



DRAFT – CARGILL CONFIDENTIAL

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

August 10, 2004

RE: Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for Further Action

Cargill, Incorporated appreciates this opportunity to comment on the FDA's advance notice of proposed rulemaking to further reduce the risk of BSE exposure through animal feed.

Cargill is an international marketer, processor and distributor of agricultural, food, financial and industrial products and services with over 100,000 employees in 61 countries.

In the area of meat and poultry, Cargill and its subsidiaries have extensive operations in the U.S. and Canada as well as Europe, Australia, Thailand, and Latin America. These include beef, pork, turkey, chicken and egg production and processing. Cargill is also a large producer of animal nutrition products including pet food. Within the U.S. beef sector we operate cattle feedlots and process over 8 million head of cattle each year at our 7 USDA inspected establishments. This includes 2 facilities that primarily process older dairy and beef animals. Additionally, our beef processing facilities typically include dedicated edible and inedible rendering operations.

CARGILL SUPPORTS AGGRESSIVE ACTIONS TO PROTECT PUBLIC HEALTH

Cargill's comments are based largely on the company's understanding of the BSE Risk Assessment Model developed by Harvard University.

Cargill supports aggressive collective action to prevent the spread of BSE and to protect public health. We have followed BSE since its discovery in 1986 and have actively promoted science-based initiatives to manage the potential risks of exposure to the animal population. Cargill fully supported actions taken by the USDA last January to enhance public health protections through the removal of non-ambulatory disabled cattle and specified risk materials (SRM) from the

human food supply. Additionally, we support recent actions taken by FDA that mirror USDA's measures in FDA regulated food and cosmetic products.

Cargill has a critical interest in this matter as it impacts producers, processors, related businesses and our domestic and export customers. Our broad diversification of potentially affected businesses provides us the opportunity to take a "big picture" look at the North American BSE situation. We have attempted to develop reasoned solutions to significantly enhance existing animal feed controls that are systematic, environmentally sustainable, relatively easy to verify, and have minimal economic impact to U.S. and Canadian beef and dairy producers.

PUBLIC HEALTH PROTECTION MEASURES DIFFER FROM BSE PREVENTION ACTIONS

We appreciate that FDA recognizes the critical difference between protective public health measures that are currently in place and the need to enhance existing animal feed regulations that were put into effect in 1997 to prevent the amplification and spread of BSE in the U.S. cattle herd if exposure had occurred. We recognize that FDA is committed to developing future U.S. animal feed policy based on scientific actions that can be implemented effectively and consistently in a verifiable manner. If we can learn one lesson from the honest policy mistakes made in the U.K. and Europe, it is that the complexity of successful implementation of animal feed controls should not be underestimated.

Cargill is deeply concerned with FDA's direction toward promulgating a rule that would prohibit all human food SRM from animal feed including pet food. Of particular concern to us is the appearance that FDA is focusing solely on a new SRM policy, and is not considering elements that could strengthen the multiple hurdle benefits that a broader systems approach would represent.

The ANPR-outlined SRM approach might theoretically enhance the existing 1997 feed regulation. However, logistical challenges presented by this approach may actually limit its timely and effective implementation while causing significant unintended consequences that adversely impact both animal and public health. Additionally, we must all bear in mind that policy decisions will have reoccurring annual costs that, if draconian in nature, could burden the economic viability of the U.S. beef sector for decades to come.

EQUIVALENT ALTERNATIVES DEVELOPED TO ENHANCE BSE PREVENTION

We believe it is critical that FDA implement an integrated system of controls that act in concert with the current animal feed regulation. Cargill recommends such a "systems approach" that provides the equivalent protection of a full SRM ban. This viable alternative is comprised of a combination of risk mitigation steps that can be more rapidly implemented with significantly less environmental consequences and economic disruption. Over the past 8 years our Cargill Taylor Beef business has developed and refined a unique multi-layered systems approach to mitigate BSE risk at our Wyalusing Pennsylvania beef processing and rendering complex.

The proposed systems approach consists of the following series of verifiable actions that work in synergy to effectively mitigate the risk of spreading BSE through animal feed ingredients.

- Discontinue the use of cattle mortalities, non-ambulatory disabled and *ante mortem* condemned cattle that are over thirty months of age in all animal feed and pet food with the exception of beef muscle harvested from these animals.
- Require the removal and subsequent non-feed disposal of the brain and spinal cord from cattle over 30 months of age at slaughter.
- Phase out the use of hypobaric (vacuum) rendering systems for the processing of all inedible ruminant materials.
- Continued application of the 1997 FDA Feed Regulation – 21 CFR 589.2000

The remainder of our comments will provide a detailed explanation of, and support for, regulatory adoption of the proposed systems approach. We provide detailed scientific data on a recently conducted risk analysis that utilized the Harvard BSE Risk Assessment Model (Harvard Model) to evaluate the effectiveness of this systems approach as compared to a prohibition of all SRM in animal feed. The results indicate that the proposed systems approach to strengthening animal feed controls is scientifically equivalent to complete SRM removal with regard to preventing future cases of BSE in the U.S.

Additionally, and very importantly, this assessment demonstrates that the risk posed by the feeding of bovine derived blood meal to cattle is negligible regardless of the approach evaluated. We are also providing information on the environmental impact, logistical feasibility and economics of each approach. Additional comments on individual questions posed by FDA in the ANPR are attached in Appendix A.

DETAILED DISCUSSION OF INDIVIDUAL CONTROL POINTS USING THE SYSTEMS APPROACH

- 1) *Discontinue the use of cattle mortalities, non-ambulatory disabled and ante mortem condemned cattle that are over thirty months of age in all animal feed and pet food with the exception of beef muscle harvested from these animals.*

Discontinuing the use of these highest risk categories of cattle in the manufacture of processed animal feed ingredients significantly reduces the risk of having BSE infectivity enter the animal feed system to start with. A landmark study, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, commissioned by USDA and conducted by the Harvard Center for Risk Analysis at the Harvard School of Public Health (the “Harvard Study”) concluded that the “disposition of cattle that die on the farm would have a substantial influence on the spread of BSE if the disease were introduced into the U.S.” In addition, the Harvard Study stated that “Prohibiting the rendering of animals that die on the farm, possibly of BSE, removes a great deal of potential contamination in the animal feed

chain and reduces the average predicted cases of BSE following introduction of ten infected cattle by 77%.”

At the time the Harvard Study was conducted, the researchers did not consider the BSE risk posed by non-ambulatory disabled cattle separate from ambulatory slaughter cattle. However, the recently updated version of the Harvard Model (version 2.01) recognizes the heightened BSE risk attributed to this category of cattle because the inability to walk is symptomatic of BSE affected cattle. The USDA recognized this fact when it targeted non-ambulatory cattle for BSE surveillance testing. Further, European BSE testing data demonstrates that the vast majority of cattle detected with BSE fall into one of these three high-risk categories of animals.

The Harvard Study did not evaluate BSE risk in terms of age for cattle mortalities, non-ambulatory disabled and *ante mortem* condemned cattle. Yet, the BSE risk from cattle carcasses of 30 months and less of age is less than that from older cattle of the same categories. The 30 month age cutoff is nearly universally recognized for purposes of defining human food SRM's and for inclusion in the USDA surveillance program. However, the fact that cattle that are 30 months and less of age at this point in time were born a minimum of 4.5 years after implementation of FDA's 1997 feed regulation suggests their risk of harboring BSE infectivity and subsequently spreading infectivity to other cattle through inclusion in non-ruminant animal feed is negligible. For these reasons, utilization of dead, non-ambulatory and *ante mortem* condemned cattle (except for neurological suspects) that are 30 months and less in age should continue for processing into prohibited animal feed ingredients for use in non-ruminant feed without the removal of any SRM.

We recognize a prohibition on utilizing materials in animal feed from cattle mortalities, non-ambulatory disabled and *ante mortem* condemned cattle that are over 30 months in age will pose logistical challenges especially for some dairy producers and slaughter establishments that specialize in older cattle. Cargill's facilities dispose of nearly 15 million pounds of these carcasses on an annual basis. However, challenges presented by the disposal of cattle carcasses are not new. For this reason, USDA commissioned a recently-completed comprehensive review on the subject of carcass disposal. Cargill supports USDA's actions to encourage the development of multiple carcass disposal alternatives. This support is evidenced in our recent co-sponsorship of a workshop at Penn State University on utilizing carcasses as a fuel source in various fluidized bed boilers.

FDA should work with USDA, producers, veterinarians and industry to ensure that future animal feed regulations do not hinder the continued submission of high-risk animals and carcasses to the enhanced BSE surveillance program. We support the incentive based approach that USDA has developed to ensure submission of brain samples into the enhanced surveillance program. Additional incentives to producers may be required to ensure the economic viability of obtaining samples if dead and non-ambulatory disabled cattle are prohibited from use in all animal feed.

2. *Require the removal and subsequent non-feed disposal of the brain and spinal cord from cattle over 30 months of age at slaughter.*

In clinically affected cattle, based on the U.K. pathogenesis study and subsequent EU Standing Veterinary Committee review, the brain and spinal cord represent the most highly infectious tissues. The removal of these 2 tissues in cattle over 30 months in age and subsequent diversion from use in animal feed is an effective means of significantly lowering the quantity of infectivity sent to inedible rendering in the event that cattle infected with BSE would enter a slaughter establishment. This step acts in synergy with the other components of the systems approach thereby absolute removal of these tissues is not required.

The removal of spinal cord from the vertebral column is an industry-wide practice at slaughter establishments. The diversion of the spinal cord tissue away from use in animal feed can be readily accomplished in both large and small establishments alike. While spinal cord from cattle over 30 months of age is removed from human food, in our experience, only trace amounts of spinal cord could not be captured for non-feed disposal and would potentially end up going to inedible rendering operations. Our Wyalusing, PA facility estimates that over 99% of the weight of spinal cord can be captured for disposal on an individual animal basis.

The removal of brain material from cattle over 30 months in age from animal feed can be achieved by several methods. The specific method of choice would be a function of the size of a slaughter establishment where this would be carried out. For ease, small establishments may simply opt to discard the entire head. However, mid to large size establishments can use simple and effective techniques to extract the brain from the skull. Our Wyalusing, PA facility developed one such technique whereby the brain is removed through the *foramen magnum* (the hole in the skull where the spinal cord attaches to the brain stem) via a suction device. In September of 1997 Dr. Thomas Nytech, a veterinarian employed by the State of New York Department of Agriculture and Markets, with assistance from Cornell University's Veterinary Diagnostic Laboratory evaluated this brain removal technique under normal operations at our Wyalusing, PA facility. Dr. Nytech determined that the method was 99.0% effective in removing brain matter from the skull with little variation [standard deviation of 0.3]. Based on these findings a minimum 98% removal tolerance could be achieved with 99.85% confidence.

3. *Phase out the use of hypobaric (vacuum) rendering systems for processing inedible ruminant materials.*

Many misconceptions regarding the ability of various rendering systems to significantly reduce BSE infectivity exist. An expert opinion prepared by Dr. David M. Taylor on the capacity of rendering systems currently used in the U.S. on their capacity to inactivate TSE agents can be found in Appendix B.

No commercial rendering system, including the EU standard requiring pressure, is thought to be capable of complete inactivation of the BSE agent. However, the typical system in use for the rendering of ruminant materials in the U.S. is capable of eliminating between 1 and 2 logs (90-99%) of infectivity if the BSE agent were to enter the process. A few processes, specifically some that evaporate moisture at lower temperatures under vacuum, provide little potential to inactivate the BSE and scrapie agents. In his expert opinion, Dr. Taylor notes,

“the most recently introduced rendering system [hypobaric] in the U.K. had little capacity to inactivate the BSE agent.”

Rendering of ruminant materials at normal “atmospheric conditions” or 1 Atmosphere is only one part of the solution for reducing the potential for BSE exposure in the animal feed supply. The timely phase-out of the use of hypobaric rendering processes for the rendering of inedible ruminant materials (including ovine, caprine and cervid materials) is a key component of the systems approach. This step coupled with avoidance of high-risk cattle, practical removal of the highest risk tissues at slaughter and compliance with the 1997 prohibition on feeding certain ruminant derived materials to ruminants provides for robust protection of the animal feed supply and hence the U.S. cattle herd. Inclusion of this step provides the additional benefit of reducing the infectivity of other TSE agents such as scrapie and chronic wasting disease if materials contaminated with such agents were to enter rendering.

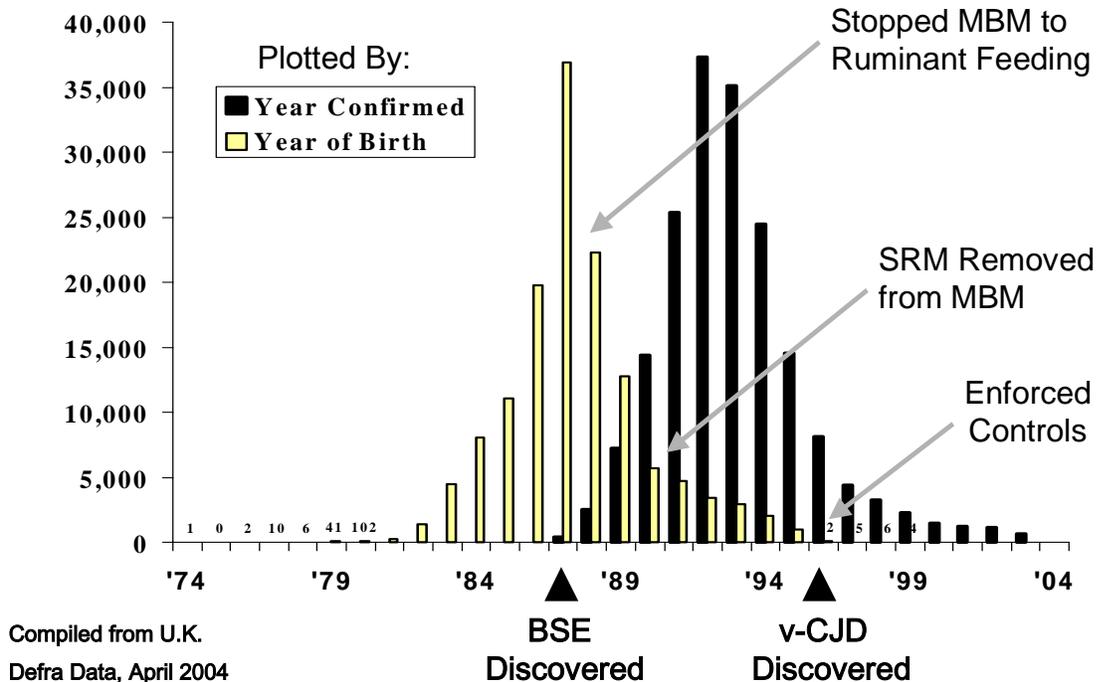
4. Continued adherence to the 1997 FDA Feed Regulation - CFR 589.2000

FDA’s proactive action taken in 1997 to prohibit certain ruminant proteins in feed for ruminant animals was a critical component to the U.S. prevention strategy. This step has protected the U.S. cattle herd from ongoing cycles of BSE exposure as experienced in the U.K. and Europe. Part of the success of this regulation is the very high level of industry support and subsequent unprecedented compliance.

An analysis of the U.K. epidemic, as seen in the following graph, demonstrates the significance of that country’s basic ban on feeding ruminant derived MBM to cattle. While the number of confirmed cases continued to rise for 5 years after enactment of this “ruminant to ruminant” feed ban, new infections were significantly reduced as seen in the reduction of cases when plotted by year of birth (light bars).

It is important to recognize that compliance with this U.K. feed ban was moderate at best due to multiple factors including inconsistent adherence to the regulation in the field. Interestingly, the effectiveness of the U.K. “SRM ban” in animal feed is difficult to ascertain from this data, because the rate of decline in new infections apparently decreased at approximately the point in time this control measure was instituted. Many attribute this to the creation of “underground” markets for SRM-containing MBM due to material economic incentives to bypass the law. This unintended consequence was also experienced in Europe and further contributed to the global spread of BSE. FDA needs to consider potential unintended consequences as it contemplates further actions.

U.K. BSE Epidemic Effect of Feed Controls



EVALUATION OF PROPOSED SYSTEMS APPROACH USING THE HARVARD MODEL

To evaluate the effectiveness of the proposed systems approach, we recently simulated several feed control scenarios utilizing the Harvard risk assessment model. This computerized probabilistic simulation model was developed to evaluate the risk of BSE for the landmark Harvard Study. This peer-reviewed study is considered the most comprehensive science based risk analysis conducted on BSE to date. The study is frequently referenced by both the USDA and FDA to support public and animal health policy decisions including the tentative decision, as announced in this ANPR, to publish a proposed rule that would require the removal of all human food SRM's from all animal feed and pet food.

Methods and Assumptions

A copy of the latest version of the Harvard model was obtained from the Harvard Center for Risk Analysis in July of 2004 (version 2.01). Harvard researchers provided assistance in specifying the parameter files for the scenarios that Cargill developed for the simulation model. The three primary scenarios simulated in the Harvard Model by Cargill are as follows:

- #1 - Current situation (Base Case 2004)

- #2 - Prohibit all SRM from feed
- #3C – Implement full systems approach

The scenarios were designed to reflect three potential policy choices. The concept was to compare the effectiveness of these different regulatory options with respect to their impact on future predicted cases of BSE. Additionally, the model evaluated the relative risk to public health by evaluating potential exposure to people through human food. In order to test the effectiveness of the scenarios in controlling BSE one must simulate the introduction of BSE infectivity into the national cattle herd. To achieve this BSE exposure, we simulated the introduction of 100 BSE infected 12-month-old cattle into the U.S. cattle herd at the start of the 20-year run. All parameters in the model remained the same across scenarios except for the modifications noted below.

The first scenario, “current situation” is essentially the base case scenario used in the Harvard Study but updated to reflect new regulatory requirements enacted earlier this year. Specifically USDA and FDA prohibited the use of non-ambulatory disabled cattle and SRM in human food products. Assumptions for compliance with the 1997 FDA feed regulation reflect 2003 FDA compliance data. To be clear, we neither expect nor desire this scenario’s consideration as a future policy option; it was included to serve as a negative control for comparison purposes.

The second scenario, “prohibit all SRM from feed”, reflects FDA’s announced intentions. In this scenario, all materials that are defined as SRM by current USDA and FDA food regulations are completely removed from animal feed. Specifically, this includes the small intestine (model lists this as “gut”) and tonsils of all cattle and the skull, brain, trigeminal ganglia, eyes, dorsal root ganglia, spinal cord and vertebral column from cattle over 30 months of age. Because practical measures to remove SRM from dead, non-ambulatory disabled and *ante mortem* condemned cattle may be difficult to verifiably implement in an economical manner, we assumed that all these high-risk categories of carcasses would be removed from animal feed use. For purposes of modeling, we assumed perfect 100% compliance with SRM removal even though experiences from Europe suggest this may be difficult to achieve.

The third scenario (3C), “implement full systems approach”, represents the policy action that Cargill has come to believe would be not only the most rational and effective feed protection enhancement to implement, but also the most economically viable. To simulate this approach we modified the model parameters in a manner that would discontinue dead, non-ambulatory disabled and *ante mortem* condemned cattle from entering animal feed while removing 98% of the brain and spinal cord from cattle over 30 months of age at slaughter. Residual brain and spinal cord and all other human food SRM remained in animal feed, however, rendering these materials using hypobaric (vacuum) conditions was discontinued being replaced by atmospheric rendering conditions that obtained a 1 log inactivation of the BSE agent.

Two secondary scenarios were simulated in order to determine the effect of implementing the systems approach in a stepwise manner. The first step (labeled 3A) eliminates dead, non-ambulatory disabled and ante mortem condemned cattle from animal feed. The second step (3B) builds on this action by implementing the practical removal of brain and spinal cord from slaughter cattle over 30 months in age from animal feed. The third and final step (3C, previously described) adds the discontinuance of hypobaric rendering to deliver the entire systems approach.

Results and Discussion

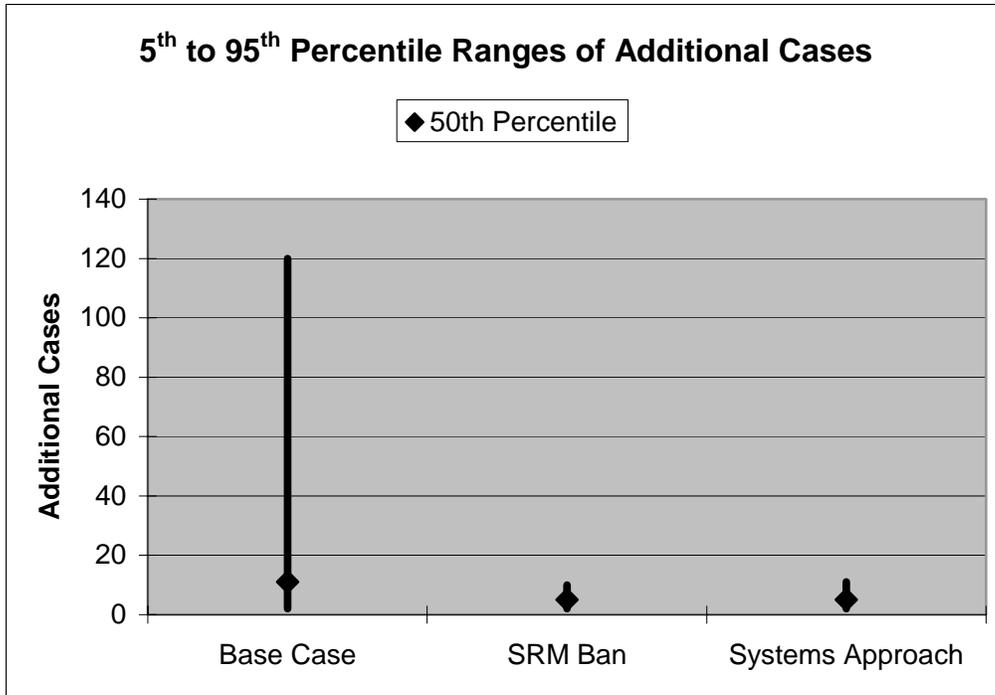
The results of all 5 simulations are contained in Appendix C. Output from each scenario reflects 500 simulation trials. Confidence intervals for the quantile range for the number of additional infected cattle and cattle oral ID50's potentially consumed by humans were calculated and are reported in Appendix D.

An average of 36, 5.6 and 5.5 additional cases of BSE developed in scenarios 1, 2 and 3C respectively. Implementation of the full systems approach was equally as effective as prohibiting all SRM from animal feed. Both measures resulted in an 85% reduction of new cases as compared to taking no further actions than the existing 1997 feed regulation.

The Harvard Model also estimates the range of possible additional BSE cases for each simulation run. The ranges in additional cases reported for the systems approach and the full SRM ban were essentially identical. However, both measures achieved a dramatic reduction in the number of predicted additional cases in the upper percentile range as compared to the base case scenario as shown on the following graph.

In order to quantify total BSE exposure to the U.S. cattle herd over the 20 year simulation period, the model uses infectivity units called "cattle oral infectious dose 50" or cattle oral ID50 for short. These units represent the amount of dose required to infect 50% of the cattle when orally exposed. Compared to the current feed rule, the base case scenario, both approaches reduced the total quantity of cattle oral ID50 consumed by cattle by over 99%.

Results from this study indicate that the proposed systems approach and the elimination of SRM from animal feed are scientifically equivalent control measures that significantly reduce the risk of spreading of BSE through animal feed.



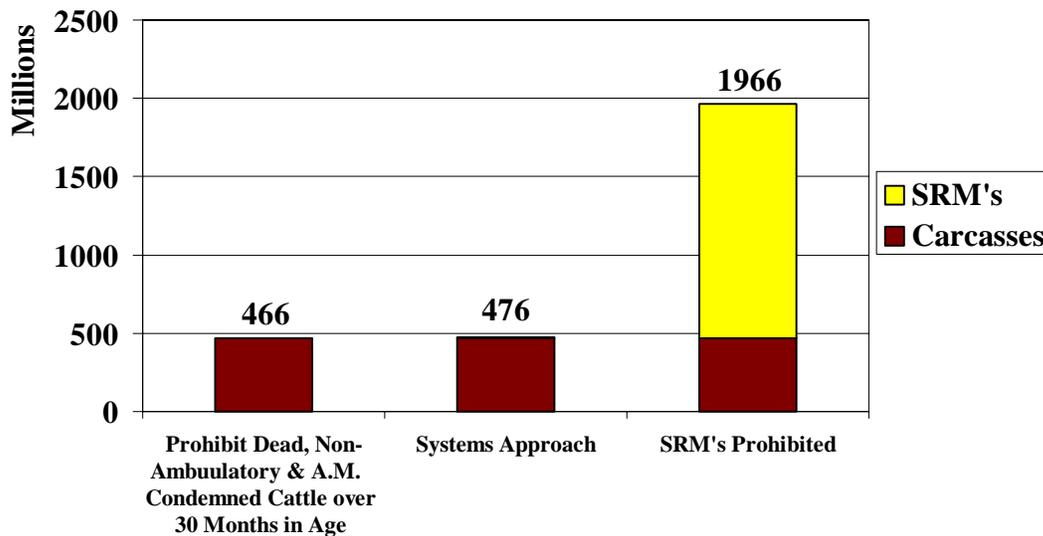
We also evaluated the stepwise combination of individual measures that combine to make up the systems approach. When a prohibition on using dead, non-ambulatory disabled and *ante mortem* condemned cattle for feed use is enacted as the sole measure, in addition to the 1997 feed rule, the average number of new cases of BSE drops from 36 to 9.5, a 74% reduction. This is comparable to the 77% reduction in average number of new cases that was reported in the Harvard Study when “dead stock” were banned from animal feed use. Including the practical removal of brain and spinal cord from slaughter cattle over 30 months in age to the previous step brings the average number of predicted new cases down to 5.9, an 84% reduction in new BSE cases. The addition of the final step, discontinuing the use of hypobaric rendering of ruminant materials, to complete the actions found in the full systems approach reduces the average number of new cases to 5.5 for an 85% reduction in new cases from the base case scenario. Again, these combined measures provide equivalent protection to animal health as the removal of SRM from all animal feed.

The estimates for the range of possible additional BSE cases for the stepwise simulated implementation of individual measures reveals that the addition of brain and spinal cord removal from cattle over 30 months in age at slaughter significantly reduces the upper (95th percentile) range for new cases of BSE from 39 to 11. The discontinuance of hypobaric rendering has little impact on reducing the number of additional cases that are predicted. However, we recommend a timely “phase out” of hypobaric rendering for inedible ruminant materials as a measure that protects the feed supply from other TSE agents and to provide redundant protection in case materials prohibited from all animal feeds are infected with BSE and are inadvertently directed to rendering for animal feed purposes.

ENVIRONMENTAL IMPACT

The total weight of all dead cattle (non-slaughter) from all sources in the US is estimated at 2.7 billion pounds annually. However, we estimate that rendering firms currently collect about 700 million pounds with 466 million derived from cattle over 30 months in age. Our comments to question 22 in Appendix A provide a detailed accounting of these figures.

Waste Generated by Policy Option U.S. Annual Pounds (in millions)



As seen in the above graph, the removal of brain and spinal cord in the systems approach adds about 10 million pounds of waste. The removal of all SRM from animal feed results in about 2 billion pounds of waste with 1.5 billion coming from disposal of SRM removed at beef packing facilities.

Regarding ease of alternative disposal mechanisms, many cow-calf and dairy producers will have access to off-site disposal options such as landfills. Other producers may opt to develop on-site disposal alternatives such as composting their dead stock. Additionally, we assume that disposal incentives would remain part of the USDA enhanced surveillance program, thus minimizing out of pocket costs for the disposal of dead stock and non-ambulatory disabled cattle over 30 months in age. We are deeply concerned that the FDA proposal fails to recognize that a suitable disposal infrastructure does not exist to deal with the very large quantities of SRM that would be generated on a daily basis at beef slaughter facilities if SRM were prohibited from use in the manufacture of animal feed ingredients.

FEASIBILITY & ECONOMICS

The disposal of large volumes of SRM will be an unimaginable logistical challenge that will take a year or more to implement unless disposal into municipal solid waste landfills are the option of choice. We are aware that some companies have petitioned the USDA and FDA with regard to a “disposal rendering” solution. While this option may be feasible in high animal concentration areas, we are doubtful that this solution will be viable at a competitive cost in many if not all regions of the country. The proposed systems approach solution to enhancing BSE feed protections can be more quickly implemented without the need for inventing a national disposal infrastructure.

The cost difference to the beef sector between our systems approach and the removal of all SRM from animal feed is quite dramatic. Reoccurring annual costs with the systems approach are under \$2 million while the full SRM approach costs over \$150 million each year. Appendix G contains a summary of disposal volumes and costs by policy option and by age of animal slaughtered. Detailed calculation sheets for determining disposal costs are in Appendix H.

Initial costs for installation of equipment and handling systems would be required for both approaches. However, the extent of the changes would be significantly less with the systems approach, as extensive material handling systems would not be required. With regard to phasing out of hypobaric rendering systems, the Harvard Study assumed that about 5% of ruminant material was rendered with such processes. We do not know the total number of such processes in operation today, however we assume the number is relatively small and that a changeover could be completed in a few years.

NEGLECTIBLE RISK FROM RUMINANT BLOOD PRODUCTS

The Harvard Study evaluated the potential risk posed from ruminant blood meal being fed to cattle and found that it did not contribute to the amplification of BSE in the cattle herd if BSE were present in the U.S. All results from our simulation runs, regardless of scenario modeled, confirmed the Harvard researchers’ initial conclusions.

Furthermore, the International Review Team (IRT) did not raise blood and blood products as a material of concern in their recommendations. In fact, the chair of the IRT specifically stated that blood and blood products were not a risk factor for feed-borne transmission of BSE during the February 4, 2004 public meeting where they discussed their recommendations.

The continued use of ruminant blood meal in feed products for dairy cows is critical to maintaining efficient milk production. Additionally, the continued use of ruminant blood plasma and serum components in nutritional products designed for calf milk replacers is beneficial for minimizing the need for antibiotic usage in calves. Based on the negligible risk posed by these critical feed ingredients, FDA should maintain the allowance of their use in ruminant feeds. Detailed comments on this issue can be found under questions 15 & 18 and in Appendices E & F.

CONCLUSIONS

Cargill supports reasoned science-based policy measures to enhance current animal feed controls that protect against the potential spread of BSE in the North American cattle herd. The North American BSE situation differs from the European situation in that multiple preventative measures were put into place well before the detection of BSE in a Canadian cow in Washington State last December. U.K. and European officials had to make policy decisions on animal feed at a time when little was known about BSE and under conditions that are very different from those in North America.

Today we have a much-improved understanding of the BSE threat. Tools such as the Harvard Model now allow us to design with greater certainty appropriate control measures rather than relying on anecdotal inferences, which are frequently found invalid at a later date.

Cargill has proposed a systems approach that is equivalent to the complete removal of SRM from animal feed. This approach is less wasteful, and is sustainable, environmentally responsible, capable of being more quickly implemented and less costly to the beef sector and ultimately to society. We ask that FDA reconsider its current thinking relative to a full SRM ban from animal feed and adopt the measures that we have outlined in these comments.

We greatly appreciate this opportunity to comment on this very important matter.

Sincerely,

David W. Harlan
BSE Task Force Leader
Cargill, Inc.

APPENDICIES

- A** SPECIFIC ANPR QUESTIONS AND RESPONSES
- B** EXPERT OPINION OF D.M. TAYLOR ON THE CAPACITY OF RENDERING SYSTEMS USED IN THE USA TO INACTIVATE TRANSMISSIBLE DEGENERATIVE ENCEPHALOPHTHY AGENTS
- C** RESULTS OF MODEL SIMULATIONS
- D** CONFIDENCE INTERVALS FOR THE QUANTILE RANGE
- E** THE SAFETY OF BOVINE BLOOD PRODUCTS AS FEED INGREDIENTS FOR RUMINANTS
- F** BLOOD MEAL USE IN DAIRY CATTLE DIETS
- G** EVALUATION OF ANIMAL FEED POLICY OPTIONS FOR SLAUGHTER CATTLE
- H** COST CALCULATIONS FOR FEED POLICY OPTIONS

APPENDIX A

SPECIFIC ANPR QUESTIONS AND RESPONSES

1. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?

FSIS correctly states that the distal ileum is the only section of the small intestine where BSE infectivity has been detected in experimentally infected animals. If FDA considers complete removal of SRM from animal feed, a step that Cargill does not support, the regulation should only list the distal ileum, not the entire small intestine. By regulation, FSIS only requires the removal of the distal ileum from human food. However in practice, FSIS currently requires removal of the entire small intestine from the human food chain because to date no agreed upon process to separate the distal ileum from the remainder of the small intestine has been approved.

Future protocol to remove only the distal ileum may be approved by FSIS once again allowing for the harvest of small intestine for human consumption. Small intestine is an important cultural food that previously added significant value to the beef supply chain. Procedures to save the non-distal ileum sections of the small intestine are accepted by and in practice in Japan. This product will be in high demand when export trade resumes with key trading partners. A higher standard should not apply to animal feed as compared to human food regulated by FSIS. Additionally it should be noted that OIE recommendations only suggest the entire small intestine be considered as a human food SRM in countries that are categorized as moderate to high BSE risk. Cargill agrees with FDA's acknowledgement in the ANPR that it is highly unlikely that the US fits into either of these OIE categories primarily due to the proactive animal feed regulation implemented in 1997.

2. What information, especially scientific data, is available to support or refute the assertion that removing SRM from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross contamination of ruminant feed with prohibited material?

While the removal of SRM from all animal feed reduces the risk of downstream cross contamination in the manufacture, distribution and transport of prohibited feeds and in feeding errors, other steps such as the systems approach that we have proposed can be used to effectively reduce the risks of cross-contamination.

A requirement for dedicated lines for the manufacturing of prohibited proteins at rendering facilities is a highly verifiable measure that would greatly reduce the impact of cross-contamination during transportation, feed manufacturing and on-farm feeding mistakes. Such a measure coupled with the systems approach that we have developed reduces both the probability

of cattle receiving infective material and significantly reduces the potential dose of the BSE agent if infected prohibited material actually did “leak” to cattle.

3. If SRM are prohibited from animal feed, should the list of SRM be the same list as for human food? What information is available to support having two different lists?

Our analysis conducted with the Harvard Model demonstrates that the systems approach, including the removal of brain and spinal cord from cattle over 30 months in age, can be utilized as an equivalent measure to removal of the complete human food SRM list from animal feed.

Separate from the above comment, we wish to point out that the use of infectivity distribution data derived from the U.K. pathogenesis study represents a something more than a *worst case* scenario as the BSE dose orally administered to the calves (300 g of brain stem from clinically infected cattle) was several hundred times more potent than what would be expected to reasonably occur under field conditions. As pointed out in the recent Interim Final Rule on food and cosmetics, BSE infectivity has only been detected in the brain, spinal cord and retina of clinically affected cattle that were infected under field conditions. The disparity between these findings is a result of the difference between the BSE dose received. While we modeled our scenarios using the default distribution of infectivity, as determined by the pathogenesis study used in the Harvard Model, a much greater proportion of BSE will be removed by the systems approach under real world conditions where transmission occurs in the field.

4. What methods are available for verifying that a feed or feed ingredient does not contain SRM?

We are not aware of any commercially available tests that could be used to verify feed ingredients do not contain SRM. State and federal meat inspection officials at slaughter establishments could verify SRM removal.

5. If SRM are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRM?

SRM specific (color) dye that is nationally uniform could be applied to SRM's after removal at slaughter establishments. SRM containing raw materials and carcasses collected at other locations should be similarly dyed prior to transport. We are not aware of methods to mark or denature SRM containing rendered products. FDA should take verifiable measures to ensure that such materials do not enter the animal feed trade. At minimum we suggest labeling of all bill of lading, transportation documents and invoices with “NOT FOR FEED MANUFACTURING, DO NOT FEED TO ANIMALS”.

6. What would be the economic and environmental impacts of prohibiting SRM from use in all animal feed?

See Appendix G & H.

7. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

The only significant human consumption of animal feed is canned pet food that is regulated under human food processing guidelines for this reason. In practice, use of SRM in the canned product category does not occur. To be consistent, FDA should prohibit all SRM in canned pet food products since deliberate human consumption of these products is known to occur on a regular basis.

The application of human food processing standards is not required by regulation for extruded and baked pet foods and to pet treats as the potential for human consumption is considered negligible. To date, no occupational risk of contracting v-CJD has been observed in farmers, veterinarians, feed mill employees and rendering plant workers despite routine handling of BSE infected animals, carcasses and rendered products during the BSE epidemic in the United Kingdom. Therefore it is logical to conclude that casual exposure by consumers to pet food products that potentially contain SRM does not pose a public health risk even if derived from BSE infected cattle. While the prevalence of BSE in the U.S. is yet to be determined, all reasonable logic tells us that it is very low as compared to that observed during the European outbreak. Additionally, the systems approach that we have proposed would negate the risks of any imaginable oral exposure that the public would have with these products as these measures have reduced the number of cattle oral ID50 incorporated into MBM to just 300 over a 20 year period which is less than 1% of that reported under the base case scenario.

8. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRM from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

We agree that SRM removal, or an equivalent alternative such as the systems approach, significantly reduces the risk associated with potential cross contamination. While Cargill's Animal Nutrition division has dedicated all of our feed manufacturing facilities globally, we do not believe these measures should become a regulatory requirement if front-end controls such as the systems approach are implemented.

Rendering facilities are uniquely situated at the "top of the pyramid" with regard to the protection of rendered animal feed ingredients. Mistakes at this point in the supply chain have the ability to adversely impact a very large number of feed manufacturers and producers. Due to their design, the ability to adequately flush rendering systems on a routine basis is questionable. For these reasons, it would be prudent that dedicated lines (not facilities) be required for the handling and processing of "prohibited" (as defined by 21 CFR 589.2000) raw materials that are converted into prohibited animal protein products. A reasonable transition period for affected facilities would be needed.

9. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

The economic and environmental impact of requiring dedicated facilities, equipment, storage, and transportation would be enormous and could easily result in closure for some facilities and businesses. A comprehensive economic study that surveyed the industry would need to be conducted to arrive at an accurate figure. One estimate would be that 80% of all commercial feed mills in the U.S. are multi-specie facilities and at least half would have to make changes to achieve "dedication". We would estimate an average of \$2 million per facility for these changes. Dedication requirements may also increase operating costs due to excess capacity and other inefficiencies. We strongly encourage that FDA conduct a full assessment of the costs associated with this option prior to moving in this direction.

10. What information, especially scientific data, is available to demonstrate that cleanout would provide adequate protection against cross contamination if SRM are excluded from all animal feed?

We believe it vital that simulations be run using the Harvard Model to evaluate the impact that routine cleanout (and on occasion, non-compliance with) would have on the prevention of future cases of BSE. We believe that the application of the systems approach, or an equivalent measure such as full SRM removal, would provide adequate protection against cross contamination when cleanout measures are appropriately practiced.

11. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

We are not aware of any valid scientific reasons for the US and Canada to take such an action. Similar actions were taken in Europe due to inadequate compliance with feed controls and other high profile feed contamination events that contributed to consumer panic that eventually lead to a loss in public confidence in the food supply. Such a situation does not exist in North America. Taking such an action would be extremely costly and provide no benefit to public or animal health or to restoration of trade in beef products.

Several of the recommendations from the IRT report appear to be based on in-depth experience from Europe. While the U.S. and Canada can learn much from these experiences, U.K. and European style control measures may not always be applicable to North America. Several key aspects of European rendering, feed and animal production industries are unlike those generally practiced in the U.S. In addition, the availability of plant based feed ingredients and calf-feeding practices differ significantly. The specialized and regionalized nature for many of these U.S. industries would be expected to provide some protection against BSE. For example, most poultry and swine feed is produced at integrated facilities that do not manufacture any ruminant feed. Furthermore, most poultry and swine rendering occurs at dedicated facilities situated at or near processing plants, thus cross contamination with ruminant MBM would not likely occur. This high level of integrated animal production and/or specialization is not typical of European practices.

12. If SRM are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

We are not aware of any scientific data that would support the necessity to prohibit all non-prohibited mammalian and avian MBM from ruminant feed.

13. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

The economic and environmental impact of such a move would be significant. We believe other groups have developed detailed cost estimates and environmental impact data on this subject.

14. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

The risk of BSE transmission through the feeding of bovine blood meal to cattle is negligible. In our simulation runs, the average number of additional BSE cases that developed due to the feeding of ruminant blood meal to cattle ranged from 0.08 to 0.18 cases over a 20-year period. Data from each simulation is located in Appendix C. Additional information to support the negligible risk status of ruminant blood products can be found in Appendix E.

15. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

The risk from plate waste is negligible considering all SRM have been removed from human food products that can subsequently end up incorporated into plate waste.

16. If FDA were to prohibit SRM from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

There does not appear to be a reasonable scientific reason to prohibit the feeding of poultry litter to ruminants based on BSE concerns if SRM removal or an equivalent alternative control system were implemented. FDA may desire to evaluate the microbiological and drug residue risks associated with the feeding of poultry litter to cattle, but this is a separate issue from BSE prevention.

17. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

See Appendix F for detailed comments related to prohibiting ruminant blood meal in ruminant feeds.

The utilization of bovine blood plasma and serum products are extremely important components of calf nutrition products. The effectiveness of these components can't be replaced with other ingredients because they deliver vital immune protection and nutrients to calves. A prohibition of these products based on a hypothetical remote risk could very well result in real world risks with animal and potentially public health consequences.

18. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRM, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

In an abundance of caution, tallow produced from high risk animals, namely dead and downer cattle over 30 months of age should not be utilized for ruminant feeding purposes. The market demand for industrial tallow far outweighs the potential supply of tallow produced from dead stock and non-ambulatory animals.

19. Can SRM be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

We are not aware of any verifiable means to remove SRM from dead and non-ambulatory cattle short of a process that includes active oversight by a government veterinary authority. The cost of such an inspection program would severely impact the economics of such a business model. However, the harvest of inedible muscle meat from such animals can be verified to be free of brain and spinal cord by use of testing protocol that utilizes GFAP as an indicator of CNS contamination. Use of this inedible muscle product in feed for non-food producing animals poses negligible risk and contributes in a positive manner to the economics of collecting dead and non-ambulatory cattle off of farms, feedlots and ranches.

20. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

We are not aware of any method other than source verification such as a packer dedicated rendering facility. USDA FSIS and state meat inspection agencies should play a role in the verification process. FDA should address issues related to the production of non-feed grade MBM at "disposal rendering" facilities. An important benefit of the systems approach is that the need for, and MBM produced from, such a disposal service is reduced by 75%. Cost-effective disposal options that do not require the manufacturing of animal protein from dead and non-ambulatory disabled cattle would be ideal.

21. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

As previously discussed, dead and non-ambulatory cattle under 30 months of age should not be prohibited from animal feed. Age can be verified either by dentition, documents and/or individual cattle ID technology. The following chart provides an annual volume estimate for various categories of dead stock and non-ambulatory disabled cattle in the U.S. Assumptions on

number of carcasses, average weight and percent currently going to rendering were based on an informal survey of several individuals in the U.S. rendering industry.

Estimated Number and Weights of Dead & Non-Ambulatory Cattle by Type

	# Carcasses	Average Weight (pounds)	Total Weight (pounds)	% Currently Rendered	Total Rendered (pounds)
Calves under 500 lbs	2,365,000	200	473,000,000	5%	23,650,000
Feedlots	300,000	750	225,000,000	90%	202,500,000
Beef Cows	1,400,000	1100	1,540,000,000	10%	154,000,000
Dairy Cows	400,000	1300	520,000,000	60%	312,000,000
Total	4,465,000		2,758,000,000		692,150,000

Assuming calves and feedlot dead stock are 30 months of age or less, our systems approach would require the alternative non-feed disposal of 466 million pounds of cattle carcasses in the U.S. each year that are currently being rendered. Disposal costs will vary based on the region and method selected. The comprehensive USDA report on carcass disposal options contains cost ranges for a variety of disposal methods. Regarding “Disposal Rendering”, independent rendering firms have informally stated that disposal services for dead stock would range from \$6 to \$10 per hundredweight if such materials were to become prohibited for use in all animal feeds.

Appendix B

*THE CAPACITY OF RENDERING SYSYEMS USED IN THE USA TO
INACTIVATE TRANSMISSIBLE DEGENERATIVE ENCEPHALOPHTHY AGENTS*

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Introduction

Bovine spongiform encephalopathy (BSE), scrapie in sheep, chronic wasting disease (CWD) in cervids, and Creutzfeldt-Jakob disease (CJD) in humans belong to a group of unusual and fatal neurological diseases (Table) known either as transmissible degenerative encephalopathies (TDEs) or transmissible spongiform encephalopathies (TSEs). TDEs are caused by unconventional transmissible agents that have not yet been definitively characterised at the molecular level (Telling *et al*, 1995; Almond & Pattison, 1997; Chesebro, 1998; Farquhar *et al*, 1998) but are known to be relatively resistant to inactivation by decontamination procedures that are effective with conventional microorganisms (Ernst & Race, 1993; Taylor *et al*, 1994; Taylor, 2000).

The association between feeding cattle with ruminant-derived meat and bone meal and their development of BSE

The convincing association between the amplification of the UK BSE epidemic and the feeding of ruminant-derived meat and bone meal (MBM) to cattle was demonstrated by Wilesmith *et al* (1988). The large epidemic of BSE that has occurred in the UK demonstrates that (one or more of) the rendering procedures used to produce MBM in the UK in the early 1980s had not inactivated the BSE agent to any significant degree. Until the late 1980s, BSE was confined to the UK. However, the later spread of BSE to other European Union (EU) and non EU-countries almost certainly resulted both from the direct and indirect exportation of MBM from the UK to these countries, and the exportation of cattle with subclinical BSE that were eventually rendered to provide MBM in the newly-affected countries (Brown, 2003).

Experimental validation studies on traditional EU rendering practices

The occurrence of BSE in member states of the EU other than the UK in the late 1980s and early 1990s resulted in experimental validation studies being funded by the European Commission (EC) with regard to rendering practices. These studies were designed to examine rendering systems used within the EU during the 1980s and early 1990s with regard to their capacity to inactivate the agents that cause BSE and scrapie. The outcome of these studies was impossible to predict, because the rendering industry had never considered the need to carry out such studies in the past; nor had regulatory authorities ever suggested that such studies needed to be carried out.

Before carrying out these experiments, it was necessary to identify the range of rendering conditions that had been used throughout the EU during the relevant time-period. This was achieved through surveys carried out by the European Renderers Association, the UK Ministry of Agriculture Fisheries and Food, and the United Kingdom Renderers Association. These revealed that the types of equipment being used by renderers in the late 1980s and early 1990s were relatively limited but that they were used in many different ways. The data from the survey were therefore used to generically define the processes and then identify the minimal and

average time/temperature combinations for each generic process in order to design the experimental protocols.

In the first phase of these experimental studies, BSE-spiked abattoir waste was exposed to the appropriate range of rendering processes, and output samples were tested for BSE infectivity by mouse bioassay. In phase two, the same types of experiments were carried out using scrapie-spiked abattoir waste.

Because the full details of these studies have been published (Taylor et al, 1995; Taylor et al, 1997), only the key elements of the results will be briefly considered here.

In the BSE-spiked experiments, the titre of infectivity in the starting material was $10^{1.7}$ mouse intracerebral ID_{50}/g . Although infectivity did survive some of the rendering processes, inactivation was achieved by the following processes:-

- *batch processing at atmospheric pressure of raw material containing only natural fat*
- *two of four continuous atmospheric processes involving raw material containing only natural fat*
- *two continuous atmospheric processes involving raw material with added fat*
- *three continuous wet rendering processes involving raw material with added fat*
- *batch rendering using hyperbaric steam at $133^{\circ}C$ involving raw material with only natural fat*

The titre reduction achieved by the effective methods was approximately $10^{1.4}$ mouse intracerebral ID_{50}/g . Infectivity was detected following two of the four continuous atmospheric processes involving raw material containing only natural fat, and after two continuous vacuum systems in which fat had been added to the raw materials. In one of the vacuum processes, the infectivity level was reduced by only 0.1 of a log to $10^{1.6} ID_{50}/g$.

The levels of infectivity remaining after the “positive” continuous atmospheric pressure processes were not measured by titration. However, it can be reasonably concluded that the loss of infectivity after these processes was greater than the modest loss achieved by the vacuum process. This is because the “neat” samples did not cause disease in all of the challenged mice: also, when mice succumbed, their average incubation periods were longer than that for the mice injected with material exposed to the vacuum process (approximately 540, compared with 440 days). These data would be consistent with there having been a titre loss of around 1 log.

In the scrapie-spiked experiments, the titre of infectivity in the starting material was $10^{3.1}$ mouse intracerebral ID_{50}/g . None of the rendering processes, apart from those involving exposure of the raw materials to steam under pressure, completely inactivated the scrapie agent.

The infectivity reduction factors for the various ineffective rendering systems were as follows:-

- *$10^{1.5}$ for batch processing at atmospheric pressure of raw material containing only natural fat*
- *$10^{1.6}$ and $10^{2.3}$ for two continuous atmospheric processes involving raw material containing only natural fat*
- *$10^{2.3}$ for a continuous atmospheric process involving raw material with added fat*
- *$10^{1.6}$ for a continuous vacuum process involving raw materials with added fat*
- *$10^{2.0}$ and $10^{2.8}$ for two continuous atmospheric wet rendering processes involving raw materials with added fat*

With the batch rendering using hyperbaric steam at 133°C for raw material containing only natural fat, after which no infectivity was detectable, the infectivity titre reduction could be calculated as $10^{2.8}$.

From the above data, one might be tempted to conclude that the scrapie agent is more thermostable than the BSE agent but this is not necessarily so. For technical reasons, the titre of infectivity in the BSE-spiked raw materials was disappointingly low (Taylor et al, 1995), and this is more likely to be the explanation for the difference in survival between the BSE and scrapie agents after rendering.

The experiments involving BSE-spiked abattoir waste demonstrated that the most-recently introduced rendering system in the UK had little capacity to inactivate the BSE agent, and produced MBM with almost as much infectivity as in the untreated, spiked raw-material. This system involved cooking the raw materials under vacuum for 10 or 40 minutes in pre-heated tallow; the temperatures at the end of these processes were 112° C and 122° C respectively. Some of the other systems were also shown to permit the survival of lower levels of BSE infectivity (Taylor et al, 1995). In the scrapie-spiked experiments, infectivity was detected after exposure to all of the rendering procedures apart from those that involved autoclaving (Taylor et al, 1997).

The relevance of the EU studies to current rendering practices in the USA

When the EU studies were carried out, it was generally considered that the range of rendering processes that existed within the EU would be comparable to those used in the USA at that time with two exceptions. Processes involving the exposure of rendered material to solvent extraction or hyperbaric steam had not been, and are still not, used in the USA. Rendering methods changed dramatically within the EU because of the outcome of the validation studies; it became a requirement that MBM for incorporation into animal feed should only be produced by using the

133°C hyperbaric steam process (European Commission, 1996). However, rendering systems used currently in the USA still involve exposure of the raw materials to processes that operate at atmospheric pressure or under vacuum, and are comparable to systems used at the time of the EU validation studies. Thus, the various degrees of inactivation of the BSE and scrapie agents achieved by these types of processes in the EU validation studies should be broadly applicable to the systems that are currently being used in the USA.

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Appendix C

RESULTS OF MODEL SIMULATIONS

The following data are presented in the tabular format used in the Harvard BSE Risk Assessment Study. If unfamiliar with this format, please consult the Harvard Study for interpretation of the labels used.

SCENARIO #1, Current Situation - Base Case 2004

Obs	Label	Mean	5th	25th	50th	75th	95th
1							
2							
3	Epidemic Statistics						
4	Total Infected	140	100	110	110	170	220
5	Total Infected w/o Imports	36	2	5	11	75	120
6	Total Clinical	43	30	36	40	48	63
7	R0 Parameter	0.2	0.02	0.048	0.099	0.43	0.54
8							
9	Mode of Infection						
10	Maternal	5.3	2	4	5	7	10
11	Spontaneous	0	0	0	0	0	0
12	Protein	31	0	0	5	68	110
13	Blood	0.18	0	0	0	0	1
14	Exogenous	0	0	0	0	0	0
15							
16	Mode of Death						
17	Slaughter	84	56	62	68	110	140
18	Die on Farm - Render	44	30	35	40	50	71
19	Die on Farm - No Render	8	3	6	8	10	14
20							
21	ID50 Sources						
22	From Slaughter	75,000	39,000	55,000	70,000	90,000	120,000
23	From Death on Farm	380,000	220,000	270,000	320,000	390,000	860,000
24							
25	Disposition of ID50s						
26	1 To Prohibited MBM	39,000	15,000	25,000	34,000	45,000	79,000
27	2 Eliminated by SRM ban	0	0	0	0	0	0
28	3 Eliminated by Rendering	380,000	220,000	270,000	320,000	400,000	830,000
29	4 To NP MBM - Contamination	0.039	0	0	0	0	0.026
30	5 To NP MBM - Mislabeling	850	0	10	100	1,000	2,500
31	6 Out After Rendering	13,000	2,800	5,100	8,700	16,000	30,000
32	7 To Prohibited Feed	26,000	8,100	16,000	22,000	31,000	53,000
33	8 To NP Feed - Misdirected	100	0	0	0	0.019	100
34	9 To NP Feed - Contamination	0.042	0	0	0	0	0.012
35	10 To NP Feed - Mislabeling	1,200	0	26	150	1,100	10,000
36	11 To Blood	8.4	1.9	3.8	6.9	11	19
37	12 Out After Feed Production	26,000	8,200	16,000	23,000	32,000	53,000
38	13 Misfed to Cattle	400	0	0	2.6	100	1,100
39	14 Total to Cattle	820	0.16	2.1	33	1,000	2,300
40	15 Total Potential to Humans	110	26	45	74	130	280
41	16 Eliminated by AM Inspector	42,000	10,000	30,000	40,000	50,000	80,000
42							
43	Human Exposure						
44	Brain	23	0	0	0	0	160
45	Spinal Cord	8.3	0	0	0	0	65
46	Blood	0.56	0	0.00002	0.089	0.33	2.3
47	Distal Ileum	0	0	0	0	0	0
48	Contaminated Organ Meat	0	0	0	0	0	0
49	Eyes	0.0014	0	0	0	0	0
50	Contaminated Muscle Meat	4.4	0.99	2.2	4.1	5.8	9.2
51	AMR	44	14	26	37	58	97
52	Beef on Bone	27	0.29	6.1	22	36	82
53	Trigeminal Ganglia	0	0	0	0	0	0
54	Tonsils	0	0	0	0	0	0

SCENARIO #2, Prohibit all SRM from feed

Obs	Label	Mean	5th	25th	50th	75th	95th
1							
2							
3	Epidemic Statistics						
4	Total Infected	110	100	100	110	110	110
5	Total Infected w/o Imports	5.6	2	4	5	7	10
6	Total Clinical	38	30	34	37	41	46
7	R0 Parameter	0.052	0.02	0.038	0.048	0.065	0.091
8							
9	Mode of Infection						
10	Maternal	4.8	2	3	5	6	9
11	Spontaneous	0	0	0	0	0	0
12	Protein	0.67	0	0	0	0	3
13	Blood	0.12	0	0	0	0	1
14	Exogenous	0	0	0	0	0	0
15							
16	Mode of Death						
17	Slaughter	62	53	59	62	66	71
18	Die on Farm - Render	0	0	0	0	0	0
19	Die on Farm - No Render	43	35	39	43	47	53
20							
21	ID50 Sources						
22	From Slaughter	67,000	34,000	50,000	66,000	83,000	110,000
23	From Death on Farm	0	0	0	0	0	0
24							
25	Disposition of ID50s						
26	1 To Prohibited MBM	300	100	150	230	400	690
27	2 Eliminated by SRM ban	25,000	8,400	16,000	24,000	32,000	45,000
28	3 Eliminated by Rendering	2,900	1,700	2,300	2,800	3,300	4,100
29	4 To NP MBM - Contamination	0.00027	0	0	0	0	0.000049
30	5 To NP MBM - Mislabeling	6.7	0	0	0.067	2.4	26
31	6 Out After Rendering	95	8.1	33	58	95	310
32	7 To Prohibited Feed	200	49	90	140	310	540
33	8 To NP Feed - Misdirected	1	0	0	0	0	0.47
34	9 To NP Feed - Contamination	0.000015	0	0	0	0	0
35	10 To NP Feed - Mislabeling	6.5	0	7.8E-6	0.094	2.5	25
36	11 To Blood	7.2	1.7	3.3	5.5	9.8	19
37	12 Out After Feed Production	210	57	98	140	320	540
38	13 Misfed to Cattle	3.4	0	0	0	0.069	12
39	14 Total to Cattle	6.8	0.064	0.27	0.83	3.2	25
40	15 Total Potential to Humans	75	21	35	51	86	220
41	16 Eliminated by AM Inspector	39,000	10,000	26,000	40,000	50,000	70,000
42							
43	Human Exposure						
44	Brain	20	0	0	0	0	160
45	Spinal Cord	5.9	0	0	0	0	65
46	Blood	0.32	0	0	0.038	0.22	1.2
47	Distal Ileum	0	0	0	0	0	0
48	Contaminated Organ Meat	0	0	0	0	0	0
49	Eyes	0.00061	0	0	0	0	0
50	Contaminated Muscle Meat	3.8	0.91	1.8	3.3	5.2	8.4
51	AMR	33	10	21	29	40	64
52	Beef on Bone	12	0	3.2	6.2	23	35
53	Trigeminal Ganglia	0	0	0	0	0	0
54	Tonsils	0	0	0	0	0	0

SCENARIO #3A, Remove dead, non-ambulatory disabled and *ante mortem* condemned cattle from animal feed use.

Obs	Label	Mean	5th	25th	50th	75th	95th
1							
2							
3	Epidemic Statistics						
4	Total Infected	110	100	100	110	110	140
5	Total Infected w/o Imports	9.5	2	4	6	9	39
6	Total Clinical	38	29	34	37	41	46
7	R0 Parameter	0.077	0.02	0.038	0.057	0.083	0.28
8							
9	Mode of Infection						
10	Maternal	4.9	2	3	5	6	9
11	Spontaneous	0	0	0	0	0	0
12	Protein	4.5	0	0	0	2	33
13	Blood	0.11	0	0	0	0	1
14	Exogenous	0	0	0	0	0	0
15							
16	Mode of Death						
17	Slaughter	65	55	59	63	67	92
18	Die on Farm - Render	0	0	0	0	0	0
19	Die on Farm - No Render	44	35	40	44	48	53
20							
21	ID50 Sources						
22	From Slaughter	69,000	34,000	54,000	67,000	82,000	110,000
23	From Death on Farm	0	0	0	0	0	0
24							
25	Disposition of ID50s						
26	1 To Prohibited MBM	2,900	670	1,200	1,900	3,100	11,000
27	2 Eliminated by SRM ban	0	0	0	0	0	0
28	3 Eliminated by Rendering	26,000	11,000	18,000	24,000	33,000	46,000
29	4 To NP MBM - Contamination	0.0017	0	0	0	0	0.000042
30	5 To NP MBM - Mislabeling	57	0	0.0007	2.6	26	260
31	6 Out After Rendering	1,100	87	220	480	1,000	5,000
32	7 To Prohibited Feed	1,800	340	690	1,100	1,900	6,500
33	8 To NP Feed - Misdirected	5.7	0	0	0	0	16
34	9 To NP Feed - Contamination	0.0068	0	0	0	0	0.000079
35	10 To NP Feed - Mislabeling	82	0	0.013	3.2	28	280
36	11 To Blood	6.9	1.8	3.4	5.4	9.1	18
37	12 Out After Feed Production	1,900	360	730	1,200	2,000	6,700
38	13 Misfed to Cattle	40	0	0	0	2.6	57
39	14 Total to Cattle	59	0.036	0.39	2.6	26	260
40	15 Total Potential to Humans	76	20	34	48	86	230
41	16 Eliminated by AM Inspector	40,000	10,000	30,000	40,000	50,000	80,000
42							
43	Human Exposure						
44	Brain	20	0	0	0	0	160
45	Spinal Cord	6.9	0	0	0	0	65
46	Blood	0.38	0	0.000065	0.056	0.28	1.5
47	Distal Ileum	0	0	0	0	0	0
48	Contaminated Organ Meat	0	0	0	0	0	0
49	Eyes	0.001	0	0	0	0	0
50	Contaminated Muscle Meat	4	0.86	1.9	3.6	5.5	9.2
51	AMR	31	11	20	28	37	65
52	Beef on Bone	14	0.096	3.2	6.3	24	46
53	Trigeminal Ganglia	0	0	0	0	0	0
54	Tonsils	0	0	0	0	0	0

SCENARIO #3B, Systems Approach less ban on Hypobaric Rendering

Obs	Label	Mean	5th	25th	50th	75th	95th
1							
2							
3	Epidemic Statistics						
4	Total Infected	110	100	100	110	110	110
5	Total Infected w/o Imports	5.9	1	3	5	7	11
6	Total Clinical	37	29	34	37	41	46
7	R0 Parameter	0.054	0.0099	0.029	0.048	0.065	0.099
8							
9	Mode of Infection						
10	Maternal	4.6	1	3	5	6	8.5
11	Spontaneous	0	0	0	0	0	0
12	Protein	1.2	0	0	0	0	5
13	Blood	0.11	0	0	0	0	1
14	Exogenous	0	0	0	0	0	0
15							
16	Mode of Death						
17	Slaughter	63	55	59	62	66	72
18	Die on Farm - Render	0	0	0	0	0	0
19	Die on Farm - No Render	43	35	40	43	46	52
20							
21	ID50 Sources						
22	From Slaughter	69,000	36,000	54,000	67,000	83,000	110,000
23	From Death on Farm	0	0	0	0	0	0
24							
25	Disposition of ID50s						
26	1 To Prohibited MBM	530	160	270	430	660	1,300
27	2 Eliminated by SRM ban	22,000	7,900	15,000	21,000	28,000	44,000
28	3 Eliminated by Rendering	5,100	2,900	3,900	4,800	5,800	9,000
29	4 To NP MBM - Contamination	0.00022	0	0	0	0	0
30	5 To NP MBM - Mislabeled	16	0	0.000026	0.51	5.1	87
31	6 Out After Rendering	180	21	59	100	220	590
32	7 To Prohibited Feed	340	94	160	240	440	900
33	8 To NP Feed - Misdirected	1.1	0	0	0	0	2.4
34	9 To NP Feed - Contamination	0.00041	0	0	0	0	0.000043
35	10 To NP Feed - Mislabeled	18	0	0.00066	1.1	6.7	100
36	11 To Blood	7	1.7	2.9	5.3	9	18
37	12 Out After Feed Production	360	100	180	270	450	900
38	13 Misfed to Cattle	5	0	0	0	0.26	26
39	14 Total to Cattle	10	0.038	0.29	0.98	3.9	30
40	15 Total Potential to Humans	66	20	33	47	71	210
41	16 Eliminated by AM Inspector	41,000	10,000	30,000	40,000	50,000	76,000
42							
43	Human Exposure						
44	Brain	13	0	0	0	0	160
45	Spinal Cord	5.8	0	0	0	0	65
46	Blood	0.27	0	0	0.038	0.2	0.9
47	Distal Ileum	0	0	0	0	0	0
48	Contaminated Organ Meat	0	0	0	0	0	0
49	Eyes	0.0016	0	0	0	0	0
50	Contaminated Muscle Meat	3.9	0.96	1.9	3.5	5.3	8.6
51	AMR	32	11	21	28	38	68
52	Beef on Bone	12	0.096	3.2	6.2	23	32
53	Trigeminal Ganglia	0	0	0	0	0	0
54	Tonsils	0	0	0	0	0	0

SCENARIO #3C, Implement full Systems Approach

Obs	Label	Mean	5th	25th	50th	75th	95th
1							
2							
3	Epidemic Statistics						
4	Total Infected	110	100	100	110	110	110
5	Total Infected w/o Imports	5.5	2	3	5	7	11
6	Total Clinical	37	29	34	37	41	46
7	R0 Parameter	0.051	0.02	0.029	0.048	0.065	0.099
8							
9	Mode of Infection						
10	Maternal	4.6	1	3	4	6	9
11	Spontaneous	0	0	0	0	0	0
12	Protein	0.73	0	0	0	0	4
13	Blood	0.084	0	0	0	0	1
14	Exogenous	0	0	0	0	0	0
15							
16	Mode of Death						
17	Slaughter	62	54	58	61	65	72
18	Die on Farm - Render	0	0	0	0	0	0
19	Die on Farm - No Render	43	35	40	44	47	51
20							
21	ID50 Sources						
22	From Slaughter	66,000	31,000	52,000	65,000	79,000	110,000
23	From Death on Farm	0	0	0	0	0	0
24							
25	Disposition of ID50s						
26	1 To Prohibited MBM	300	140	200	270	360	510
27	2 Eliminated by SRM ban	22,000	7,300	14,000	20,000	29,000	42,000
28	3 Eliminated by Rendering	5,300	3,000	4,000	5,000	6,000	8,400
29	4 To NP MBM - Contamination	0.00015	0	0	0	0	5.1E-7
30	5 To NP MBM - Mislabeling	7.3	0	0	0.26	3.3	30
31	6 Out After Rendering	94	22	49	80	120	210
32	7 To Prohibited Feed	200	73	130	170	250	380
33	8 To NP Feed - Misdirected	0.53	0	0	0	0	0.53
34	9 To NP Feed - Contamination	0.00038	0	0	0	0	0
35	10 To NP Feed - Mislabeling	7.9	0	0.0029	0.9	5.1	29
36	11 To Blood	6.7	1.8	3.1	5	8.5	17
37	12 Out After Feed Production	210	75	130	180	260	390
38	13 Misfed to Cattle	3	0	0	0	0.26	24
39	14 Total to Cattle	6.3	0.018	0.27	0.93	3.3	26
40	15 Total Potential to Humans	66	19	32	46	75	210
41	16 Eliminated by AM Inspector	39,000	10,000	25,000	40,000	50,000	70,000
42							
43	Human Exposure						
44	Brain	14	0	0	0	0	160
45	Spinal Cord	6.8	0	0	0	0	65
46	Blood	0.37	0	0	0.051	0.25	1.4
47	Distal Ileum	0	0	0	0	0	0
48	Contaminated Organ Meat	0	0	0	0	0	0
49	Eyes	0.00022	0	0	0	0	0
50	Contaminated Muscle Meat	3.8	0.96	1.8	3.3	5.1	8.8
51	AMR	31	10	20	28	37	65
52	Beef on Bone	11	0	3.1	6.1	23	32
53	Trigeminal Ganglia	0	0	0	0	0	0
54	Tonsils	0	0	0	0	0	0

APPENDIX D
Simulation Confidence Intervals for 500 Runs

Quantile Range for Number of Additional Infected Cattle: 0.025 to 0.975

Obs	Scenario	Statistic	Mean	5th	25th	50th	75th	95th
1								
2	Base Case	Lower	32	2	5	9	39	103
3		Central	36.3	2	5	11	74	117
4		Upper	40.7	2	6	14	78	152
5								
6	Scenario 3A	Lower	8.3	2	4	5	8	26
7		Central	9.46	2	4	6	9	38
8		Upper	10.6	2	4	6	9	48
9								
10	Scenario 2	Lower	5.22	1	3	5	6	9
11		Central	5.59	2	4	5	7	10
12		Upper	5.96	2	4	5	7	11
13								
14	Scenario 3B	Lower	5.45	1	3	5	6	10
15		Central	5.92	1	3	5	7	11
16		Upper	6.39	2	4	5	7	12
17								
18	Scenario 3C	Lower	5.1	1	3	5	6	10
19		Central	5.45	2	3	5	7	11
20		Upper	5.8	2	4	5	7	12

Quantile Range for Cattle Oral ID50s Potentially to Humans: 0.025 to 0.975

Obs	Scenario	Statistic	Mean	5th	25th	50th	75th	95th
1								
2	Base Case	Lower	98.9	23.2	42.6	68.4	117	254
3		Central	107	26.1	45.5	73.5	129	282
4		Upper	115	29.1	50.8	83.4	149	310
5								
6	Scenario 3A	Lower	69.5	17.4	30.8	45.7	73.8	206
7		Central	75.8	20.1	33.6	48.4	85.7	230
8		Upper	82.2	22	35.3	52.1	101	252
9								
10	Scenario 2	Lower	68.9	16.7	32.8	48	74.7	206
11		Central	74.6	20.4	35.4	50.6	85.2	217
12		Upper	80.3	22.6	37.1	53.9	96.1	232
13								
14	Scenario 3B	Lower	61.2	16.7	31.4	44.8	66.2	187
15		Central	66	19.6	33.4	46.7	71	207
16		Upper	70.9	21.5	35.2	49.8	78.1	226
17								
18	Scenario 3C	Lower	61.4	16.1	29.6	42.4	67.6	197
19		Central	66.5	18.9	31.5	46.1	74.9	207
20		Upper	71.6	21.2	34	49.9	84.8	218

APPENDIX E

The Safety of Bovine Blood Products as Feed Ingredients for Ruminants

The safety of processed bovine blood products as animal feed ingredients for ruminants has come into question due to the recent discovery of 2 native cases of BSE in North America. Both cases appear to have been born prior to implementation of preventative feed controls in August of 1997. Epidemiological evidence points to the feeding of cattle derived meat and bone meal back to cattle as the mechanism that amplified BSE in the U.K. Amplification of BSE occurred because meat and bone meal contained what are now known as specified risk materials (SRM). These SRM are the tissues that have been shown to potentially harbor BSE infectivity in animals that are incubating the disease. Blood is not considered a SRM and, as demonstrated by the Harvard Study, the risk of BSE amplification posed by the feeding of blood meal to cattle is negligible.

Infectivity has not been detected in blood from clinically affected cattle. The Harvard Study evaluated the potential for dried blood meal fed to cattle to amplify BSE, in a sensitivity analysis, using the assumption that inherent infectivity existed at the level of detection of the mouse bioassay. In addition, the study evaluated the potential for infectivity from brain macro-emboli that can result from captive bolt stunning methods and from “brain drip” that could potentially cross contaminate raw blood as it was collected. The Harvard Study concluded that a mean of 0.12 cases would arise due to the import of 10 infected animals.

Blood products are manufactured from fresh blood that is collected from cattle that have passed ante mortem inspection conducted by USDA veterinarians. The USDA requirement requiring cattle to be ambulatory at slaughter coupled with the recent prohibition on the use of air injection stunning and other slaughter controls have further reduced the already low risk of amplifying BSE via the feeding of blood meal to ruminants.

A new risk assessment that considers recent regulatory changes at slaughter establishments should be completed and available for public comment prior to any changes to the exempt status of blood products as contained in 21 CFR 589.2000.

APPENDIX F

Blood Meal in Dairy Cattle Diets

Loss of Product Value

The Sparks Company conducted a study for the National Renderers Association in June 2001. Among several items, the study evaluated potential regulatory changes that would impact the use of blood meal as a feed ingredient. In 2000, 1.48 billion pounds of blood were generated from the slaughter of cattle. A resulting 121.9 million pounds of cattle blood meal and 49.8 million pounds of mixed species blood meal were in turn manufactured. Total ruminant containing blood meal produced was 171.7 million pounds, 70% of which was utilized in ruminant diets. The study determined that if the use of blood meal were prohibited in cattle diets a product loss of \$45.3 million would be realized by the cattle sector. Additional indirect losses from reduced animal productivity at the farm level were not considered by the report and are estimated below. The entire report is available at http://www.renderers.org/economic_impact/index.htm

Environmental Consequences of Reduced Nutrient Efficiency

Blood meal has unique nutritional properties that provide a very high return to dairy producers. Blood meal provides a high quality source of rumen undegradable amino acids, most specifically a high lysine content that is unmatched by any other ingredient available. Lysine is considered the first limiting amino acid to high milk production in most dairy rations. Reduction in supply of this first limiting nutrient will result in reduced milk production down to a point where another nutrient becomes the first limiting factor. Unlike poultry and swine, synthetic lysine can't be utilized to balance the amino acid requirements of high producing dairy cattle. Loss of blood meal as an ingredient in dairy cattle rations would result in a combination of the following situations.

- 1) In order to maintain a specific level of milk production, higher concentrations of protein would need to be fed resulting in higher cost of milk production. This reduced efficiency of protein utilization would result in an increased urinary excretion of nitrogen into the environment. Additional grain feeding would be required as an energy source in order to convert waste nitrogen into urea prior to excretion. Animal health and reproductive efficiency would be hampered by increased protein feeding, further exacerbating the reduced efficiency of milk production.
- 2) In order to comply with environmental regulations on nutrient management, the protein content of dairy cattle diets would not be altered. Milk production per cow would decline due to less lysine available to support milk production. The quantity of nitrogen excreted by dairy cattle per unit of milk produced would increase. Additional dairy cattle, forage crops, feed grains, crop and energy inputs, land base and infrastructure to raise, feed and

house additional cattle would be required to maintain milk production if blood meal became unavailable as a nutritional tool to dairy producers. In addition, methane production per unit of milk produced would also increase.



Value of Lost Milk Production

Typically 0.5 pounds/day of dried blood meal is fed to dairy cattle. A reduction of 4 pounds of milk/cow/day would be expected if blood meal was no longer utilized in high producing dairy diets. Using the figure from the Sparks report that 70% of ruminant blood meal was utilized in dairy rations, an overall drop in milk production of 9.6 million hundredweight would occur. At \$12/cwt this loss in milk production would reduce dairy farm income by \$115.4 million.

**Combined losses to the Beef cattle and Dairy sectors
would total \$160.7 million annually.**

An environmental and economic impact study should be required prior to any removal of the exemption for blood products in 21 CFR 589.2000. This exemption allows for the inclusion of ruminant derived blood products in ruminant diets.

APPENDIX G

Evaluation of Animal Feed Policy Options for Slaughter Cattle (10) (U.S. Figures)

Policy Option	Cost per head (7)	# Slaughter Cattle Affected	Total Annual Industry Cost (7)	Wet Waste (pounds)	SRM MBM if Rendered (pounds)
SYSTEMS APPROACH					
> 30 month, Remove Brain & Spinal Cord (1)	\$0.21	8,000,000	\$1,680,000	10,471,850	650,357
FULL SRM REMOVAL					
> 30 month of age Cattle (2)	\$10.70	8,000,000	\$85,600,000	698,986,067	208,004,010
< 30 month of age Cattle (3,9)	\$2.55	28,000,000	\$71,400,000	792,412,606	39,616,662
Total Average Cost of SRM Removal <i>(blended cost for all animals > and < 30 months age)</i>	\$4.36	36,000,000	\$157,000,000	1,491,398,672	247,620,672

Notes

- (1) Removal tolerance for brain and spinal cord is 98%
- (2) Includes skull, brain, trigeminal ganglia, dorsal root ganglia, spinal cord, vertebral column, small intestine, tonsils and eyes
- (3) Includes small intestine and tonsils.
- (7) Assumes SRM removed will be processed by disposal rendering service for with resulting solids portion being landfilled.
Disposal Rendering fee including pickup = \$7.65/cwt, Landfill & Trucking fee = \$75/short ton
Cost includes loss of MBM sold valued at past 4-year average price of \$180/ton.
Fat that is recovered and will be marketed for industrial uses, 4-year average price of \$0.18/pound.
Does not include one time transition costs.
- (9) Includes fed-cattle only. Calf slaughter not evaluated.
- (10) Does not evaluate control measures for disposal of non-marketed fallen and non-ambulatory cattle

APPENDIX H

Cost Calculation of full SRM removal from Cattle 30 months of age and under

	Pounds	Labor	Disposal	MBM Yield %	Tallow Yield %	MBM # Yield	Tallow # Yield	
Tonsil	0.300		\$0.011	5%	15%	0.02	0.05	
Small Intestine	28.000	\$0.200	\$1.050	5%	16%	1.40	4.48	
TOTAL	28.3	\$0.200	\$1.061			1.4	4.5	
					Value/#	\$0.090	\$0.180	Valued at 4-year average market price
		Disposal fee	\$75.00/ST		Lost value	\$0.127	\$0.815	
	LAND FILL	Raw Disposal cost	\$1.06					
		Separation Labor	\$0.20					
		Product loss	\$0.94					
LANDFILL COST	----->	Total loss for raw disposal	\$2.20					
		Raw Processing fee	\$6.00/cwt raw					
		Raw transportation fee	\$1.65/cwt raw					
OR		Raw transportation	\$0.47					
		Separation Labor	\$0.20					
		Raw Processing cost	\$1.70					
		MBM Disposal cost	\$0.05					
		MBM loss	\$0.13					
DISPOSAL RENDERING	----->	Total rendering disposal	\$2.55/head					

TOTAL FOR SECTOR
 28 Million head < 30 months
 792 Total Raw Waste Generated (million pounds)
 40 Total waste MBM if disposal rendering (million pounds)
 \$61.69 Disposal Cost - landfill option (\$ Millions)
 \$71.27 Disposal Rendering Cost - reclaim tallow (\$ Millions)

Cost Calculation of full SRM removal from Cattle over 30 months of age

	Pounds	Labor	Disposal	MBM Yield %	Tallow Yield %	MBM # Yield	Tallow # Yield
Brain	0.936	See Skull	\$0.035	6%	5%	0.06	0.05
Spinal Cord	0.374	See Skull	\$0.014	7%	5%	0.03	0.02
Eyes	0.220	See Skull	\$0.008	15%	10%	0.03	0.02
Tonsil	0.300	\$0.100	\$0.011	5%	15%	0.02	0.05
Skull & TGG	15.200	\$0.100	\$0.570	44%	11%	6.69	1.67
vertebral column	36.500	\$0.200	\$1.369	48%	13%	17.52	4.75
small intestine	35.000	\$0.200	\$1.313	5%	16%	1.75	5.60
TOTAL	88.5	\$0.600	\$3.320			26.1	12.1

Value/# \$0.090 \$0.180 Valued at 4-year average market price
 Lost value \$2.348 \$2.187

LANDFILL ----->

Total loss for raw disposal \$8.45/head

8 Million head > 30 months

708 Total Raw Waste Generated (million pounds)

209 Total MBM Waste Generated from disposal rendering (million pounds)

OR

Raw Processing fee \$6.00 /cwt raw
 Raw transportation fee \$1.65 /cwt raw

\$67.64 Disposal Cost - landfill option (\$ Millions)

\$85.59 Disposal Rendering Cost - reclaim tallow (\$ Millions)

Raw transportation \$1.46
 Separation Labor \$0.60
 Raw Processing cost \$5.31
 MBM Disposal cost \$0.98
 MBM loss \$2.35

DISPOSAL RENDERING ----->

Total rendering disposal **\$10.70 /HEAD**

COST CALCULATION FOR SYSTEMS APPROACH

	Pounds	Labor	Disposal	MBM Yield %	Tallow Yield %	MBM # Yield	Tallow # Yield	
Brain	0.936	\$0.100	\$0.035	6%	5%	0.06	0.05	
Spinal Cord	0.374		\$0.014	7%	5%	0.03	0.02	
			\$0.000	5%	16%	0.00	0.00	
TOTAL	1.3	\$0.100	\$0.049			0.1	0.1	
					Value/#	\$0.090	\$0.180	Valued at 4-year average market price
		Disposal fee	\$75.00/ST		Lost value	\$0.007	\$0.012	
		Raw Disposal cost	\$0.05					
		Separation Labor	\$0.10					
		Product loss	\$0.02					
LANDFILL ----->		Total loss for raw disposal	\$0.17/head					
OR								
		Raw Processing fee	\$6.00/cwt raw					8 Million head > 30 months
		Raw transportation fee	\$1.65/cwt raw					10 Total Raw Waste Generated (million pounds)
								0.7 Total MBM Waste Generated from disposal rendering (million pounds)
								\$1.35 Disposal Cost - landfill option (\$ Millions)
								\$1.69 Disposal Rendering Cost - reclaim tallow (\$ Millions)
		Raw transportation	\$0.02					
		Separation Labor	\$0.10					
		Raw Processing cost	\$0.08					
		MBM Disposal cost	\$0.00					
		MBM loss	\$0.01					
DISPOSAL RENDERING ----->		Total rendering disposal						
								\$0.21/head