____ Phone number: _____

_____ Type of Firm: _____ Packer Renderer
(please check one) _____ Independent Renderer

** Please complete a separate questionnaire for **each active plant** in your company*

If you have any questions regarding this survey, or need clarification on any of the questions below, please contact Mark Jekanowski of Informa Economics, at 703-734-8787 or mark.jekanowski@informaecon.com. Additional detail, comments or clarification can be provided on page 4 of this survey form.

1. Annual volume of raw material processed (exclude restaurant grease) 2000 2003 2005*
   Please specify units, e.g. pounds or tons
   * Expected volume for the entire year

2. Do you currently accept dead or disabled cattle or calves for rendering? _____ Yes No
   If "Yes" proceed to question 3. If "No" Proceed to Question 8.

3. Estimated annual volume of dead (including 3D/4D) cattle collected (No. of head, OR pounds. Please Specify)

	2000	2003	2005*
Calves (under 500 lbs)			
Feedlot Cattle			
Other Cattle over 30 months			
Other Cattle under 30 months			

* Expected volume for the entire year

4. In a typical 12 month period, what percentage of dead cattle and calves are in condition good enough to remove the brain and spinal cord prior to rendering?* _____ %
   * Based on number of head, **not** weight

5. Do you currently have the equipment necessary to remove the brains and spinal cords from dead cattle and calves? _____ Yes No

The following questions address the dead and downer cattle provisions of FDA's proposed rule. These provisions would prohibit the ability to market the protein (i.e. Meat and Bone Meal) from dead and downer cattle if the brains and spinal cords from these animals have not been removed for alternative disposal. Questions 6 and 7 consider your willingness and ability to remove brains and spinal cords from such cattle, and the fees you might require for these services.

We consider the following options that might be available to renderers:

a. Remove brain and spinal cord prior to rendering (if technically feasible on such cattle)
b. Remove entire head and spinal column prior to rendering (potentially appropriate on cattle where excessive decomposition makes it infeasible to remove **only** the brain and spinal cord)
c. Remove nothing from the cattle, but keep all protein material from these cattle separate from existing food and feed markets by disposing of it by alternative means

6. Estimated impact on deadstock collection fees (per animal OR per pound of raw material. Please Specify)

		Estimated Fee under a scenario of:		
	Current Fee	Brain and spinal cord removal	Head and spinal column removal	Accept but not render for feed
Calves (under 500 lbs)				
Feedlot Cattle				
Other Cattle over 30 months				
Other Cattle under 30 months				

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7. Estimated impact on deadstock collection volume:

If FDA's proposed rule is enacted, what percent of your current cattle deadstock volume do you plan to:

	No longer accept	Remove brain and spinal cord	Remove head and spinal column	Accept but not render for feed	Total
Calves (under 500 lbs)					100%
Feedlot Cattle					100%
Other Cattle over 30 months					100%
Other Cattle under 30 months					100%

How much volume do you expect to lose due to higher deadstock collection fees?

Calves (under 500 lbs) _____ %
Feedlot Cattle _____ %
Other Cattle over 30 months _____ %
Other Cattle under 30 months _____ %

Impact on other deadstock species:

Do you plan to continue to accept other deadstock species for rendering? _____ Yes No

Impact on estimated collection fees _____ %
Impact on estimated collected volume _____ %

8. Estimated current annual volume of non-ruminant deadstock rendered (please specify units, e.g. head, tons, lbs)

Hogs	Poultry	Horses	*other:*	*other:*

*The following questions address FDA's proposed rule concerning disposal of brains and spinal cords from **all slaughter cattle 30 months of age or older**. The proposed rule would require that this material not enter the food and feed chain, and be kept entirely separate from all material destined for rendering, including the use of separate sealed containers for transport.*

9. Do you currently process ruminant material at this plant? _____ Yes No

If no, you need not answer any other questions. Please return your survey in the envelope provided

9.a What proportion of your annual volume is comprised of ruminant materials? _____ %
(Excluding restaurant grease)

10. What proportion of the **ruminant** material you process is rendered using the following processes?

Batch _____ %
Carver-Greenfield Slurry System (stage 1, 2 or 3) _____ %
Atmospheric Continuous (fat added) _____ %
Atmospheric Continuous (no fat added) _____ %

11. Would you be willing to accept and dispose of brains and spinal cords from cattle over 30 months of age if this material is properly removed by a packer? _____ Yes No

11.a If yes, what do you expect to charge for this service? ($/ton) _____ $ _____ /ton

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12. FDA identified several potential disposal outlets for this prohibited material. Which option(s) would you consider most economically viable and practically feasible for your own operation?

	Infeasible	*please circle one*			Feasible
a. Direct landfilling of prohibited material	1	2	3	4	5
b. Rendering prohibited material (on dedicated lines/equipment) prior to landfilling*	1	2	3	4	5
c. Alkaline hydrolysis digesters	1	2	3	4	5
d. Incineration	1	2	3	4	5
e. Composting	1	2	3	4	5

* allows collection of tallow from prohibited materials for sale into existing markets if it meets a 0.15% impurities specification

13. Do you have access to landfills that would be willing to accept and dispose of materials prohibited from the food and feed chain? *Please circle Yes or No* Yes No

13.a If yes, what do you anticipate the "tipping fees" would be? $ _____ /ton

14. Would you consider installing a separate line to process material prohibited from feed use? Yes No

15. **All Renderers:** What is your estimate of the cost if you were to install separate lines/equipment to handle the volume of prohibited material you expect to collect?
- Capital cost $ _____
- Operating cost $ _____ /year
- Annual volume _____ ton/year

15.a **Packer Renderers Only:** What is your estimated cost to remove, handle and keep separate the volume of prohibited material from cattle you expect to collect?
- Capital cost $ _____
- Operating cost $ _____ /year
- Annual volume _____ ton/year

16. What is your estimate of the additional transportation and handling cost if prohibited material must be kept separate from material rendered for feed use? $ _____ /ton

17. What percent of your **ruminant material volume** (excluding restaurant grease) is from the following types of meatpacking facilities?

Federally Inspected	_____ %	Custom	_____ %	
State Inspected	_____ %	Other non-inspected	_____ %	(e.g. deadstock collectors)

17.a Would FDA's proposed regulations affect your willingness and/or ability to continue to accept material from these plants?

Federally Inspected	Yes	No	Custom	Yes	No	
State Inspected	Yes	No	Other non-inspected	Yes	No	(e.g. deadstock collectors)

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Please use the following area to expand upon any of the issues highlighted in the above survey, or provide additional perspective on how this proposed rule might affect your operation or the industry as a whole.

Thank you for participating in this important survey.

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Appendix II: Survey Comments

The following comments were provided by renderers that responded to our survey. Some comments were withheld to protect confidentiality or limit redundancy. Some responses were reworded slightly also to protect confidentiality by removing firm-specific information.[17]

1. If no regulatory inspection of farms or dead stock is done, we will lose 90% of the cattle to the ditch. (#3)

2. Control mechanisms would need to be put in place in order to verify the removal of CMPFA by the small, independent 4-D dead stock collectors. (#7)

3. There are concerns that the extra work needed to remove the brain and spinal cord will result in a higher charge that our customers will not be willing to pay. There is also a concern and question about the removal of the spinal cord. There is a concern that all of the spinal cord may not be removed to the point of pleasing the FDA inspector. Depending on the punishment by the inspector, the risk may not be worth the reward. With only 5.3% of our volume coming from dead cattle, the possibility of discontinuing dead cattle removal is there. Another option is to send all cattle to a pet food/red meat plant where they might be able to split the carcass and remove the spinal cord. The main concern here is that a charge will have to initiate in feedlot areas not accustomed to being charged for mortality removal. If a charge is initiated, a large percentage of feedlots will look for an alternative to rendering. I am also concerned that the brains and spinal cord may not be accepted at landfills after a while. (#8)

4. In order to receive or accept any heads or vertebral columns from federally inspected, or state inspected slaughter facility, each head and vertebral would need to be certified by a government inspector as to being brain and spinal cord free. Since custom plants are not inspected, we would not be able to take any head or vertebral column as we have no way of knowing if the animal was under or over 30 months.

   With this comes the problem of aging. As the brain and spinal cord of animals slaughtered less than 30 mos. Of age are exempted from removal, renderers have no way of knowing if in fact those heads and vertebral columns are truly from animals 30 mos and younger. Because all ramifications fall on the renderer, it is not in our best interest to process the head or vertebral column. The burden of proof is left to the renderer who will be penalized if he is found to have rendered brains and spinal cords of animals greater than 30 mos. But no penalties exist for those who slaughter animals of any age. We will be subject to a recall of our finished rendered products that could easily exceed $2 million per instance. Not only are putting out operation at risk, the entire rendering industry will be made out to be violating the proposed rule changes.

[17] The numbers in parentheses are for internal identification purposes only.

In order to accept any carcasses from 3D/4D plants, the brains and spinal cords must be removed. Again, the renderer is being told to police the removal, a task that is daunting at best. The only way a renderer would accept the head and vertebral column from those facilities would be under government inspection certifying that the brain and spinal cord have been removed and not included with the rest of the inedible by-products.

We estimate that the cost per head of picking up dead ruminants no matter their age would be at least $85. This includes the cost of transportation, removal of SRM's and their disposal. There are very few cattle producers that would be willing to pay that amount for removal, especially those with large herds that experience daily death loss. I already know of 3D/4D haulers that have lost 73% of their volume since they instituted a $50 charge to pick up each animal regardless of age.

Several attempts have been made to effectively remove the spinal cord from a fallen ruminant regardless of the age. The only way to completely remove the spinal cord is to completely remove the vertebral column. Contrary to the ERG study, very few renderers process dead cows for the meat and sell that meat into the pet food industry. The only way to remove the spinal column is to completely remove the vertebral column and the only way to accomplish this task is to use a saw. No matter what type of saw is used, the employee using the saw is put at great risk for a severe accident no matter what precautions are implemented. Even if this could be accomplished, some measure of government inspection would be required to assure FDA that a renderer was in fact in compliance.

To remove, haul, and dispose of SRM's, new or used trucks would be needed, drivers hired and trained and approved landfills found. Trucks are the easy part of the equation as far as availability is concerned. The biggest obstacle is the hiring of drivers. There is currently a shortage of drivers in my state. In order to lure them away from their current driving jobs, we would need to offer wages and benefits higher than they currently receive. This is not practical. To heighten the problem, not every landfill accepts carcasses nor are they conveniently located next to a renderer.

The installation of a separate rendering system could be next to impossible. Each new system would need to go through the permitting process, which is very time consuming. If in fact a new system were to be permitted, each new system would need separate odor control equipment and waste water equipment. As state above, new or used trucks would be needed, drivers and plant people trained and hired and security established. In order to support the separate SRM facility, charges for removal, transportation and rendering would need to be passed along to each customer as the meat and bone meal derived has little or no sales value, new uses would need to be found.

Burning of SRM derived meat and bone meal is an option. This would provide fuel for the separate plant but at a huge cost for equipment needed to effectively burn the meat and bone meal as fuel and to comply with current air emission standards. In order to accomplish this task would need large government subsidies.

The current proposed FDA rules leave the renderer exposed from all sides. As currently written, we are to assure the United States and the global community that no brain or spinal cord material enters the animal feed chain and suffer all consequences if we fail. We are the watchdogs while all other sectors of the ruminant food or deadstock business have no obligation in insure that the SRM's are properly removed.

We have taken the responsibility of rendering materials that have the opportunity to cause animal and human diseases and pathogens that can harm the environment. We were not asked to do this by the government. Now we must certify all is well without the help of any federal or state inspected slaughter, independent deadstock haulers, the FDA, USDA, and the global community. (#12)

5. If the new feed rule goes into effect, the farmers/renderers will either go for direct burial or composting rather than pay higher removal fees. (#14)

6. From previous year's experience, we expect to lose the majority of our dead stock customers if we increase our service charge to $160.00 per cow. Most farms will compost the dead stock and the farms that would continue to use our service would be widely spread apart, which would drive the unit cost higher and would most likely inhibit us from continued service. (#15)

7. All federally inspected facilities will have to remove the SRM's in order to sell the meat, and since they are inspected, will handle them properly. Custom farm slaughter people should also remove them to comply with the regulation, but who is responsible for ensuring compliance? We do not want to be the regulatory agency. Can we get a certification [from the custom slaughter operation] either yearly or with each pickup, or would we need some other means of verifying compliance? (#16)

8. This rule will force us to raise our charges to a point that is cost-prohibitive. As a result, the higher cost will discourage farmers from using our service. In the past, we have experienced a severe decline of use of our service due to higher pick-up fees. Secondly, this proposed rule will force farmers to load landfills with recyclable material, and worse yet, leave carcasses to contaminate and spread disease throughout rural communities. Furthermore, if this rule comes to pass, it will raise other environmental concerns that will affect many communities nation wide. These concerns are the troublesome odor and scavenger population associated with rotting carcasses (as well as fear of rabies) and contamination of surface and ground (drinking) water. This FDA proposal will ultimately force this operation of business without government support (#18).

9. Our business has dropped off enough with the BSE that we felt it was in our best interest to process 100% poultry beginning Jan. 2006. We will no longer accept any product unless it is 100% poultry. (#22)

10. We would most likely discontinue dead animal removal service completely and use the resources in other areas. A major are of concern is how would FDA police the removal of spinal columns and brains from the animals slaughtered in small facilities or non inspected facilities? (#23)

11. Strictly, from a cost perspective, duplication of systems/equipment would be required and be an immediate cost w/ zero return. Employee retraining and additional costs—higher wages for more skilled workers; increased workers compensation; higher workers compensation experience modification—would be other areas of "hidden" direct costs. As with any rule or regulation the more difficult and costly it is to comply the higher the incidences of non-compliance (#25)

12. If the proposed FDA rule is placed in service as proposed, we will cease dead animal removal service as well as locker plants and custom slaughter because of the burden of full responsibility placed on the rendering industry for all raw products and finish meal and no ability to control 100% of removal of effected SRM's. (#26)

13. Calves under 400 lbs would not have the prohibited material removed because the value and quantity of finished product derived from these animals would not be sufficient to offset the labor cost of removing the prohibited material. Producers in our area would not be willing to compensate the renderer for the cost of removing prohibited material or for the cost of collection and disposal in a landfill and would dispose of these animals using alternative methods.

    Approximately 70% of our feedlot customers and over 90% of dairy and farm customers have stated that they will not pay more for the removal of deadstock from their operations. These operations have all said they will use alternative methods of disposal ranging from burial or composting to dumping in pastures.

    One aspect of the proposed rule that will affect our operation is its impact on processing line speed. We are capable of processing 1,200 head per day with our current system. We feel that the only viable method for removing the prohibited materials from deadstock would be to split the carcass and access the vertebral column. In adding this extra step to the process we anticipate that our line speed would be decreased by 35-50%, directly reducing our daily processing abilities to approximately 600 head per day with our current system.

    Our processing ability is critical because of the high concentration of cattle on feed in the areas we service, as well as the highly concentrated cow-calf population. During period of severe weather, it is not unusual to collect more than 1,000 head per day. Reducing our processing capacity during these peak periods will result in the obvious increased operational costs due to lack of efficiency, but moreover would force our operation into stockpiling animals outside our facility, or stockpiling of animals at various farms and ranches awaiting pickup as our processing abilities allow. (#29)

14. The cost of collection would be very high to the slaughterhouse. Some are putting into dumpsters now (for other animals to dig into and spread disease) to save pick up charges. With meat & bone meal prices so low how would the renderer make any money with out some type of federal or state subsidies? (#43)

15. Deadstock processing is a significant portion of our business. FDA's proposed rule would force us to either discontinue picking up dead cattle, or to reconfigure our plant to remove brains and spinal columns. The first choice would reduce our volume to the point where it is no longer viable to operate our plant. The second would require us to spend tens of thousands of dollars on equipment and plant alterations, and thousands more on labor to remove this material. But then what do we do with this material? Local landfill will not accept animal carcasses, so would almost certainly not accept this material, either. This rule would force us to choose between shutting down our business or making massive new investments, but even after the investments are made we have no guidance as to how we handle or dispose of the material. Then, there is nothing stopping FDA from amending the rule later to ban all livestock material—putting us out of business, anyway.

    What will be done with the tens of thousands of dead/downer cattle that will no longer be rendered? Composting is regarded as an option, but I sincerely doubt that many farmers will have the time or inclination to do it properly, resulting in thousands of rotting animal carcasses all over the country and the consequent threat of disease. The proposed rule states that rendering reduces the infectivity of the BSE prion by two logs. If so, how can it be more beneficial to compost these cattle carcasses (rendering normally heats the material to 260-280 degrees F, whereas composting heats only to about 160 degrees F), the product of which will be spread all over pastures, fields, etc., only increasing the chance of cattle ingesting these prions? (#42)

16. The FDA rule as we see it only adds costs and weakens drop value for cattle. (#54)

17. We feel the proposed rule would devastate the rendering industry. I do not believe it would be possible to remove SRM's from a high percentage of dead animals. We are certain that we would stop accepting most dead animals. (#68)

18. In order to remove and/or handle prohibited materials, adequate volumes must be available [so] costs for transportation and disposal plus a margin can be covered. Transportation costs are based on current fuels costs and would need to increase or decrease as fuel prices change. Impact of the proposed rule on state and custom slaughter facilities will be determined by our ability to satisfy FDA that prohibited materials were removed at slaughter. Language in the proposed rule is too subjective and unclear regarding such requirements. The subjectivity leaves too much to the individual inspector' discretion. If the rule is published, we would be forced to do a risk assessment on each individual account in order to minimize the company's exposure to a recall or other regulatory action. Federally inspected facilities should offer the lowest risk. Other facilities having a state inspector present during slaughter who can verify that the prohibited materials are removed would also be considered to be of lower risk. Slaughter facilities that do not have continuous inspection may pose the greatest risk. (#69)

19. Ruminant material accounts for a small amount (<10%) of our volume. If FDA regulations become too onerous, we will likely discontinue picking up ANY ruminant material. There currently is only one other renderer in [this state] that accepts ruminant material. (#88)

nra NATIONAL RENDERERS ASSOCIATION, Inc.

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January 11, 2008

The Honorable Richard Crowder
Office of the United States Trade Representative
17th St. N.W.
Washington, D.C. 20509

RE: Summary of comments about a final rule titled: Substances Prohibited from Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy

Dear Ambassador Crowder:

The National Renderers Association (NRA) appreciated the opportunity to meet you and Leslie O'Connor on January 8, 2008. We were pleased that you would meet with us and hear us out on the issue of the proposed FDA Feed Rule changes.

NRA believes that additional safeguards against bovine spongiform encephalopathy (BSE) are unnecessary. FDA reported on October 3, 2007 that compliance with the current 21 CFR 589.2000 is extremely high—of the 6602 firms handling prohibited materials, none required official action after inspections and only 190 (2.9 %) had minor technical violations rule requiring changes in recordkeeping or conditions involving non-ruminant feeds. The Animal and Plant Health Inspection Service (APHIS) of USDA concluded after the testing of more than 787,000 cattle that the number of cattle in the U.S. infected with BSE is extremely low. This high level of compliance combined with a very low incidence of BSE suggests that the risk of BSE in the United States is already negligible.

We are concerned with your comments that the rule change is a good idea because it would reduce risk. We disagree with this conclusion and our position that the risk reduction achieved by implementing the rule changes would be negligible is supported by APHIS risk analysis, the updated Harvard risk assessment, and by FDA's own recent statements. Of particular concern is repetition of the FDA observation that removing brain and spinal cord "reduces risk by 90%." This statement gives an exaggerated sense of the proposal's effectiveness because the use of percentages to compare two numbers so close to zero is not appropriate. Also, there is no risk of SRMs from cattle that are not infected—and the APHIS testing proves that U.S. cattle are not infected.

We are troubled that in spite of negligible risk improvement provided by the proposed rule and the significant added costs for the rendering, meat packing, and

livestock producing industries, that the primary driving force moving this proposed rule toward implementation is the hope that it will open beef trade with Japan, Korea, and Russia. The NRA is very disappointed that meeting unreasonable trade demands may trump sound science and risk assessment as reasons to promulgate new and onerous regulation.

NRA does not know the extent of SRM removal required in the latest version of the final rule. However, there is no version of a "short list" or age cut off that would make SRM removal from dead stock plants practical, enforceable, or safe for plant workers.

In our comments to FDA in 2005, the NRA provided data showing that implementing a ban on CMPAF would cost more than $127.7 million per year. Copies of this economic assessment, conducted and written by Informa Economics, were provided to you at our January meeting. Because of increases in production costs and in the market value of finished rendered products over the past two years, we believe the cost of implementing and complying with the proposed regulations would now be even greater than originally estimated.

In addition to being unnecessary and expensive, the proposed rule is likely to have unintended consequences including animal and human health risks due to improper disposal of dead animals as a result of high priced or non-existent dead animal pick up because of the devaluation caused by the proposed rule. These impacts are also detailed in the 2005 Informa Economics assessment which is still very much relevant.

In summary, NRA does not believe the proposed rule is necessary. We do not believe the rule is enforceable, and we believe it will be more expensive and have a greater negative impact on the environment than predicted by FDA. Ignoring the unintended consequences and poor cost benefit ratio in order to "hopefully, maybe" break the beef trade logjam with countries that have not negotiated in good faith would be ill advised. We encourage the administration not to implement the proposed rule.

Sincerely,

Thomas M. Cook

Thomas M. Cook
President, National Renderers Association

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January 11, 2008

Ms. Susan Dudley, Administrator
Office of Information and Regulatory Affairs
The Office of Management and Budget
EEOB Room 262
Washington, D.C. 20503

RE: Summary of comments about a final rule titled: Substances Prohibited From Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy (RIN: 0910-AF46)

Dear Ms. Dudley:

The National Renderers Association (NRA) appreciated the opportunity to meet with Mr. Kevin Neyland, Deputy Administrator, Ms. Fume Greigo and other OMB staff on December 13, 2007.

The NRA is the international trade association for the industry that safely and efficiently recycles animal agriculture by-products into valuable ingredients for the livestock, pet food, chemical and consumer product industries. NRA represents its members' interests to Congress, regulatory and other government agencies, promotes greater use of rendered products, and fosters the opening and expansion of trade between North American exporters and foreign buyers. NRA's membership represents more than 98% of the rendering capacity in both the U.S. and Canada.

The purpose of the meeting was to share industry concerns regarding the FDA proposed rule amending 21 CFR 589.2000 and prohibiting the use of certain cattle origin materials from all animal feed. The October 6, 2005 proposed rule refers to these prohibited materials as "CMPAF", which it defined to include: 1) the brain and spinal cord from cattle 30 months and older that are inspected and passed for human consumption; 2) the brain and spinal cord from cattle of any age not inspected and passed for human consumption; and 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed. We believe FDA intends to finalize the proposed rule, although the agency may allow brain and spinal cord from cattle not inspected and passed for human consumption to be used in animal feed, if the age of such cattle can be verified to be less than 30 months.

NRA believes that additional safeguards against bovine spongiform encephalopathy (BSE) are unnecessary. FDA reported on October 3, 2007 that compliance with the current 21 CFR 589.2000 is extremely high—of the 6602 firms handling prohibited materials, none required official action after inspections and only 190 (2.9 %) had minor technical violations rule requiring changes in recordkeeping or conditions involving non-ruminant feeds. The Animal and Plant

Health Inspection Service (APHIS) of USDA concluded after the testing of more than 787,000 cattle that the number of cattle in the U.S. infected with BSE is extremely low. This high level of compliance combined with a very low incidence of BSE suggests that the risk of BSE in the United States is already negligible.

In our comments to FDA in 2005, the NRA provided data showing that implementing a ban on CMPAF would cost more than $127.7 million per year. Copies of this economic assessment, conducted and written by Informa Economics, were provided to OMB at our December meeting and previously. Because of increases in production costs and in the market value of finished rendered products over the past two years, we believe the cost of implementing and complying with the proposed regulations would now be even greater than originally estimated.

In addition to being unnecessary and expensive, the proposed rule is likely to have unintended consequences including animal and human health risks due to improper disposal of dead animals as a result of high priced or non-existent dead animal pick up because of the devaluation caused by the proposed rule. These impacts are also detailed in the 2005 Informa Economics assessment which is still very much relevant.

In follow up meetings with Dr. Richard Crowder and others at the Office of the U.S. Trade Representative, we learned that in spite of negligible risk improvement provided by the proposed rule and the significant added costs for the rendering, meat packing, and livestock producing industries, that the primary driving force moving this proposed rule toward implementation is the hope that it will open beef trade with Japan, Korea, and Russia. The NRA is very disappointed that meeting unreasonable trade demands may trump sound science and risk assessment as reasons to promulgate new and onerous regulation.

NRA does not know the extent of SRM removal required in the latest version of the final rule. However, there is no version of a "short list" or age cut off that would make SRM removal from dead stock plants practical, enforceable, or safe for plant workers. These impacts are detailed in a letter from NRA member Darling International, Inc. on January 3, 2008, which NRA agrees with.

In summary, NRA does not believe the proposed rule is necessary. We do not believe the rule is enforceable, and we believe it will be more expensive and have a greater negative impact on the environment than predicted by FDA. Ignoring the unintended consequences and poor cost benefit ratio in order to "hopefully, maybe" break the beef trade logjam with countries that have not negotiated in good faith would be ill advised. We encourage the administration not to implement the proposed rule.

Sincerely,

Thomas M. Cook

Thomas M. Cook
President, National Renderers Association

- The OIE
- The Veterinary Services
- Press releases/Editorials
- International meetings
- World animal health situation
  - OIE Mandate
  - WAHID (>2004)
  - Information (<2005)
  - Bov. spongif. encephalopathy
  - Emergency preparedness
  - OIE-info distribution list
- Official animal health status
- Animal diseases data
- OIE Expertise
- Certification of diagnostic assays
- Health standards
- OIE Publications
- Jobs/Internships/Services
- Links

• Number of cases in the United Kingdom
• Number of reported cases worldwide (excluding the United Kingdom) • Cases in imported animals only
• Annual incidence rate

Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide*(excluding the United Kingdom)

Country/Year	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Austria	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	2	1(c)
Belgium	0	0	0	0	0	0	0	0	1	6	3	9	46	38	15	11	2	2	
Canada	0	0	0	0	1(b)	0	0	0	0	0	0	0	0	0	2(a)	1	1	5	3
Czech Republic	0	0	0	0	0	0	0	0	0	0	0	0	2	2	4	7	8	3	0(c)
Denmark	0	0	0	1(b)	0	0	0	0	0	0	0	1	6	3	2	1	1	0	
Finland	0	0	0	0	0	0	0	0	0	0	0	0	1(a)	0	0	0	0	0	
France	0	0	5	0	1	4	3	12	6	18	31 (a)	161 (d)	274 (e)	239 (f)	137 (g)	54 (h)	31	8	
Germany	0	0	0	1(b)	0	3(b)	0	0	2(b)	0	0	7	125	106	54	65	32	16	4(c)
Greece	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
Ireland	15 (a)	14 (a)	17 (a)	18 (a)	16	19 (a)	16 (a)	73	80	83	91	149 (d)	246 (e)	333 (f)	183 (g)	126 (h)	69(i)	41(j)	24 (c)
Israel	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0(c)
Italy	0	0	0	0	0	2(b)	0	0	0	0	0	0	48	38 (a)	29	7	8	7	2(c)
Japan	0	0	0	0	0	0	0	0	0	0	0	0	3(e)	2	4(g)	5	7	10	3(c)
Liechtenstein	0	0	0	0	0	0	0	0	0	2(a)	0	0	0	0	0	0	0	0	
Luxembourg	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	1	0	0(c)
Netherlands	0	0	0	0	0	0	0	0	2	2	2	2	20	24	19	6	3	2	
Poland	0	0	0	0	0	0	0	0	0	0	0	0	0	4(f)	5	11	19	10	7(c)
Portugal	0	1(b)	1(b)	1(b)	3(b)	12	15	31	30	127	159	149 (a)	110	86	133	92 (a)	46	33	
Slovakia	0	0	0	0	0	0	0	0	0	0	0	0	5	6	2	7	3	0	
Slovenia	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	2(a)	1	1	1(c)
Spain	0	0	0	0	0	0	0	0	0	0	0	2	82	127	167	137	98	68	26 (c)
Sweden	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
Switzerland	0	2	8	15	29	64	68	45	38	14	50	33 (d)	42	24	21 (g)	3	3(i)	5	0(c)
United Kingdom	see particular table																		
United States of America	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0(c)

* Cases are shown by year of confirmation.
... Not available

(a) **Canada**: 1 case diagnosed in Canada in May 2003 + 1 case diagnosed in the United States of America in December 2003 and confirmed as having been imported from Canada.
Finland: date of confirmation of the case: 7 December 2001.
France: includes 1 imported case (confirmed on 13 August 1999).
Ireland: includes imported cases: 5 in 1989, 1 in 1990, 2 in 1991 and 1992, 1 in 1994 and 1995.
Italy: includes 2 imported cases.
Liechtenstein : date of the last confirmation of a case: 30 September 1998.
Portugal: includes 1 imported case.
Slovenia: includes 1 imported case.

(b) Imported case(s).

(c)
Austria - Data as of 30 June 2007.
Czech (Rep.) - Data as of 30 June 2007.
Germany - Data as of 30 June 2007.
Ireland - Data as of 20 December 2007. Cases detected by the passive surveillance programme = 5. Cases detected by the active surveillance programme = 19.
Israel - Data as of 30 June 2007.
Italy - Data as of 30 June 2007.
Japan - Data as of 21 December 2007.
Luxembourg - Data as of 30 June 2007.
Poland - Data as of 20 December 2007.
Slovenia- Data as of 30 June 2007.
Spain- Data as of 30 June 2007.

Switzerland - Data as of 30 June 2007.
United States of America - Data as of 30 June 2007.

(d) **France year 2000** - Clinical cases = 101. Cases detected within the framework of the research programme launched on 8 June 2000 = 60.
Ireland year 2000 - Clinical cases = 138. Cases identified by active surveillance of at risk cattle populations = 7. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
Switzerland year 2000 - Clinical cases = 17. Cases detected within the framework of the investigation programme = 16.

(e) **France year 2001** - Clinical cases = 91. Cases detected at rendering (bovines at risk) = 100 (out of 139,500 bovines tested). Cases detected as result of routine screening at the abattoir = 83 (out of 2,373,000 bovines tested).
Ireland year 2001 - Clinical cases = 123. Cases identified by systematic active surveillance of all adult bovines = 119. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
Japan year 2001 - Clinical cases = 1. Cases detected as result of screening at the abattoir = 2.

(f) **France year 2002** - Clinical cases = 41. Cases detected at rendering (bovines at risk) = 124 (out of 274,143 bovines tested). Cases detected as result of systematic screening at the abattoir = 74 (out of 2,915,103 bovines tested). The active BSE surveillance programmes implemented in France in 2002 led to routine examination of cattle aged over 24 months, which were slaughtered for consumption purposes, were euthanised or died due to other reasons.
Ireland year 2002 - Clinical cases = 108. Cases detected by the active surveillance programme = 221. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
Poland year 2002 - Clinical cases = 1. Cases detected as result of routine screening at the abattoir (cattle over 30 months) = 3.

(g) **France year 2003** - Clinical cases = 13. Cases detected at rendering (bovines at risk) = 87. Cases detected as result of systematic screening at the abattoir = 37.
Japan year 2003 - The 9th case was a bullock aged 21 months.
Ireland year 2003 - Clinical cases = 41. Cases detected by the active surveillance programme = 140.
Switzerland year 2003 - Clinical cases: 8. Cases detected within the framework of the official surveillance programme: 11. Cases detected through voluntary testing following routine slaughter: 2.

(h) **France year 2004** - Clinical cases = 8. Cases detected at rendering (bovines at risk) = 29. Cases detected as result of systematic screening at the abattoir = 17.
Ireland year 2004 - Clinical cases = 31. Cases detected by the active surveillance programme = 94. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 1.

(i) **Ireland year 2005** - Cases detected by the passive surveillance programme = 13. Cases detected by the active surveillance programme = 56.
Switzerland year 2005 - Cases detected by the passive surveillance programme = 1. Cases detected within the framework of the official surveillance programme: 1. Cases detected through voluntary testing following routine slaughter = 1.

(j) **Ireland year 2006** - Cases detected by the passive surveillance programme = 5. Cases detected by the active surveillance programme = 36.

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▪ Number of cases in the United Kingdom ▪ Number of reported cases worldwide (excluding the United Kingdom) ▪ Cases in imported animals only ▪ Annual incidence rate

Number of cases of bovine spongiform encephalopathy (BSE) reported in the United Kingdom (1)

	Alderney	Great Britain	Guernsey (3)	Isle of Man (2)	Jersey	Northern Ireland	Total United Kingdom
1987 and before(4)	0	442	4	0	0	0	446
1988(4)	0	2 469	34	6	1	4	2 514
1989	0	7 137	52	6	4	29	7 228
1990	0	14 181	83	22	8	113	14 407
1991	0	25 032	75	67	15	170	25 359
1992	0	36 682	92	109	23	374	37 280
1993	0	34 370	115	111	35	459	35 090
1994	2	23 945	69	55	22	345	24 438
1995	0	14 302	44	33	10	173	14 562
1996	0	8 016	36	11	12	74	8 149
1997	0	4 312	44	9	5	23	4 393
1998	0	3 179	25	5	8	18	3 235
1999	0	2 274	11	3	6	7	2 301
2000	0	1 355	13	0	0	75	1 443
2001	0	1,113	2	0	0	87	1,202
2002	0	1,044	1	0	1	98	1,144
2003	0	549	0	0	0	62	611
2004	0	309	0	0	0	34	343
2005	0	203	0	0	0	22	225
2006	0	104	0	0	0	10	114
2007(5)	0	37	0	0	0	12	49

(1) Cases are shown by year of restriction.

(2) In the isle of Man BSE is confirmed on the basis of a laboratory examination of tissues for the first case on a farm and thereafter by clinical signs only. However, all cases in animals born after the introduction of the feed ban have been subjected to histopathological/scrapie-associated fibrils analysis. To date, a total of 277 animals have been confirmed on clinical grounds only.

(3) In Guernsey BSE is generally confirmed on the basis of clinical signs only. To date, a total of 600 animals have been confirmed without laboratory examination.

(4) Cases prior to BSE being made notifiable are shown by year of report, apart from cases in Great Britain which are shown by year of clinical onset of disease.

(5) Data as of 30 September 2007.

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