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

Re: Docket No. 2002N-0273, Substances Prohibited From use in Animal Food or Feed

To Whom It May Concern:

The National Renderers Association (NRA) references FDA's Docket No. 2002N-0273, the agency's proposed rule and the invitation to comment on substances prohibited from use in animal food or feed.

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 disagrees with the basic conclusion that further action proposed in the rule is necessary, and in this letter and attachment, supplies data more current and accurate than data used by FDA to justify the proposed rule. The economic and environmental effects of the proposed rule easily surpass the threshold set by the Unfunded Mandates Reform Act of 1995 that mandates in-depth impact studies. We believe these studies must be conducted using current and representative data before formalizing any proposed rule.

The Animal Protein Producers Industry (APPI) recently merged with the NRA. The source of these comments is consistent with both organizations and we stand by our joint comments of August 13, 2004 on FDA's Docket No. 2004N-0264, the agency's advance notice of proposed rulemaking (ANPR) on federal measures to mitigate BSE risks.

No Changes in the Feed Rule are Needed
NRA continues to support scientifically based animal feeding regulations to restrict the use of certain animal proteins derived from mammalian tissues used in ruminant feeds. We agree that animal feed regulations need to be reviewed from time to time if new risks are identified or new, relevant science is brought to light. However, our analysis of the facts makes us believe FDA's preliminary conclusion to remove cattle brains and spinal cord and rendered dead animals from all animal feed is not warranted, and this action aimed at removing a very minute risk from BSE will increase risks from other diseases, cause environmental degradation, and cost much more than can be justified. The 1997 feed rule is working and compliance is extremely high. The USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 548,786 surveillance samples from high risk groups and 21,216 healthy animals over the past 15 months showing the incidence of BSE in the U.S. to be near zero. No additional regulation is needed at this time.

The proposed rule invites comments on many issues and we will address those issues in this document. The agency also uses assumptions, data, and forecasts in making its case for minimal environmental and economic impacts of the proposal. The attached study by Informa Economics, McLean, VA, entitled "Economic Impacts of Proposed Changes to Livestock Feed Regulations" commissioned by NRA will also provide accurate and current industry data to make the case to reexamine the conclusions in the proposed rule.

Incidence of BSE in the U.S.
In the EU in 2001 and 2002, there was one positive case found in each 1068 high risk cattle and one positive in each 29,594 healthy cattle over 30 months of age. Using this ratio, the one positive in the U.S. found in 548,786 high risk cattle would indicate an infection rate in the U.S. of one in more than 15.2 million cattle over 30 months of age (Table 1). The National Cattleman's Beef Association (NCBA) estimates the total number of cattle in the U.S. born before the feed ban to be less than 12 million. In other words, the data show the infection rate to be very near zero—for all practical purposes, it is statistically zero.

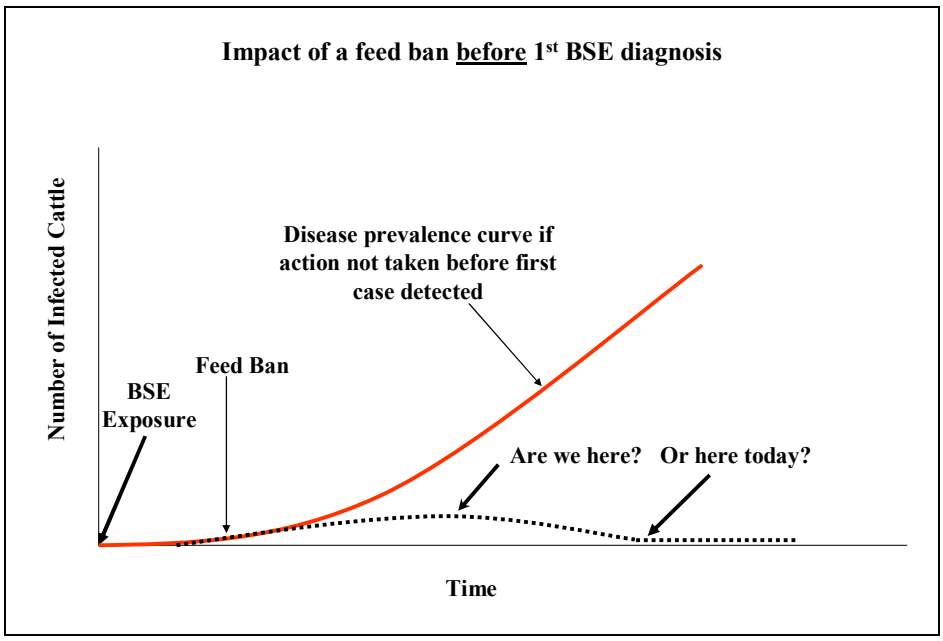
Table 1. EU Experience: Positives/Tests Run Versus U.S. Situation 2004/05.

Year	EU, 2001 - 2002	U.S. Estimates
Clinical Suspects	1/3.55	0/4600 (1990-2005)
Fallen stock & emergency slaughter	1/1068	1/548,786 (Expanded surveillance 2004-2005)
Healthy Slaughter	1/29,594	<1/15,200,000 (Estimated maximum in over 30 month cattle)

Eurocentric View of Risk is Inappropriate
Applying the same rules as recommended in Europe is unjustified. The incidence in the U.S. is at least 500-fold lower than in the European Union. The U.S. instituted preventive measures long before Europe, and extremely early in the epidemiological curve (Figure 1, courtesy NCBA). It is also worth noting the rendering industry in Europe is heavily

subsidized so that prohibited materials are picked up, processed, and incinerated avoiding a massive disposal problem.

Figure 1: Theoretical BSE epidemiological curve.



Relevancy of Data

NRA believes that current, accurate statistics are needed to estimate the volume of rendered materials currently coming from dead cattle and the volume that would need to be disposed of by alternate means under the proposed changes in the feed rule. For that reason, NRA commissioned a new study (attached) by Informa Economics to provide these data and other important analyses to supply information for these comments. The survey was sent to 52 rendering companies (many with multiple plants) that are members of NRA and 22 non-members, which taken together represent virtually all of the rendering capacity in the United States and is a truly representative sample.

No Need to Restrict 4-D Cattle over 30 Months of Age

We believe there is no added risk reduction by requiring removal of brains and spinal cords from cattle more than 30 months of age not passed for human consumption. Even though new cases of BSE are most likely to appear in this group of cattle, the surveillance program shows this event to be extremely unlikely. The other safeguards in place, most notably the current ruminant feed rule, would prevent this potential minute amount of material from spreading BSE. The added expense of removing either the SRM material from the 4-D cattle over 30 months in the United States or the cattle themselves, is disproportionate to the miniscule benefit. It has been stated the majority of risk lies in this group of cattle, but it is important to recognize the majority of something near zero is still near zero. To say restricting this class of animals would "remove 82% of the residual BSE Lethal Doses (LD-50 is the dose needed to infect 50% of animals exposed) in the total U.S. cattle population"

may be mathematically accurate, but gives a false assurance that significant risk is actually being removed. There is no significant risk to be removed.

No Need to Restrict Young Animals

We believe there is certainly no added risk reduction by requiring removal of brains and spinal cords from cattle less than 30 months of age not passed for human consumption, and this should not be required of calves or of cattle that can be verified less than 30 months of age from producer records. Prohibiting from animal feed any more cattle materials than necessary will contribute to increased risks to other diseases, cause environmental degradation, and cause unnecessary economic disruption to producers and renderers. There would be no BSE LD-50 doses in animals younger than 30 months even if BSE infection existed in the U.S. It would be a waste of resources to expect renderers to remove the brains and spinal cords from calves and obviously young animals (steers and heifers). Systems to verify age of cattle mortalities can be established for cattle less than 30 months old. FDA should provide guidance for acceptable procedures to verify that carcasses are less than 30 months of age, such as certification of age based on a record in a national animal identification program, written farm records or other documentation, or dentition. It should not be necessary to require a federal or state inspector to determine age, provided the facility uses certain procedures and can verify their use through documentation.

Cross-Contamination

FDA expresses concerns about cross-contamination and cites preliminary data from an unpublished study showing the minimum infectious dose for BSE may be lower than previously thought. The rendering and feed manufacturing industries have updated facilities and systems to comply with the 1997 ruminant feed rule and high compliance has been validated by the FDA. Misfeeding and cross-contamination are not problems large enough to be concerned about. Further, since the incidence of BSE is near zero, the likelihood that any feed is contaminated with the BSE agent is extremely low, making the few breaches of the ruminant feeding rule insignificant, even if the infectious dose were lower than published scientific studies show it to be. The USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 548,786 surveillance samples from high risk groups over the past 15 months showing the incidence of BSE in the U.S. to be near zero. The incidence in the U.S. is likely to be less than one in 15 million. The chances of infected material also being miss-fed to a ruminant animal are so small, that even a tiny dose is extremely unlikely given normal dilution factors that occur in mixing feed.

Feasibility of SRM Removal from Dead Stock

The most recent analysis, detailed in the attached 2005 study by Informa Economics, calculates the average percent of cattle believed to be in good enough condition to remove the brain and spinal cord to be 54.4% and the average volume to be 54.8%. Starting with nearly half of all current deadstock collected by renderers deteriorated to the point where brain and spinal cord removal is infeasible or impractical, it would be necessary to either remove a significantly greater volume of material from each dead bovine collected, or for renderers to refuse to collect a significant proportion of the current volume of cattle and calves processed. Either way, the volume of material requiring disposal by alternative means

and the potential losses to the rendering industry, would increase greatly under the proposed rule, and would be much higher than estimated by FDA in the proposed rule.

The new Informa Economics study shows the capital investment required by renderers and meatpackers to remove the brain and spinal cord will be significant. The industry-wide capital investment required would be $80,000,000. Annualizing this over ten years at a 7% discount rate suggests annual capital expenditures of $11.3 million

There are factors other than carcass deterioration that impact success rates of SRM removal. Rendering companies are progressive and competitive and have anticipated some of the proposed restrictions. Several have tested equipment to remove brains and spinal cords from cattle mortalities and have tried very hard to make it work. In the best case scenario so far, a full-service Midwest pick-up service taking cattle of all ages was successful in completely removing the brains and spinal cords from 30 percent of the dead cattle. This varied greatly, with the success rate on feedlot cattle (600 to 800 lb.) somewhat higher and the success rate on larger, older stock cattle and dairy cattle very low because of the distortion and breakage of spinal columns even in cattle with little decomposition.

There continues to be questions about unclear intentions in the proposed rule—such as, how perfect do the removals need to be? Does the requirement of separate equipment or containers also mean the brain and spinal cord removal area (floor, table, or platform) has to be outside the area where dead stock are normally processed? How will removal procedures be validated? Are tests going to be used on products to determine whether brains and spinal cords have been removed? Until some of these uncertainties are resolved, renderers cannot make decisions on capital investments and business plans. It certainly would take some time for the industry to stabilize a routine after such a crucial change in regulations.

NRA stands by its previous statements that the feasibility of Cattle Materials Prohibited in Animal Feed (CMPAF) removal from dead stock is very low except under the best conditions of weather, climate, distance between production and rendering locations, age, size, and condition of cattle, worker skill, and equipment and technology.

Tallow

Tallow with impurities of less than 0.15% insoluble impurities do not pose any risk of BSE transmission, regardless of the source of the raw material. The OIE categorizes tallow with insoluble impurities of no more than 0.15% to be protein-free tallow and indicates tallow meeting this standard can be safely consumed by animals, regardless of the source raw materials. Speculation that the infective dose of the BSE agent may be lower than published scientific studies show it to be does not change this fact. The impurities consist principally of bone, dirt and sand, and protein is a minor component of the impurity fraction. Because of the proteinaceous nature of the BSE agent, it tends to remain with the cellular residues of meat and bone meal (MBM) during the extraction process, rather than being extracted with the lipids of the tallow.

The USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 548,786 surveillance samples from high risk groups over

the past 15 months showing the incidence of BSE in the U.S. to be near zero. USDA researchers calculate the highest potential number of cattle infected with BSE would be three in 10 million. The chances of infected material ending up in tallow is so small, that even a tiny dose is extremely unlikely given normal dilution factors that occur in mixing feed.

Numerous research studies (referenced in our comments of August 13, 2004 on FDA's Docket No. 2004N-0264) show no association between the occurrence of BSE and the consumption of tallow by cattle and no infectivity in tallow produced by traditional rendering procedures. There is also no reason to require non-CMPAF-derived tallow used in animal feeds to meet the 0.15 percent limit.

Disposal Volumes

NRA disagrees with FDA that additional material from animals being disposed of by means other than rendering will be modest. NRA commissioned a new study of the industry to determine the impact of this proposed rule on the number of these cattle that would be disposed of by rendering.

There are at least two ways 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, processing, and lost product revenues. 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 simply scale-back their deadstock collection activities, focusing only on customers that generate sufficient volume and/or cattle and calves that whose condition has not deteriorated to such a level that brains and spinal cords cannot be removed.

The most recent analysis, detailed in the attached 2005 study by Informa Economics, calculates that under the proposed rule, the number of cattle and calf mortalities processed by renderers would decline severely, including a decline in volume of nearly 24% (across all categories) which 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.

In addition to the disposal problems to producers and feedlots caused by renderers unable or unwilling to collect deadstock, the 2005 study shows 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 finalized. The FDA inadequately addresses which means of disposal might be feasible or appropriate for these materials and assigns a cost of $12/cwt for disposal in landfills which we believe to be an underestimate of cost even if it were advisable. Renderers and slaughter facilities may face daunting challenges to identify the appropriate disposal technique and outlets, and costs could far exceed current estimates. Until an appropriate disposal 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.

Rendering Takes Care of Materials "Otherwise Unfit for Food"
FDA asked for comment on the interpretation that these materials would be "otherwise unfit for food" under section 402(a)(3) of the Act. Restricting cattle materials from use in ruminant feeds is sufficient to decrease risk from BSE. Other risks are better mitigated by continuing to render dead stock. When rendered, materials otherwise "filthy, putrid, or decomposed substance, or otherwise unfit for food" are broken down to basic protein, fat, and mineral components that are safe and useful for feed. The rendering process inactivates virtually all harmful bacteria, viruses, and parasites. Changing how these materials are handled will do more harm than good.

Even though the infective BSE agent is not totally inactivated by rendering, since poultry, swine, and other non-ruminants in which most of the materials would be fed are not infected by prions, the rendered materials would be fit for animal feed. As stated before, misfeeding and cross-contamination are not problems large enough to be concerned about. Further, since the incidence of BSE is near zero, the likelihood that any feed is contaminated with the BSE agent is extremely low and given normal dilution factors that occur in mixing feed, the few breaches of the ruminant feeding rule are statistically insignificant even if the infectious dose were lower than published scientific studies show it to be.

As stated earlier, the infection rate in the U.S. is likely less than one in 15.2 million cattle over 30 months of age. These materials should not be defined as "filthy, putrid, or decomposed substance, or otherwise unfit for food" because the rendering process makes them fit for non-ruminants.

Cost of Record Keeping and Labeling Requirements
The burden of compliance without any benefit of definitive analytical methods relies entirely upon records and the responsibility is directed specifically to renderers. Most of these materials originate in production and slaughter operations that have the information, opportunity and responsibility to keep CMPAF materials separate from materials allowed in animal feed. Absolving all other sectors from any responsibility in tracking prohibited materials invites the possibility of accidents or deliberate short-cuts leading to contamination with the responsibility falling on renderers. In addition to the issue of fairness, the FDA once again understated the possibility that additional costs to renderers could be significant.

Since the FDA compliance system is based on recordkeeping it does not make sense that the agency arbitrarily decided that the entire burden of recordkeeping should be placed on renderers. The proposed rule does not specify the types of records that would need to be maintained in order to comply with the requirements. This is another unclear area ripe for uneven and arbitrary actions by agency field personnel.

Number and Percent of Cattle Rendered Currently and Under Proposal
NRA disagrees with FDA that only 17% of cattle mortalities are rendered and that the proposed rule will not significantly impact disposal volumes. The most recent analysis,

detailed in the attached 2005 study by Informa Economics, shows the number and volume of cattle mortalities collected in total by 45 of the 102 responding firms has held steady in recent years, contrary to some industry speculation that the role of the rendering industry in livestock disposal might be declining in response to changing economic conditions and regulatory pressures.

The 45 firms collecting dead cattle in 2005 process more than half of all adult cattle mortalities and nearly 40% of calf mortalities, accounting for about 45% of all dead and downer cattle in the United States (see detailed data in the Informa report, attached). These data support past rendering industry studies and information submitted by NRA in our comments of August 13, 2004 on FDA's Docket No. 2004N-0264, the agency's advance notice of proposed rulemaking (ANPR) on federal measures to mitigate BSE risks that were deemed inaccurate and outdated by FDA.

The attached Informa Economics study, calculates that under the proposed rule, the number of cattle and calf mortalities processed by renderers would decline severely, including a decline in volume of nearly 24% (across all categories) which 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.

Feed Substitution Costs

The FDA estimates the rule will decrease the annual production of MBM available for feed by about 15 million pounds, which would be a tiny 0.3 percent of the total volume produced in the U.S. The new Informa study calculates the volume to be more than 79 million pounds valued at $7.1 million of MBM and 48 million pounds of tallow valued at $8.6 million lost from rendering when accounting for the unintended impacts that will lead to many dead and downer cattle being excluded from processing.

Many renderers believe this restriction on dead stock will be the beginning of untenable economic pressure on dead stock collection that could eventually lead to the end of the service for all species. If this were the case, the proposed rule would decrease the annual total production of MBM and fats available for feed by about 4 percent. Since many livestock and poultry rations use least-cost formulation and many ingredients can be substituted by competing products, any decrease in protein or fat supply will raise feed costs to producers.

Costs passed through to Consumers and Producers

The greatest economic impact on livestock producers will occur as a result of higher fees charged by renderers if the FDA rule is finalized. The attached 2005 study shows that on average, renderers would likely charge collection fees at least double, and in some cases, increases by a factor of six or more. 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. The study shows that 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. Even the best-intentioned livestock producers will be tempted to overlook some environmental concerns in order to save thousands or tens of thousands of dollars per year. Without enforceable regulation of mortality disposal, unapproved and dangerous methods could find widespread use, including burial without regard to environmental considerations or faulty, inadequate attempts at composting or incineration.

The attached 2005 study estimates that more than 444,000 cattle and calves will no longer be accepted by renderers under FDA's proposed rule. The costs for burial of these deads and downers are estimated at nearly $17.5 million, far exceeding the $1 million used by FDA in the proposal. When burial is not feasible, producers might be forced to turn to alternative disposal methods such as incineration or composting, both of which far exceed the expected cost of burial.

Another concern about the requirement for brain and spinal cord removal from raw materials for rendering is verification for small packers and locker plants that are not federally inspected, as well as custom slaughter plants and 4-D plants that are not continuously inspected (in some states, facilities may be inspected, but an inspector is not always present when animals are slaughtered). Unless adequate procedures to verify brain and spinal cord removal are developed, rendering companies will be unable to collect and process by-products, animals dying in transit, and downers from such establishments. This will create a hardship on these small businesses and make it difficult for farmers to find a market for cull cows, which will exacerbate any disposal issues.

Government Costs
One of the reasons FDA expects the increased expenditures to be non-significant is that the burden of the rule is put upon the rendering industry. It is unreasonable to expect renderers to absorb costs such as verification of proper brain and spinal cord removal from raw materials for rendering coming from small packers and locker plants that are not federally inspected. Either the government will incur increased expenditures to ensure the integrity of the by-product rendering system, or there will be much higher disposal costs to small packers and locker plants and/or environmental problems for society.

Costs to Society of the Disposal Methods
In 2004, the National Agricultural Biosecurity Center Consortium which includes Kansas State University, Texas A&M University and Purdue University published *Carcass Disposal: A Comprehensive Review*. In the section describing burial, the report describes the risk of disease agents persisting in the environment (e.g., anthrax, transmissible spongiform encephalopathy agents, etc.) and states: "Trench burial serves as a means of placing carcasses 'out of site (sic), out of mind' while they decompose, but it does not represent a consistent, validated means of eliminating disease agents." The report also cites the European Commission Scientific Steering Committee conclusion that burial of animal material which could possibly be contaminated with BSE/TSEs "poses a risk except under highly controlled conditions."

The primary benefit of the proposed rule is described as "elimination of the vast majority of the risk of spreading BSE to other cattle from intentional or unintentional use of non-

ruminant feed for ruminants or cross-contamination of ruminant feed with non-ruminant feed or ingredients intended for non-ruminant feed." The risks eliminated by the proposal are likely much smaller than the future risks of burying carcasses and disease agents on the farm at best, and more inappropriate methods at worse.

The FDA proposal will divert a small volume of material from use in rendered ingredients for non-ruminant feed, and in doing so will create a new class of material with a non-quantified level of risk because a much more substantial volume of dead and downer animals are likely to be disposed of by burial, composting, or abandonment on farms. Neither FDA, nor USDA has jurisdiction over this new on-farm risk. This rule will likely cause environmental and animal health risks unless legislative and regulatory initiatives provide for regulation of on-farm carcass disposal. This would impact and cause concern for producers. Therefore, the disposal issue to be addressed by a federal agency task force with USDA in the lead. USDA and EPA have been studying carcass disposal and SRM disposal for three years and 18 months, respectively, with some input from FDA and the Department of Homeland Security. It has been necessary for EPA to focus much of its resources to address disposal issues caused by the unusually active hurricane season and can only provide guidelines for carcass disposal to the states, since animal mortalities and by-products are not hazardous waste. Since USDA has broad authority regarding animal health issues, published an ANPR on animal mortality disposal about three years ago, and has knowledge about animal tissues, USDA should take a leadership role in addressing this issue.

FDA states: "Additional on-farm disposal of dead and non-ambulatory disabled cattle is expected to increase compliance costs from about $1.02 million to $2.53 million annually (including labor and equipment)." This would not be the case if on-farm disposal were regulated, and certainly is an underestimate of the environmental and animal health consequences of diverting these materials and dead animals away from rendering.

The disposal of animal mortalities and animal byproducts resulting from the production and processing of meat is a serious matter that impacts both animal and public health. Such materials are unstable and frequently contaminated with viral and bacterial pathogens that may spread to other animals and humans. Disposing of such materials without first processing with heat or chemicals to deactivate conventional pathogens is a danger to human health, animal health and the environment. In addition, as cattle mortalities and CMPAF are unintentionally steered away from the rendering industry by well-intended rulemaking, the incidence of improper disposal will increase, as will the potential for public and animal exposure to pathogens.

Following their experiences with BSE and Foot and Mouth Disease (FMD), the United Kingdom Department of Health evaluated various methods of animal mortality disposal for potential risks to public health. Compared with landfills and burial, disposal methods that involved heat processing, such as rendering and incineration, were more effective at controlling biological hazards, including food pathogens (such as E. Coli, Listeria, Salmonella and Campylobacter), organisms that cause diseases (such as anthrax, botulism, leptospirosis, bovine tuberculosis, plague and tetanus) and surface and ground water pathogens (cryptosporidium and giardia).

Mitigating Costs of Additional Regulation to Agriculture and Society
FDA, in a joint effort with USDA and EPA, should assess the potential for increased risk from conventional pathogens should the agency's actions cause an increase in improper disposal of dead animals and byproducts. A thorough risk assessment such as done by Harvard and Tuskegee Universities on the BSE issue would be useful for disease potential resulting from disrupting the current system. Also, FDA should join NRA in encouraging federal grant agencies to place a high priority on research focusing on new uses for materials that would be banned in a final rule.

Dedicated Facilities
The agency requests comment and data on the need for a requirement for dedicated facilities/ equipment for those facilities that handle both mammalian proteins currently prohibited in ruminant feed and ruminant feed when a CMPAF ban also exists.

The current USDA surveillance program substantiates the infection rate to be very near zero in the United States, and no scientific reason for prohibiting CMPAF in animal feed other than cattle feed. Preventive measures have been adopted by the feed industry extending from the origin of ingredients to feeding that minimize the occurrence of feeding errors and cross contamination. Inspections and audits by FDA concluded there is 99%+ compliance with the MBM feed ban for ruminant animals. Thus, dedicated facilities, equipment, storage, and transportation to prevent cross-contamination are unnecessary.

If FDA were to prohibit CMPAF from animal feed and feed ingredients, there would be no need to require the handling of these materials through dedicated facilities, equipment, storage, and transportation. The current FDA "feed rule" (CFR21 589.2000) allows renderers to use an approved clean-out procedure for rendering lines used to produce both prohibited and non-prohibited materials. Most independent rendering facilities in the U.S. employ single processing lines. An approved clean-out procedure allowing facilities to safely process both categories of materials is necessary or few facilities will handle prohibited materials, further eroding APHIS access to targeted cattle populations for surveillance. Lack of an approved clean-out procedure would also encourage further expansion of improper and illegal disposal of prohibited materials.

If the FDA requires dedicated facilities, equipment, storage, and transportation equipment to handle CMPAF, it may not be economically feasible for industry to continue processing such material. It would be more likely for this material to be deposited in landfills, resulting in increased environmental exposure because of the high biological load of this material in its unprocessed state.

Dedicated trucks for the transport of CMPAF-containing finished proteins are not economically feasible, logistically practical, or environmentally sound. In fact, there simply are not enough trucks available to do this. The cost of transporting prohibited proteins would more than double if dedicated trucks are required. The agricultural commodity industries use a network of independent trucking firms to transport a variety of bulk commodities throughout North America. The efficiency of this system depends upon the ability to arrange backhauls in close proximity to prior delivery points or even between two plants owned by

the same company. The operation of this network is based upon the ability to haul a wide variety of commodities in each truck. This is an efficient use of resources and reduces the number of trucks on the roadways. The unintended expenses and consequences of requiring dedicated vehicles and creating a new category of "toxic waste" could include expensive or unavailable insurance, unnecessarily expensive spill clean-up regulations, and special DOT placards. Independent renderers without their own truck fleets would be burdened with the cost of establishing their own private truck fleets in order to have dedicated transportation for CMPAF-containing material.

The necessary equipment (installed in the existing plant) to process approximately 12,000 tons of material a year would likely require a $2-$3 million investment at each facility. This would be a fixed investment in plant and equipment of $241 per ton of prohibited material, and annual operating costs of $86.83 per ton to handle and process this material.

The costs of processing such materials could be partially offset by productive use of the resulting by-products, but under current conditions, the meat and bone meal from such an operation would most likely need to be deposited in landfills at additional expense. While some value could be extracted from the tallow derived through this process, it would be insufficient to cover the expected operating costs. The 2005 Informa Economics study (using estimates on tallow yield and prices consistent with those used in the ERG/FDA study) shows for each ton of prohibited material 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.

Poultry Litter

NRA maintains there is no scientific justification to prohibit CMPAF from all animal feed. Even if there is no change to regulations concerning the inclusion of cattle materials in animal feed, there is no scientific basis for the prohibition of poultry litter in ruminant feed. The policy statement made by the CVM in 1998 is still applicable today, "FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract."

In addition, the extremely low likelihood that any feed is contaminated with the BSE agent makes cross-contamination from non-ruminant feed spilled into poultry litter irrelevant, even if the infectious dose were lower than published scientific studies show it to be.

Blood

There is no need to stop the feeding of ruminant blood products to ruminants or any other animals because there is no science to support such a restriction. There is no scientific or peer reviewed literature linking the feeding of bovine blood in the form of blood meal or other blood products in feed to any risk of BSE transmission in cattle and other ruminants. Bovine blood has never been implicated in bovine-to-bovine transmission of either natural or experimental BSE.

Recently, concerns have surfaced over a claim that neural tissue could be observed in the blood collection tank at a commercial beef slaughter facility. While bovine blood does not contain the BSE infective agent, we recognize the possibility that blood could be contaminated with neural tissue and emboli as a result of certain stunning methods. This possibility was considered in the Harvard Risk Analysis and not deemed a significant risk to spread BSE.

If new information elevated the concern of risk from blood contaminated with neural tissue, technology can be employed to remove neural tissue from blood from animals stunned with a penetrating device during processing. Products resulting from processes such as filtering or centrifuging should be allowed to be imported because these steps would remove any particles or tissue residue.

Plate Waste

Plate waste consists of predominantly non-meat products, and with current FDA regulations, CMPAF are extremely unlikely to be included. A conclusion in the 2001 Harvard Risk Assessment states: "Plate waste consists of little mammalian protein, and the tissues that are included in this waste are unlikely to contain BSE infectivity. Moreover, plate waste undergoes a substantial amount of heat treatment, which would further reduce the level of infectivity in this material."

Sanitary collection, processing and regulations that prohibit its use and inclusion in ruminant rations, as with other ruminant raw material, is the most effective method for handling and processing plate waste.

It is important to note used cooking oils collected from restaurants and snack food manufactures are not plate waste. There are no risks associated with this product since it does not contain any CMPAF.

Rendering Dedicated to Disposal

Surprisingly, the disposal of animal mortalities and animal byproducts resulting from the production and processing of meat is not uniformly regulated in the United States. Such materials are unstable and frequently contaminated with viral and bacterial pathogens that may spread to other animals and humans. Disposing of such materials without first processing with heat or chemicals to deactivate conventional pathogens presents a danger to human health, animal health and the environment.

If FDA's proposed rule were implemented and cattle mortalities and CMPAF are banned from animal feed, the incidence of improper disposal will increase, as will the potential for public and animal exposure to pathogens. Development of rendering industry infrastructure for disposal only of CMPAF and dead animals would be a solution for the large volumes of material in need of proper disposal generated under the proposed regulation. A system similar to this exists in Europe; however the EU heavily subsidizes this system.

The problem with developing such a system in the U.S. is that it will not happen unless the economics are favorable—that is, a fair price paid to renderers for the services provided.

Also, without national regulations on dead animal disposal, producers may be more likely to use cheaper, but not necessarily environmentally safe, methods of disposal. Such regulations should provide uniform standards for traceability, biosecurity, and environmental protection and allow only federally licensed or permitted operators to collect, process, and dispose of, or recycle all animal byproducts and mortalities.

Without addressing the above concerns, FDA cannot expect a disposal-only industry to develop. This level of investment can put a company at risk if there is not sufficient material throughput at a profitable rate.

Economic Impact of Rule

The proposed restrictions on feed ingredients would cause the immediate loss of the current market revenue renderers generate from the sale of meat and bone meal (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 SRM segregation and disposal).

According to the 2005 Rendering Industry Study, among renderers that collect cattle and calf mortalities, 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 independent renderers. 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.

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). 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 new equipment. There is some uncertainty about the type of equipment that might be needed and its ultimate cost. For small plants, circular cutting saws to remove the entire head and spinal column, their installation, and disposal bins to collect this prohibited material are estimated to cost from $7,000 to $12,000 per plant. However, plants that process significant numbers of deadstock would require larger saws capable of accommodating faster line speeds, which can easily cost $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 and 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.

Regardless of the capital investment to remove brains and spinal cords at the plant, there will almost certainly be a significant reduction in the speed at which deadstock can be processed. 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.

Summary

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," the new Informa Economics analysis suggests a much larger impact, with the potential for severe economic distress among many renderers.

The new findings estimate the 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 CMPAF 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, the impact exceeds the current threshold in Section 202(a) of the Unfunded Mandates Reform Act of 1995 which, after adjustment for inflation, is $115 million. Federal law thus requires an assessment of anticipated costs and benefits before the proposed regulation can be finalized. Other important conclusions of the Informa analysis include:

- The proportion of deadstock cattle and calves rendered in the United States far exceeds 17%.

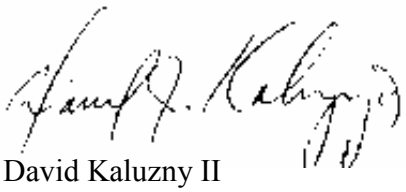
- The proposed rule will severely reduce the number of dead/downer cattle and calves rendered in the United States.
- The reduced availability of deadstock collection services by renderers and higher fees will create a high potential for adverse environmental consequences.
- Reduced sales of MBM and 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.
- Costs of deadstock disposal faced by livestock producers could increase by up to $112 million per year under the proposed rule.
- The capital investment required by renderers and meatpackers to comply with this rule will be significant. The industry-wide capital investment required would be $80,000,000. Annualizing this over ten years at a 7% discount rate suggests annual capital expenditures of $11.3 million.
- Disposal of PCM generated by meatpackers and renderers will be costly, and no universally appropriate methods of handling and disposal have been identified.

The NRA has been and continues to be completely dedicated to following science and risk analysis while regulating to prevent the introduction, amplification and spread of BSE. However, our analysis of the facts make us believe FDA's preliminary conclusion to remove cattle brains and spinal cord and rendered dead animals from all animal feed is not warranted. Actions started over 15 ago have worked well, and analysis of results in both Europe and the U.S., and especially data from the expanded BSE surveillance program, indicate no reason to support the FDA altering the existing feed regulations.

The 1997 feed rule is working and compliance is extremely high. The USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 548,786 surveillance samples from high risk groups over the past 15 months showing the incidence of BSE in the U.S. to be near zero.

If the FDA has questions regarding comments from the National Renderers Association, they can be directed to Dr. David L. Meeker, Vice President, Scientific Services, at dmeeker@nationalrenderers.com or by phone 703-683-2263.

Respectfully submitted by:



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