CENTER FOR BIOSECURITY, FOOD SAFETY, & PUBLIC HEALTH

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

Dear Sir or Madam,

The Center for Bio-security, Food Safety and Public Health (CBFSPH), a registered corporation in the State of Florida, references FDA's Docket No. 2004N-0264, the agency's advance notice of proposed rulemaking (ANPR) invitation to comment on federal measures to mitigate BSE risks: Considerations for further action. Under separate cover, CBFSPH will mail copies and the Docket references to the two agencies (APHIS and FSIS) of the Department of Agriculture with an interest in this ANPR.

CBFSPH (further defined as the Center in this communiqué) is aware that the three agencies are considering added safeguards and other considerate options based on recommendations of an international review team (IRT) that reported to the Secretary of Agriculture in the latter part of January of this year. As a Center, we are also aware of the background of BSE, the regulatory/policy initiatives instituted over the years, the surveillance and testing, including the emergency response programs, the Harvard-Tuskegee Risk Analysis (HTRA), the relevance of the BSE case in Washington State and the subsequent comprehensive investigations and analyses. This obviously includes the epidemiological determinants and defining of risks as perceived by the international team of specialists convened by Secretary Veneman. (The Center also plans to make comments applicable to the Interim Final Rule Use of Materials Derived From Cattle in Human Food and Cosmetics, and the Proposed Rule – Record-keeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle.)

To expedite optimally the use of time during the short time frame limit of 30 days for comments required by FDA, the Center will address directly the many questions posed for mitigation in the ANPR.

Based on USDA's (APHIS) requests:

1. Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?

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Actually, as a note of interest, the original BSE committee appointed by APHIS early in the 1990s to serve as a broad overview of BSE (and the other transmissible spongiform encephalopathies in general) covered a broad representation from government (both research and regulatory), academia, and industry professionals with an interest in the disease, was never officially disbanded. It served as a standing committee until 1996 and met regularly at different university settings throughout the country or at federal facilities e.g. Riverdale, Ames, University of Wisconsin (Madison) etc. The genesis of vCJD in May of 1996 in the United Kingdom put the entire subject at a different level, and the standing committee was no longer used as a resource and became non-functional.

A committee as proposed (the name is immaterial) could serve as a benefit to government by following the trends of BSE and related diseases globally and sharing information, including keeping up with the published literature and research, and the overall epidemiology and state of the art of these diseases. The discussions emanating within the committee's deliberations could be of value to the government, and could take the form of recommendations like is traditional with most standing government committees today. The important ingredient for the success of any committee is bringing dedicated people with a broad knowledge of the disease (s) who are prepared to devote time and energy by active contributions.

FSIS and FDA requests:

2. 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?

Research findings have clearly indicated that the distal ileum is the tissue in cattle where the infectious agent is first detected, as early as 6 months post-exposure in many cases. (Ref. Bovine spongiform encephalopathy, M.J.Prince et al. Rev. sci. tech. Off. Int. Epiz. 2003, 22. (1), 37-60.) FSIS' requirement for the removal of the entire small intestine obviously takes care of the infectivity factor. On the other hand, if a processor can develop a program, on principle, whether it is practical or not, to remove only the infectious tissue, the agency would be hard-pressed to prevent such a program, unless it is proven to cross-contaminate other edible tissue or result in adulteration.

FDA seeks comments on:

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or 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?

The removal of SRMs from cattle feed has been consensually accepted internationally as central to the control of BSE. This has been referenced in the published literature and recommended by regulatory agencies, including the World Health Organization (WHO), as mandatory to prevent transmission and amplification of the disease. The regulatory pertinence in the United States is whether SRMs should be removed from all animal feed to preclude cross-contamination of ruminant feed or potential feeding errors at the farm level

Based on the current feed rule, processing and sourcing practices in the rendering/feed industries, and the FDA findings that compliance with the feed rule exceeds 99 percent, would not provide supporting evidence to necessitate removal of SRMs from ALL ANIMAL FEED. The controls in place in rendering and feed manufacturing and the compliance with the feed rule should make this concern moot. Granted, the IRT made inference to the European experience of cross-contamination and the concerns of the low infectious dose of the agent needed to transmit disease as rational considerations and "lessons to learn from" for others, the assumption of the IRT is that there is risk equity between Europe, with 99.6 percent of all BSE cases and the United States, with one reported case in a Canadian imported cow. This would disenfranchise manufacturers of animal feed and producers who have done everything possible to preclude the entrance of BSE and possible amplification of the disease in this country

While human error is always a possible factor in anything that is done in life, there is no indication that on-farm feeding errors or cross-contamination of ruminant feed with prohibited material takes place.

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

Assuming that SRMs are prohibited from animal feed, the SRM tissues prohibited should be contextual to risk, and the human food policy should not be the same for SRMs going into animal feed. As an analogy, the SRMs going into the rendering/feed chain would be subjected to the rigorous temperature of processing that although would not completely

inactive the prions, the assumed causative agent of the TSEs, would reduce the infectivity by likely more than 2 logs. Also, all regulatory agencies need to remember that by eliminating just the brain and spinal cord infectivity would be reduced by 90% (Ref: Assessment of the risk factors related to bovine spongiform encephalopathy, Morley, RS, Chen S. and Rheault, N. Rev. sci. tech. Off. Int. Epiz. 2003, 22 (1), 157-178. In essence, the options must be put in perspective based on risk. Another important consideration, reemphasizing, the elements of risk is that rendered products (animal proteins of interest to the subject) would be at an inclusion rate level in animal feed rations varying from 3-5%. This minimizes risk potential even when the infectious dose that transmits the disease is very small.

A sensible option that would work well, and reduce infectivity markedly based on risk is just the removal of the head alone with 64% of infectivity. That could be readily handled by renderers instead of the other burdensome approach of removal of all SRMs.

Writing regulations must be coordinated with the scientific information available, and not on conjecture or what is convenient, and should be based on minimization and elimination of risk.

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

Currently, the only official method available for the detection of mammalian meat and bone meal (MBM) in animal feed is inspection by feed microscopy. The method depends largely on the presence of bones and allows differentiation between bones of terrestrial animals. The method can distinguish between mammalian bones and poultry bones.

The method is time consuming, laborious, costly, and depends on the experience of the microscopist. Other methods are being developed e.g. polymerase chain reaction (PCR), enzyme-linked immunosorbent assay (ELISA) and near infrared microscopy (NIRM), and near infrared spectroscopy (NIRS) that may serve to identify/verify in the future. But, currently, there are distinct limits for verification (Ref: An overview of tests for animal tissues in feeds applied in response to public health concerns regarding bovine spongiform encephalopathy. Gizzi, G. et al Rev. sci. tech. Off. Int. Epiz. 2003, 22 (1) 311-331.)

New technology using markers like glyceroltriheptanoate (GTH) can be added to the raw material at the transport screws. The GTH dosage pump would automatically switch on when the screws are working. A sample can be taken every 8 hours of the products. The findings indicate that the

added GPH is found in every sample. CCL Research in the Netherlands can be a resource for further discussions.

6. If SRMs 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 SRMs?

Prohibited SRMs can be handled to prevent cross-contamination by the use of color decharacterizing agents and proper marking and labeling of containers, as currently used in FSIS facilities for control and movement of product. A problem could develop in cattle slaughter plants that kill cattle across different age limits e.g. a plant killing "fats" and adult cattle, but that in no way modifies the above recommendations

7. What would be the economic and environmental impacts of prohibiting SRMs from use in animal feed?

First, SRMs should be limited in cattle food rations only, and not in animal feeds for species not susceptible to BSE or a BSE-like disease e g swine, poultry etc. The economic and environmental impacts could be severe and would not be fully appreciated until actual assessments are made instead of extrapolated projections. Studies done for the National Renderers Association (NRA) in the past by the Sparks Company provided a detailed analysis of the negative impact and are available for the agencies' evaluation. Also, many companies could provide individual perspectives of both the economic and environmental impacts associated with prohibition of SRMs use in animal feed. Attempting to provide a useful assessment of this impact is a comprehensive professional undertaking and cannot be achieved within the established response timeframe, other than to suggest that the non-use of SRMs in all animal feed without scientific justification mocks justification.

8. 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?

There is no data available or reported in the medical literature to implicate any relevance of disease transmission to humans of a transmissible spongiform encephalopathy linked to animal feed including pet food. One could speculate that the worst-case scenario could be

associated with people exposed to the slaughter environment where (cattle) nervous tissue provides the greatest exposure potential, and epidemiological assessments have never determined an increase in cases of v-CJD or another human TSE like classical CJD in workers in this environment. The infectious titer from these potential exposures to humans would be great compared to the infectious titers based on inclusion rates of animal proteins (of ruminant origin) in processed animal feeds, including pet food.

This potential exposure has no supporting epidemiology to make it a relevant concern to support SRM removal from all animal feed. If feed, including pet food, was or had the possibility to be an "infectious vector," there would have emerged some evidence in sectors of the world e.g. Europe with over 99% of the disease (BSE). I have personally visited rendering facilities in the United Kingdom with contaminated meat and bone meal, and never considered that route (mere exposure) a source of infection.

We are still basing our concerns on the assumption that BSE exists in the United States. Without an infectious agent, and an infectious dose, there is no likelihood of disease transmission.

FDA seeks comments on the following:

9. 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 SRMs 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?

There is no scientific data that specifically addresses the necessity for dedicated facilities, equipment, storage and transportation for the prevention of cross-contamination in the United States, and it would take time to do a comprehensive assessment of the need if FDA were to ban SRMs in all animal feed. Certainly, it could not be done with the FDA's ANPR timeframe

An analogy could be made to Europe where BSE is epidemic and controls in many of the countries of the European Union (EU) embraced one or more of the projected controls mentioned in this ANPR. Interestingly, in spite of all the instituted prohibitions and preventive controls there are still cases of BSE born after the reinforced ban (BARB) that appear to be

in excess of what would be normally anticipated with lack of compliance (Wilesmith, United Kingdom).

And, while in the EU the general prevalence of BSE has markedly decreased, there are still BSE cases being reported as of this writing, albeit at a very reduced rate.

Prohibiting SRMs from other than cattle feed in the U.S. is not indicated based on the existing epidemiology and compliance with the feed rule (over 99%), including the country's BSE incidence and risk factors, making moot the need for dedicated facilities, and the lack of scientific validation to include any prohibition other than in cattle feed.

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

A lot of companies have accumulated preliminary data on the economic and environmental impacts of the requirements. Most of this information is not representative of the entire rendering/feed industries and is incomplete. Doubtless, the agency proposing the requirements must have also done evaluations, and it would be of benefit to good government – industry relations to see the government's projections and thinking on the subject.

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

In its initial final rule, published June 5, 1997, FDA explained that the need for regulatory action is based on the risk that BSE will be established and proliferate in the United States. Fortunately, seven years later this has not occurred. In the interim, concurrent with the rule in which the agency defined applicable and appropriate cleanout procedures that would be acceptable, supported by a comprehensive set of guidelines (guidance documents) describing the procedures to comply that included equipment modifications by the regulated industries. Now the agency resurfaces the same question in spite of excellent compliance and no evidence that the risk factors have changed in the country to transmit or cause amplification of the infectious agent of BSE, other than a recommendation by the IRT, that brought a definite European bias in their recommendations and assessments of risk. (Reference: Federal Register: Part II, Department of Health and Human Services, Food and Drug Administration: 21 CFR Part 589, Substances Prohibited From Use

in Animal Food or Feed, Animal Proteins Prohibited in Ruminant Feed, Final Rule, June 5, 1997.)

FDA seeks comments on the following.

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

There is no scientific data that supports the banning of all mammalian (other than ruminant derived) and avian MBM in ruminant feed. The early epidemiology by Wilesmith in 1987, who identified MBM as the probable vector of BSE, was followed by the U.K. government introduction of measures to prevent further infection by instituting a ban on incorporating ruminant protein in ruminant feed. This had a dramatic effect in reducing to a fraction what has been an escalating rate of infection. The report further states that the cases of BSE identified between 1986 and 1988 were not index cases, and were the consequences of recycling of cattle infected with BSE itself. The BSE agent was spread in MBM (Ref: The Phillips Commission. The BSE Inquiry: The Report. The Inquiry into BSE and variant CJD in the United Kingdom, 2000.) Therefore, whatever the origin of BSE, it should be evident that the infection was recycled and amplified in the form of cattle material from infected cattle.

Using the United Kingdom as inference, it is obvious that under that country's farming system that pigs and poultry have undeniably been exposed to the infectious agent of BSE. They also consumed the same ruminant protein that gave rise to the BSE epidemic in cattle, but there has never been any evidence of disease transmission to these species. Further experimental evidence has shown pigs to be resistant to oral exposure with BSE-infected cattle brain. Studies in domestic chickens indicate that they are resistant to both parenteral and oral challenge. Basically, we are dealing with a unique cattle disease, period! (Ref: The potential for transmissible spongiform encephalopathies in non-ruminant livestock and fish. Matthews, D., and Cooke, BC: Rev. sci. tech. Off. Int. Epiz. 2003, (22 (1), 283-296.

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

Refer to answer of question 12. There is no scientific data to imply risk with the feeding of other than ruminant-derived proteins to ruminants.

The science simply does not support that type of control measure unless the country was in the midst of a BSE epidemic, and all the traditional efforts or initiatives had completely failed to minimize the spread of the disease.

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

Due to the time constraints of getting the opinions of a broad representation of the economic and environmental impacts associated with mammals other than cattle and avian products from ruminant feed, the raw numbers should provide a quick insight to both the economic and environmental consequences – we slaughter and process close to 8 billion chickens (turkeys not included) and about 100 million pigs. There is no need to amplify the negative economic and environmental consequences if these materials cannot be used in ruminant feed.

15. 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?

First, there is no scientific or peer review literature that links the feeding of bovine blood in the form of blood meal or other blood products in feed poses any risk of BSE transmission in cattle and other ruminants that will permit an agency to take regulatory action at this time. Blood infectivity has not been found in BSE-infected cattle (Ref: Evaluation of the Potential for Bovine Spongiform Encehalopathy in the United States, Harvard Center for Risk Analysis, November 2001.)

"Blood, bone, certain other tissues, and tallow do not transmit TSE to the experimentally exposed mice whereas samples of brain, spinal cord, eyes, and some areas of the intestinal tract from cattle that died of BSE transmit a TSE to the mice." This was a reference quoted in the Federal Register by FDA in the agency's consideration during the 1997 rule to permit blood (blood meal) and blood products in feed. Nothing has changed to refute that position.

COMMENT: There have been all types of suggestions in research settings that heighten the issue of the safety of blood. Some of the research did amplify worst-case scenarios with attempts to extrapolate safety relevance, especially with blood transfusions in the human etc. The issue should remain is processed blood safe to use in feed, considering its potential to transmit BSE - the answer should be yes, even in ruminant feed

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

None. There are approximately 6 processors of plate waste in the country, and bakery products comprise approximately 90% of all plate waste going to animal feed. The "waste" is predominantly non-meat products and it has been determined that infective tissues of ruminant origin are extremely unlikely to be included in plate waste. A conclusion in the 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." (Ref: Harvard Center for Risk Analysis: Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: A Report to the Department of Agriculture, November 26, 2001.)

17. If FDA were to prohibit SRMs 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?

To recapitulate, the agency should not consider prohibiting SRMs from all animal feed. There is no scientific justification for doing so. The analogy to the safety of poultry litter remains a comment made by Dr. Joe Gibbs (now deceased and formerly of NIH), without any supporting scientific data or references from the literature to uphold his opinion. It was nothing more than an opinion and I attended the meeting that the remarks were made – simply, Dr. Gibbs stated that he thought that the infectious agent of BSE could survive the gastrointestinal tract of chickens.

More logical and sensible was the policy statement made by the Center for Veterinary Medicine (CVM) as early as June 14, 1998, and is still applicable today in spite of the sensationalism of the subject. "FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract."

Worst-case scenario calculations were used to assess any likely risk associated with the feeding of poultry litter to ruminants. The calculations assumed that ALL ANIMAL PROTEINS used in poultry rations are of ruminant origin and yet determined that a range of 0.23% - 0.28% resulted in ruminant protein in poultry litter. Also, collaborative discussions with sectors in both the poultry and cattle industries indicate that approximately 1% of all poultry litter generated is fed to ruminants in

the United States (Ref. McCaskey, T. Microbiologist, Auburn University – Personal Communication).

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

Many studies from the involved sectors have been shared with FDA on the economic and environmental impacts, especially representatives from blood processors and the poultry industry. Collectively, the dual impacts (economic and environmental) could be very great on the industries. But, the collective impact would take a long time to determine and involve working collaboratively with different industries to assess the results and establish a commonality of findings. It would be of interest to see the data that the agency itself has generated over the years on this subject, and in a benefit to government – industry relations, recommend they be discussed objectively.

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, 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%?

No. Research to substantiate and validate any potential for BSE transmission to cattle by tallow impurities would take years. The determining factors would be research in experimental models (e.g. mice) with titrated levels of the tallow impurities to assess the transmission potential. But, there are extensive research findings to indicate the safety of tallow contextual to BSE transmission.

The World Health Organization (WHO), as early as 1991, assembled specialists in the transmissible spongiform encephalopathies (TSEs) and determined that tallow was safe, and not a risk to animal or human health. The organization went on further in comments in 2001 to conclude that because of the proteinaceous nature of the TSE agents, they will tend 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 (Ref: World Health Organization, Geneva, Switzerland, 2001.)

A rendering study funded jointly by the European Union (EU) and the Ministry of Agriculture, Fisheries, and Foods (MAFF) in 1997 showed that tallow can be considered safe even if its treatment does not achieve the 133C/20 minutes/3 bars of pressure minimum treatment standard. (Ref: Taylor et. al. 1997, MAFF 2001). The Harvard Center for Risk Analysis (HCRA) referenced this study and determined that the

assumption is that recycling this material poses little risk of exposing cattle to BSE (Ref: Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States – November 26, 2001.)

Work done by Taylor and associates at the Animal Health Institute (AHI) in Edinburgh, Scotland, which has become the premier reference on the safety of tallow indicates that: (1) epidemiological studies failed to find any association between the occurrence of BSE and the consumption of tallow by cattle; and (2) in BSE spiked rendering studies, NO INFECTIVITY was detected in CRUDE, UNFILTERED TALLOW produced by a traditional rendering procedure.

The research findings were validated by injecting homogenates of spiked-BSE infected tallow intro-cerebrally (IC) into experimental mice and could not demonstrate the classical spongiform changes associated with transmissible spongiform encephalopathy (TSE), even after a prolonged period of observation. Ref. Taylor, DM, Woodgate, SL. Rendering Practices and Inactivation of Transmissible Spongiform Encephalopathy Agents. In Risk analysis of prion diseases in animals. World Organization for Animal Health (OIE), Vol. 22 (1), 2003.

Realistically, there is not even a need for establishing a level of protein residues as risk based on these references and research findings. If an impurity level is established, it should be done through commerce, and not regulatory.

20. Can SRMs 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?

This question is impossible to answer without a detailed analysis of the economics involved and whether or not the investment in labor, equipment, facilities, and other associated costs of SRM removal would be worthwhile. One analogy is that anything could be done for a price, but the reality is that costing has limits.

The removal of SRM from dead stock and non-ambulatory cattle during the summer months in most parts of the country could be problematic dependent on time, possible tissue degradation etc.

The suggestion, however, that it may be necessary to prohibit carcasses of both dead and non-ambulatory ("downer") cattle from rendering and eventual use in all animal feed is not validated by science, nor even determined to be a risk factor to other than ruminants. The other

consideration is the environmental (and economic) burden of getting rid of this volume of raw material and whether the benefits can be affirmed by excluding material that does not pose a risk to certain species e.g. swine, poultry etc.

We need to remember that, contrary to common belief, MBM began to be introduced into feeds for cattle more than a century ago (Ref: Protein nutrition for ruminants in European countries, in the light of animal feeding regulations linked to bovine spongiform encephalopathy, Sellier, P., Rev. sci. tech. Off. Int. Epiz., 2003, 22 (1), 259-269. And, until the promulgation of the feed rule in 1997 in the U.S., MBM was fed without disease incident to cattle. Why in a country like England change will occur after over a century of the feeding practice, remains a challenge to all with an interest in these diseases?

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

Refer to answer of question 5. To reiterate the only official method available for the detection of mammalian MBM in animal feed is inspection by feed microscopy. Commercial ventures have developed test kits that show great promise and applicability e.g. ELISA, that could help the verification process.

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

The National Renderers Association (NRA) through contract with Sparks Commodities had an extensive analysis of both the economic and environmental impacts that reflected the situation through the year 2001. That data is obsolete and a new analysis is needed to determine the currency of the industry. That will take time to complete.

APHIS welcomes comment on the following:

23. What other innovative solutions could be explored?

The rendering industry recognizes that government plays an important role as a resource to provide advice, direction, and an examination of options in situations that could involve negative economic consequences due to the promulgation of rules, and takes this opportunity to commend the agency for this approach

The rendering industry is innovative and its success has been based on its ability to adjust and conform to change, including the acceptance of new economic initiatives. The pilot projects (renewable energy systems) alluded to as potential investments for the continued utilization of material that could be prohibited from traditional uses is excellent government – industry relations. These novel initiatives, however, may not apply to many of the smaller operations without meaningful incentives.

The energy options while promoted and make sense, create other barriers with government agencies like the Environmental Protection Agency (EPA) that may place burdensome requirements for the applicability of these materials e.g. protein as a fuel source, unless a coordinated effort by the agencies involved takes place to examine the impact/benefits to the programs proposed

That acceptance of goodwill, nonetheless, does not deviate from the industry's recommendation that the writing of rules must be scientifically affirmed and with risk relevance in the case of BSE, and prays the agency will follow that principle.

24. When and under what circumstances should the program transition from voluntary to mandatory?

One of the most applicable recommendations of the IRT is the importance of effective identification and traceability systems in disease control and surveillance. This is a mandate that cannot be ignored. The process of doing so is not simple and needs to be phased in over a period of time, but the objective should be the establishment of a mandatory system of ID/traceability as soon as possible. The discussions have been ongoing for decades, now is the time to act. New emerging technology like radio frequency technology for cattle could be considered versus visible identification tags. The swine industry has had mandatory identification requirements since 1988

25. What species should be covered, both initially and in the longer term? Specifically, should the initial emphasis be on cattle, or also cover other species? If so which? Which species should be covered by the program when it is fully implemented? What priority should be given to including different species?

A national identification program should cover all species in the food production cycle as a priority. Initially, because of the existing pertinence of cattle to BSE and the other planned controls that will take place by

regulation, it would seem initially that cattle should be prioritized in the plan. As mentioned earlier the swine industry has mandatory identification for years. The sheep industry can use a system that has worked for them with the scrapie program. The poultry industry, albeit, somewhat unique from an individual identification standpoint should be a part of the national initiative, and they should be able to put a plan in place. The bottom line is that a comprehensive, coordinated, integrated surveillance system is the foundation for animal health and food safety, and cannot be successful without a program of identification and traceability

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

The Center is very supportive of the IRT recommendations that BSE educational programs must be designed to cover a broad spectrum of the population with different levels of scientific training or knowledge

The efforts should address a wide range of topics to satisfy the needs, among them is the option for government informational material to include graphics/pictures with explanations written at a 9th grade level with questions and answers on some of the basics e.g. issues associated with food safety and BSE that the average consumer is most concerned about. Emphasis should overview the surveillance program in place, including the testing rationale should be highlighted so consumers and the public get a sense of the whole picture. This can take the form of brochures, videos, cassettes, or even a "comic book" type format for the less informed.

The educational materials should also address in detail the major aspects of risk and what the government has done to prevent the disease that will foster public trust and confidence in government policies and the safety of the food chain. Interestingly, APHIS has done a lot in print of all the relevant TSEs, and should be commended for these efforts. But, a need still exists to broad the scope of information to be more inclusive.

27. How can the Federal Government increase access to these materials?

A lot of valuable information about BSE and other information are already in circulation. Informed people with an interest in the disease and similar type diseases are aware of how to access needed information through the applicable agencies and the internet etc. That is not the target population. The media briefings also serve as a valuable resource for disseminating information. The hope is that it is further transmitted with

objectivity, and devoid of the sensationalism that now seems traditional with these diseases!

The challenge is how to get materials that provide good information to a broader "audience" – the average housewife, high schools, teachers, the bus driver, the waiter/waitress, the minister. That should be part of the objective for broader dissemination.

FDA has an interest in the following:

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

Absolutely. That is being progressive. The entire philosophy in dealing with the "encephalopathies" should be to keep an open mind. We have learnt so much since the initial report of BSE in 1986, and likely will continue to learn as new research/information is generated. Some hypotheses that were considered sacrosanct in the early epidemiology e.g. that BSE resulted from the consumption of scrapie-infected meat and bone meal has been proven fallacious. Realistically, the cause of the disease still has to be validated. Caution and objectivity, including ongoing risk assessments should be encouraged.

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

There are different methods currently applied for the analysis of feed (refer to question/answer 5) – microscopy, immunoassay, PCR and spectroscopy. There is no ultimate approach that would fulfill all requirements. FDA has to decide in the evaluation of the performance of the test the purpose of the analysis e.g. enforcing the ban of MBM in ruminant feed would require a method that allows for the determination of mammalian tissue in feed, whereas the prohibition other type tests would require a species-specific analysis etc.

The bottom line like all other test approvals is to establish a list of parameters for approval and have a review process to determine whether the criteria for approval is met. The agency is fully aware of this! Considerable progress has been achieved with PCR, except that the sensitivity approximates forensic levels that could be problematic.

30. Do FDA's existing authorities under the Federal, Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in non-ruminant animal feed (e.g. feed for horses, pigs, poultry etc.) notwithstanding that such materials have not been shown to pose a direct risk to non-ruminant animals? More specifically, under FDA's existing authorities, would the potential occurrence of on-farm feeding errors of cross-contamination of ruminant feed with SRMs and other cattle material, or of human exposure to non-ruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

FDA, in an effort to profile its authority to promulgate rules under two existing acts, poses a very important question that must be addressed. It is a troubling question that must be examined objectively, however, and begs, does the agency have a legal basis to ban the use of SRMs and other cattle material in non-ruminant animal feed that has not been affirmed by science to pose a direct, or indirect for that matter, to non-ruminant animals?

Obviously, the courts have at times ruled on the limits of an agency's authority when challenged, and the Center is of the opinion that the agency is taking the adulteration clause to an extreme regulatory limit, even bordering on a "stretch" of the flexibility of interpretation. This is a disappointment, because the agency should serve as a "guardian" of the science-based approach in formatting rules, and every responsible individual condones and supports the agency's efforts to provide for the general health protection, welfare, and safety of the American public. Historically, in their wisdom, the courts have also supported this tenet. But, the agency has enough authority to protect animal and human health based on the existing science without resorting to an embrace of an extreme approach, even in an environment of "an abundance of caution."

There was minimal or no dissent within the rendering/feed industry when based on compelling epidemiology from the United Kingdom that BSE had a likely link to a newly defined disease,v-Creutzfeldt-Jakob, and the agency's subsequent decision to format a rule that became final in 1997, to protect animal and human health, and preclude the "transmission and amplification" of the infectious agent of BSE.

During one of the early meetings with the agency and in recognition of its role in preventive controls, the rendering industry made an immediate commitment, much to the surprise of the agency leadership, that it was willing to fully support the planned regulatory proposals. The industry's commitment in 1996, and subsequent efforts have been reflected in the

FDA's compliance findings over the past 3 years. That is a reflection of the "perfect world" – coordination of effort and cooperation for the common good between the regulated industry and government.

The agency continues to question its legal authority by posing another pointed question that involves "potential occurrence" of errors to include human exposure to non-ruminant feed (including pet food), and other elements of cross-contamination that could provide a basis to ban SRMs and other cattle material from all animal feed.

Herein, lies a serious concern. If we attempt to use legal authority to address the possibilities of "potential occurrence" of errors, we now have a challenge that threatens the limits of rationality. The mere word potential is problematic, and means existing but not fully developed or expressing possibility (that may exist or happen). And, a link to occurrence would mock interpretation and uniformity. Does one truly regulate anything based on potential occurrence? Does an agency with broad public health authority really need to resort to that type of "grayness" in attempts to promulgate a rule? That is why use of the known and accepted science, in spite of the complex unknowns associated with the TSEs, is the logical regulatory option. Other than that, an agency could mean well in efforts to protect animal and human health as mandated in its mission, but create chaos in the process, and disenfranchisement of many.

The aforementioned in no way provides a basis for the banning of SRMs and cattle material from ALL ANIMAL FEED. To pursue that approach would be close to an abuse of the authority that the agency already has.

31. Are there other related legal issues on which FDA should focus?

No.

FSIS welcomes comments on the following:

32. What measures are necessary to prevent cross-contamination between carcasses?

None. That is not the problem. Disease transmission is the result of an infectious dose infecting a susceptible host. The measures already instituted by the agency to date, and the recognition of the fact that 90% of BSE infectivity is limited to the brain and spinal cord should suffice

Attempts to do anything in the kill floor environment would be senseless and do nothing to protect human health.

33. In establishments that predominantly slaughter cattle 30 months of age or older, are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?

The agency should follow its existing policies for the separation of edible and inedible material. Since SRMs are inedible/condemned, the necessary separation and other controls that are current policy should suffice.

If the agency carefully considers their options for instituting additional sanitation requirements, it would become apparent that with prion diseases, like BSE, there would be severe limits over and above what can be practically accomplished in a slaughterhouse environment over and above controls established by hazard analysis and critical control points (HACCP).

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?

No. The agency should develop its own standards for determining a country's BSE risk and equivalency. In doing so, a careful considerate option could be given to relying on third party validation

35. If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the agency apply to determine a country's BSE status?

Refer to previous answer (34). The agency, nonetheless, if an exemption became policy should make a comprehensive assessment of the country's animal health controls, surveillance/testing programs, laboratory support systems, rules and regulations, compliance with existing rules, livestock ID/traceability systems, veterinary professional infrastructure, and compare them with all the preventive controls that are in place in this country and use that as the parameters for the decision-making determinants.

36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

Refer to earlier answers (34 and 35). OIE should not become a factor or party to determine equivalence. Nonetheless, OIE has excellent reference guidelines that FSIS could consider incorporating in its standards and assessments.

SUMMARY

CBFSPH (the Center) enjoys this opportunity to comment on the diverse issues brought by the different agencies involved with the control and prevention of BSE, and the inferences associated with feed/food safety in the process of promulgating rules. The subject is complex, with many unknowns, yet over the years, sufficient information on the prion diseases has evolved to serve as a guide for establishing sound policies to protect animal and human health. Granted, there is a need for more research and resolution of doubts that persist to this day, but the Center is in full concurrence with the risk analysis done by the Harvard – Tuskegee epidemiologists, and the supporting summary that defines the limited risk of disease amplification in either animals or man. This document should serve as the "gold standard" in the development of policies/regulations. There were attributes to the IRT recommendations, but many amplified aspects of risk with a European bias that the Center did not feel presented an objective analysis of the problem. Nonetheless, their input served to force us to look at another perspective, which is not necessarily negative.

While the Center may not agree with some of the directional impetus based on some of the questions posed (exemplified by FDA), it, nonetheless, fully supports the overall efforts made by the government agencies, and commend all for the professionalism and dedication to prevent the infectious agent of BSE from ever being a public health menace to the country. The Center as per custom looks forward to contributing in any way that the agencies involved in protection may deem necessary.

In closing, the Center is of the opinion that all the agencies should consider options carefully and not hurry to publish a final rule without a comprehensive analysis and evaluation of the inputs provided by the many who took the time to respond to the questions posed by the three agencies

Sincerely,

Don A. Franco

Don A. Franco
President