



FATS AND PROTEINS RESEARCH FOUNDATION, INC.

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5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Reference: Docket No. 2004N-0264

and

Regulatory Analysis and Development,
PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, Maryland 20737-1238
Reference: Docket No. 04-047-1

and

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street
S.W., Room 102 Cotton Annex
Washington, DC 20250
Reference: Docket No. 04-021ANPR

This document is submitted on behalf of the Fats and Proteins Research Foundation, Inc. and references the requests for invitation of comments from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS), U.S. Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) and Department of Health and Human Services – Food and Drug Administration (HHS_FDA) as announced in a series of regulatory actions and policy changes in the context of advance notice of proposed rulemaking (ANPR) interim final rules (IFR) and recommendations pertinent to any further necessary safeguards directed at bovine spongiform encephalopathy (BSE) and published July 14, 2004.

2004N-0264

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The Fats and Proteins Research Foundation, Inc. (FPRF) is a nonprofit, non-lobbying organization established in 1962 to coordinate the financial support and conduct of viable research programs that highlight the attributes and safety of rendered animal byproducts/coproducts. FPRF is privately funded primarily by U.S. independent renderers, though including, meat and poultry packing, processing and allied industry supporting members with both domestic and international origin. Via this support, over 550 research projects have been completed by university, private and public research institutions. Research objectives have focused on the use of animal byproduct ingredients defining nutrient and disease prevention initiatives. Projects with objectives directed at alternative uses such as non-feed/non-food utilizations have included biofuels, biodiesel, soil amendments, phase change material applications, catalysts and biosecurity validation of rendering processes have been numerous.

FPRF coordinates and affiliates with other rendering and allied associates namely National Renderers Association (NRA), American Protein Producers Industry (APPI), the Canadian Renderers Association (CRA) and American Feed Industry Association. FPRF is the only research organization devoted exclusively with a research mission for rendered products and processes.

FPRF is in the final stages of formalizing an Animal Co-Products Research and Education Center with Clemson University, Clemson, South Carolina. The organizational documents and agreements are expected to be finalized in October 2004. An inaugural base of nine specific interdisciplinary alternative use and biosecurity projects were initiated in April 2004. As a prelude to the remaining comments, the respective agencies of USDA-APHIS, USDA-FSIS and HHS-FDA are encouraged to become involved, supportive and willing to invest cooperatively to pursue the mission of the only Research Center in the world to focus specifically on animal co-product utilization.

The following will address each of the thirty-six questions posed as Sections to the initial referenced documents.

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

FPRF and numerous other organizations responded to the ANPR request of Docket No. 96N-0135 of 1996 in which an advisory committee, standing subcommittees, research coalitions, enhanced surveillance and routine symposia were all suggested as recommended procedures for FDA to adopt on BSE. The 2004/05 targets adopted for surveillance of BSE is to be commended. However the remaining components of the 1996 recommendations all remain as valuable and necessary actions to be adopted.

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?

Scientific information reports that the distal ileum is a primary infection site in cattle with the infective agent detected as early as 6 months. Confirmation of the conclusions developed from a bioassay infectivity study concluded that pathogenesis of BSE is initiated in the distal ileum. The study demonstrated the presence of infectivity at the distal ileal site at 6 months of age. The low level infection identified in this study

compared to that reported for central nervous tissue (CNS) was the result of tissues derived from animals in which experimental inoculations, using extremely high infective dose rates that do not replicate the concern for oral transmission via animal feeds that contain a relatively low level of infective material and fed at rates generally used in formulating ruminant and other animal species diets. The conclusions based on the referenced study requires replication. However on the basis of the current data, if the distal ileum can be aseptically removed from the other portions of the intestinal tract or by necessity the entire intestinal tract or gastrointestinal tract because of practicality it cannot be aseptically removed, the removed tissue however should be withheld from entering the human food chain.

The current prohibitions, as defined in 62FR303936; June 5, 1997: codified at 21CFR589.2000 is specifically directed at preventing infectious tissue presence in animal feeds or ingredients to be fed to ruminants. Thus there is no need to remove these tissues from the animal feed chain.

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?**

Based on the current feed rule as referenced in response to question 2, there is no scientific evidence to support the removal of SRM's from all animal feed. Preventive measures have been adopted by the feed industry extending from the origin of ingredients to on-farm feeding practices that minimize the occurrence of feeding and cross contamination. Documentation has been well established that the current feed rule has been implemented with an unprecedented compliance record. The IRT referenced "lessons to be learned from others" but failed to discuss the importance of compliance. The results of non-compliance and the lack of effective regulatory analytical confirmation for compliance and its relationship to ineffective control of regulations and incidence of infection was not however referenced.

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?**

As referenced previously, the regulations and/or policy for human food should not be the same as that for animal feed in respect to SRM's. Additionally it seems redundant to emphasize again that the "ruminant to ruminant" feed rule, the established validation for compliance and the potential for any transmission via cross contamination, errors and the knowingly low inclusion of animal protein in livestock and poultry rations all minimizes potential risk. Any further regulations should be considered only if further surveillance data identifies animals diagnosed with BSE infections that were born after the current feed rule became effective and epidemiology documentation is made that reveals no violation of the feed rule was implicated. The separation of cause and effects must be

established in a manner that does not punish the complaint ingredient suppliers, feed manufacturers and farmers with undue consequences.

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

Currently, all analytical methods for detecting individual species or specific tissues from any given species are compromised in respect to specificity and sensitivity. The official method for differentiating mammalian meat and bone meal in animal feed is via microscopy in both the U.S. and the U.K. The technique requires a significant input and interpretation in terms of operator expertise. The number of trained Feed Microscopists in the U.S. is extremely limited. With the exception of differentiation between terrestrial and fish, species detection capability is extremely limited. There are no detectable differences in mammalian bone or muscle fibers among species. Soft tissues such as brain, spinal cord, lymph nodes, and even smooth muscle tissue (distal ileum) are not detectable following post rendering procedures or even after limited autolysis.

Other analytical procedures include various adaptations of the enzyme-linked immunosorbent assay (ELISA) and polymerase chain reaction (PCR). Both have limitations in specificity and sensitivity. An ELISA analysis is commercially available for detecting ruminant tissue in both animal protein meal and formulated feeds. These (Reveal® Test Kits – Neogen Corporation, 620 Leshler Place, Lansing, Michigan 48912) analytical products have received AOAC validation and have been shown to be assets in monitoring errors in labeling or cross-contamination should they occur.

FPRF is currently supporting basic research at Florida State University with the objective of enhancing species detection analyses technology. The agencies are encouraged to be much more supportive in assisting with pursuing the private sectors initiatives in this research and development process.

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

There is no current scientific evidence to support the removal of SRM's from animal feed. But, should the "abundance of precaution" prevail over science the prohibited SRM's must be accompanied with specific required processing and disposal regulations, procedures to identify the material with an easily detectable assay such as the use of micro tracers, specific dyes etc. Different categories of SRM's, such as would be the case with that derived from different age groups or segments of the cattle population (non-ambulatory, fallen animals), would provide problematic identification of material source. Should SRM's be removed from the feed chain, proper handling, processing and disposal methods have not been determined and pose environmental, human and animal health hazards that are unrelated to BSE, and hazards that remain for years as very possible contaminants to water, soil and air. This fact was appropriately pointed out in the International review Team (IRT) report. Certainly if these tissues are determined to be

hazardous in feed, they must certainly be determined to be hazardous to our environment. Recent data has suggested that chronic wasting disease (CWD) is transmitted by environmental exposures. The procedures of collection, transport and proper processing must be articulated. The rendering process and infrastructure is currently the only regulated entity meeting these requirements.

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

The environmental and economic impacts as referenced in question 7 are anticipated as being severe, significant and not fully assessed but is critical to the biosecurity to both human and animal health. The allowable time frame for assessment is too limited to fully and accurately project consequences. Past economic studies have been provided by the National Renderers Association for the U.S. and by the Canadian Renderers Association for Canada. Both detail negative impacts, even though Canada has greater land volume per human or bovine population when compared to the U.S. which lessens the environmental impacts of hazardous disposal options such as burial, landfilling and composting. However, these and other options are problematic for both economic and environmental tragedies

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 are no data known to implicate any transmission of transmissible spongiform encephalopathies to humans via animal feed including pet food whether exposed via ingestion or contact. Demographic data have not differentiated a higher incidence of CJD or vCJD cases by occupation or incidence of exposure to known infected bovine or slaughter house environments such as farmers, dairy employees or meat processors. The inference of oral transmission of CJD or vCJD from BSE infected beef still remains to be scientifically confirmed other than empirical association. Therefore without supporting data as requested in the first question of section 8, there is no relevant concern or justification for supporting SRM removal from all animal feed as suggested in the second question of section 8.

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?

The feed industry has a long and documented history as well as medicated drug records that provides data that with proper manufacturing practices, cross contamination is

prevented without the necessity of dedicated or duplicated facilities, equipment, storage and transportation vessels. The rendering industry as an important and economic supplier of feed ingredients to the feed industry abides by similar manufacturing practices of Good Manufacturing Practices (GMP's), Hazard Analysis and Critical Control Point (HACCP) and ISO 9000 programs that also negates the need of dedicated or duplicated facilities.

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

The time frame provided for responses will not allow a comprehensive economic assessment resulting from duplicate facilities from start to finish for the manufacturing and transportation of feed. A 30 day time-frame is not sufficient to project costs any more accurately than billions of dollars to the feed manufacturing, ingredient industries and the producers of U.S. meat, milk, eggs, fiber and bioenergy.

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?

The data provided for surveillance provides a base of confidence that BSE is being controlled with the current feed rule published June 5, 1997. Past surveillance criteria for the U.S. cattle population has exceeded the scientific risk assessment guidelines as published by the Harvard-Tuskegee Study as well as those established by numerous international organizations that included the World Organization for Animal Health (OIE). The current concentrated surveillance program to examine over 200,000 bovine animals from targeted risk population segments is to be commended. The initial completed tests from the enhanced program now nearly equal past annual numbers (28,000) with negative findings. These and past surveillance data would suggest that adequate protection is in place and cross-contamination from "possible" or "abundance of caution" requiring SRM exclusion from all animal feed from occurring or any further necessary actions required. The data obtained from the intensive surveillance program underway should be completed, evaluated and guide any further actions.

Historically the feed and ingredient industries have been charged with guidelines and regulations that reference cross-contamination and clean out procedures. Namely, the medicated feed issues of the past, is remindful of the investments made in equipment modification and drug assays to document compliance in preventing cross-contamination that meet stringent requirements. Therefore, defining the parameters of cross-contamination in the context of prohibited substances in animal feed certainly has been done by the agencies in the past using analytical procedures of greater proficiency than those currently available for SRM sensitivity and specificity. The feed and ingredient industries with over a hundred years of experience in providing nutrition to billions of animals have provided empirical data and demonstrated that it is being done.

FDA seeks comments on the following:

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

There are no scientific data that supports the banning of all mammalian and avian MBM in ruminant feed. There are no scientific data presented or available to support the conclusions that the two North American BSE positive cases were the result of oral transmission from the consumption of “infected” animal proteins meals.

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?

The questions (Section 13) as stated infers that there is scientific data to support the “required” action to remove SRM’s from all animal feed. To the contrary there has not been scientific data published to support that requirement. Additionally there are no scientific data to support the amendment of the existing feed rule.

There have been two North American cases that has not been scientifically proven to be the result of the actual transmission from animal feed. The epidemiology in both of these specific cases have been the result of the “idea” that they acquired prions from their feed. The North American BSE cases could well have arisen spontaneously.

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

Past economic projections have been published and provided by industry studies conducted for the NRA by the Sparks Company, document severe economic, environmental and animal health negative impacts of prohibiting various mammalian or avian derived protein meals or fat from animal feed. The time constraints placed on providing responses to the referenced documents of 36 segments does not allow for a full assessment of current impacts.

The U.S. meat and meat-based products requires the production and annual slaughter of approximately 139 million head of livestock as well as 36 billion pounds of poultry and a growing aquaculture industry. The current average slaughter and processing of 100 million hogs, 35 million cattle and approximately 8 billion chickens which makes it first in beef and poultry and second in pork production in the world. The production and processing of these animals results in approximately one-half (1/2) of their live body weight in inedible raw material. Animal raw material is a highly perishable material, highly laden with microorganisms, many of which are pathogenic to both humans and animals and research has validated the presence of a high incidence of foodborne pathogens within its contents. The current annual amount of raw material generated from meat production and processing exceeds 50 billion pounds and if all could be accounted for may exceed 54 billion pounds. Current projections are not possible within the limited time frame provided but the inedible by-product/co-product portion continues to increase as further processing and table ready entrees are developed.

As has been documented via centuries of utilization of these by-product materials as resources for significant uses as well as volumes of scientific references validating their nutritional qualities, the products produced from the inedible raw material make significant economic, environmental, human and animal health contributions to their allied industries and society. The economic impacts should be fully assessed for each of the respective impact segments should these materials not be used in ruminant feed, mammalian feed or avian 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?

Oral transmission of BSE via bovine blood has not been definitely demonstrated. No BSE infectivity has been detected in bovine blood in either natural or experimental cases. (Bradley, 1999, 2000) (Fraser et. al. 1992) (Kimberlin and Wilesmith 1994) (Middleton and Barlow 1993) (Moon 1996). There is no evidence that tissue including blood from swine or poultry harbor the infective agent for BSE.

Perhaps the agencies have conflicting data that specifically addresses infection resulting via oral transmission from blood. It should be made public for scientific review if available.

Should action be deemed necessary in any prohibition of blood in animal feed, a very effective public relations program to protect the integrity of meat should be in place and prominent. Red meat as visualized by the consumer whether in commercials or the meat case is associated with the presence of red color and liquids. Any restrictions to blood products as feed ingredients creates image implications and consumer scrutiny concerns for the consumption of red meat.

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

Plate waste having been subjected to heat treatment during cooking and subsequently by rendering, as well as being composed of minimal mammalian protein, from most assessments pose minimal risks of containing BSE infectivity. Plate waste being a potential mixture of species meat tissue, while being of minimal human or animal health risks, presents speciation and sensitivity concerns in developing and implementing analytical procedures to accompany any prohibition or regulatory action.

Plate waste following “table harvest” is subjected to post harvest contamination exposure that unless properly handled and processed is a human and animal health potential hazard. Foodborne pathogens and potential animal pathogens can be transmitted thru unacceptable disposal alternatives such as landfilling, composting or burial. If the “possibility” exists for plate waste to pose a risk of BSE transmission in cattle or other ruminants the “possibility” of environmental exposure transmission exists for inadequate disposal options. 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.

- 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?**

There has been no evidence presented that poultry litter contains infective doses of BSE whether derived from spilled feed that may have contained ruminant material or feed formulated with ruminant material that would survive the gastrointestinal tract and be passed in the feces. Such opinions have been expressed but without supporting scientific evidence.

There are private studies that detail worst-case assessments for the amount of feed wastage in poultry litter, the relative amounts of poultry litter fed to ruminants and the upper most level of ruminant protein meals that would be formulated in to poultry diets. These studies and modeling assessments indicate an extremely low risk associated with the practice. These studies and results will be provided by other commenting parties and warrants careful review. The removal of SRM's have little relevance to decisions made concerning poultry litter other than the increases in production costs for meat, milk and eggs.

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

This section #18 question combines the potential economic and environmental impacts of three previously referenced sections. As was previously stated each has an significant economic impact on the industries producing and processing meat, milk and eggs as well as the co-products industry. In composite, but without sufficient time opportunities to research all of the impacts, one can only state that the collective impact would take a longer time to generate while incurring substantial expense.

- 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%?**

There have been no scientific data presented to incriminate tallow, tallow derivative, and insoluble impurities in tallow as being a significant risk of BSE transmission irrespective of its raw material derivation. Dr. David Taylor and associates have completed epidemiological studies that failed to demonstrate BSE infectivity from tallow rendered from BSE spiked raw material offered orally as crude, unfiltered tallow. This finding is confirmed in the "Animal Fats – BSE and After" by K.G. Berger (ISBN 0-9526542-9-6). Dr. Bram E.C. Schreuder in his "Epidemiological Aspects of Scrapie and BSE Including a Risk Assessment Study" thesis carried out at the DLO – Institute for Animal Science and Health, Lelystad, Netherlands concluded that most protein containing tissues excepting milk should be considered as possible potential altered protein (prion) containing tissues. Similarly non-protein containing tissues such as tallow are not

referenced as potential possible risk factors. Tallow has been injected intra-cerebrally into experimental BSE susceptible mice without success of BSE transmission. There have been no scientific data presented to demonstrate a BSE transmission risk from tallow excepting the association of its content of insoluble impurities. The international health authorities have generally established a maximum insoluble impurity level of 0.15%.

Insoluble impurities is defined as the small amount of sediment that is included as a routine analysis for all fats and oils including tallow referred to as MIU analysis. The moisture, impurities and unsaponifiables (MIU) are commercial trading specifications established for fats and oils. The impurities characterize the small amount of sediment that are of nonglyceride content. The impurities consist principally of free fatty acids and sterol glucoides, which are colorless and heat stable but for all practical purposes inert.

Phosphatides, mucilaginous material, precipitates from processing and transport equipment and fragments of the refining and bleaching processes are all inconsequential components of the impurities. Protein is a very small component of the impurity fraction. The fats and oils industry and specifically the rendering industry and commercial laboratories have equipped their laboratories to perform the MIU analysis as routine procedures. The industry standard has been the American Oil Chemist Society (AOCS). AOCS has been organized since 1909 as an independent educational and scientific organization to serve the fats and oils industry without a purpose to promote any product, manufacturer, laboratory or business. Via a peer-reviewed committee structure, AOCS approves laboratory procedures, certifies laboratories and individual chemists. An AOCS analytical procedure has been approved and utilized by virtually every laboratory in the U.S. for the determination of insoluble impurities in fats and oils including tallow.

The proposed analytical method by the agencies is that of a hexane-insoluble matter assay as described in the 5th edition of the Food Chemicals Codex. This reference method is not standard to the industry. In a survey of commercial laboratories, there were no facilities equipped to perform the hexane-insoluble matter assay. There is no current laboratory operated by the rendering industry in North America that is equipped to perform the hexane-insoluble matter assay. Substantial investments to transform laboratories to safely handle provide safe disposal systems for hexane and purchase of the specified filter funnel will be required. An initial estimate of per assay costs are \$275.00 - \$300.00 for the referenced assay which compares to \$10.00 - \$20.00 for the AOCS procedure. Hexane is a hazardous chemical requiring dedicated laboratory facilities equipped with specialized ventilation. Its disposal and associative air toxics are highly regulated.

The agency has been consulted (Ms. Rebecca Brickner) relative to alternative methods. Other methods equivalent in accuracy, precision and sensitivity have been provided for as referenced in the ANPR, however the equivalency validation is the responsibility of the private sector. FPRF and Clemson University (Animal Co-Products Research and Education Center) has initiated protocol development and plans for the completion of validation of equivalency methods. Requests for protocol comments and the agencies support in these initiatives will be forthcoming and greatly appreciated.

In summary the need for the establishment of a maximum level of insoluble impurities is not supported by science based on the available data of transmission failure via tallow, BSE spiked tallow as well as the characteristics and extremely low amounts of residues present in tallow. Further the analytical procedures for determining the content of insoluble impurities should not be altered from the commercially and industry used procedure that is readily available, economic, safe to perform and certified/approved by a highly recognized scientific society.

- 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?**

It is not necessary to prohibit the entire carcass from dead stock, non-ambulatory cattle or SRM's thereof. The agencies have in past published data referencing the numbers of dead stock and non-ambulatory segments comprising the U.S. cattle population. Observations of illegal and compromising disposal practices suggest that the estimates are understated. With this said accurate analysis of the economic and infrastructure necessities to accomplish the provisions outlined in Question 20 have not been determined. Numerous documentations of hazardous practices of animal disposal, on farm and off location salvaging of non-ambulatory animals under current conditions are projected to exacerbate if further SRM removal processes are implemented. The human and animal health risks associated with these practices become much greater and important risks than the transmission and amplification of BSE in the U.S. under current conditions, rules and compliance records.

- 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?**

There is none!

- 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?**

Past economic studies (NRA-Sparks Commodities 1996 and 2001) are not indicative of current economic and alternative disposal conditions. To complete and provide such for current conditions will require time and substantial industry investment. The determination by the Office of Management and Budget (OMB) that the economic impacts of the respective proposed segments to be minor for the purposes of accordance with the Small Business Regulatory Enforcement Fairness Act indicates that economic projections have been completed for the respective segments. The data, assumptions, interpretations and projected economic impacts for each of the proposed regulations and actions should be made public. Additionally, the time frame for the respective industries (livestock production, meat production and processing, feed and rendering) should be

extended to fully research and quantify the negative economic consequences known to occur as a result of the proposed implementation of each and every referenced action.

The International Review Team (IRT) concluded that adequate procedures are not in place to cope with the transition of removing all SRM's, dead stock and non-ambulatory cattle from animal feed. The multiple steps required for an integrated system from all inter-related agency proposals are not developed. In 1997 a mammalian to mammalian feed restriction rule with scientific based exclusions was developed for the purpose of restricting ruminant protein meals from ruminant feeds. This scientifically based rule with precautionary principles included therein is to prevent the transmission and amplification of BSE in the domestic cattle herd. Currently over 28,000 bovine animals have been tested since June 1, 2004 with numbers enhanced daily. The surveillance data gives strong initial evidence for a very low incidence, if any, for BSE in the U.S. cattle population. It would therefore be irresponsible not to be prudent in the implementation of actions known to disrupt the meat production infrastructure that has proven to be the most efficient and safe when compared to the rest of the world. It is an industry that is multi-dimensional and infrastructure dependent on innumerable ancillary industries that include in part rendering, ingredient and feed.

FPRF has developed the intellectual and interdisciplinary structure to effectively research, develop and implement innovative solutions with the Animal Co-Products Research and Education Center in Cooperation with Clemson University. Nine specific projects were initiated in April 2004 that included research objectives that include development of Z and F values for thermally resistant bacteria, separable fractions of protein, bioactive peptides, biodiesel, dioxin and dioxin-like toxicants, and analytical technology. The intellectual and financial resource is substantial and currently supported by private industry (FPRF) and Clemson University. The agencies are encouraged to be innovative in their support to supplement the resources to pursue innovative solutions. Solutions not provided for in the small producer loan program.

The USDA Rural Business Cooperative Service providing guaranteed loans offers minimal opportunity and probability that scientific based and approved procedures for the development of renewable energy systems will result. In contrast the announced program provides for the opportunity for further non-researched, non-regulated, potential human and animal health hazards and other soil, water or air contamination to be potentated without regulatory supervision.

APHIS welcomes comment on the following:

23. What other innovative solutions could be explored?

Innovative and scientifically based solutions have already been implemented in the context of risk relevance. FPRF has an ongoing and expanding research agenda. The production of bioenergy (biofuels, biodiesel and co-firing systems), soil amendments and new use applications have been extensively researched. All currently explored alternative uses generally results in negative economic impacts. Current incentives in the form of

small producer loans provide little incentive and application opportunities to pursue the research and resources required for innovative solutions.

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

Animal traceability should be mandatory. This recommendation was primary within the report of the IRT and should be seriously considered. Traceability of bovine animals should be mandated to include its ultimate utilization and/or disposal.

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?

Ultimately all meat animals should be included in the mandatory program. The swine industry has cooperated in a program of traceability for a number of years directed at the control and eradication of specific diseases, such as hog cholera and pseudorabies. It has proven successful for its intended objectives. New and innovative technologies have been developed and utilized in other industries. With the importance of BSE, cattle should receive priority, however all food animals must be included in the program. The threat of foreign animal disease epidemics, bioterrorism and food safety issues all dictate that an effective traceability system be the foundation for disease prevention control for both humans and animals. BSE is a primary incentive for a traceability program but is only one small factor in evaluating its importance.

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

Every stakeholder in the meat production and supply chain has an integrated and important role to contribute. The respective agencies are to be commended in the efforts extended in late December and first months of this year for their educational and public relation efforts. Food safety, however, becomes a year-around effort requiring the public and private cooperation. The forum for today's communication is tremendous with innumerable alternatives. All of which should be utilized but not only in the presence of a "media induced" need but in a continuous flow of food safety initiatives with supporting documentation, incorporating messages directed at multiple demographics.

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

Involve the affiliated and responsible industries. The Animal Co-Products Research and Education Center was developed and titled specifically to include "Education" within its mission. websites are extremely effective means by which to communicate. Rendering and its coproducts are an integral and necessary component for an economic, safe and sustainable animal agriculture. Therefore the Animal Coproducts Research and Education Center within its mission will assume a responsibility in the education and information

transfer for “all of the animal”. It is also understood that the Federal Government has an extremely complex website system. But using the example for the need to use 58 input keys to access the initial document of the proposed rulemaking of July 14, 2004 is not a user-friendly procedure to encourage the average consumer to pursue the process. Unfortunately the most common form of providing current educational materials from the Federal Government replicates the illustration.

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?**

The knowledge, research and science of TSE’s is still in its infancy when compared to other disease conditions. Much of the current written and reported literature has not been validated by science or replicated studies. Certainly much of the guidance has been obtained via the experiences of the U.K. It must be recognized that the U.K. has been under epidemic BSE conditions since 1986. It must also be accepted that the U.S. cannot be analyzed and develop risk assessment conclusions that are analogous.

The 1997 feed rule and numerous others were developed and implemented based on science while incorporating numerous precautionary principles. As the need to enhance or exempt “precautionary principles” or “abundance of precaution” based on new science, or as risk analysis parameters that specifically relate to the U.S. change, provisions to alter the regulatory process should be progressively implemented.

- 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?**

Concerns have been expressed for the knowledge that the regulatory process has and as proposed will exceed the technology (test methods) to validate compliance. It has taken nearly 7 years for both government and private industry to become comfortable with the current status and documentation that the current rule is associated with a very low non-compliance rate to current regulations. The current proposed rules if adopted must be done so with the knowledge that technology and analytical validation procedures are not developed for the establishment of compliance.

As was referenced in section 5 there is no current assay procedure that provides the confidence and reliability requirements to enforce SRM (tissue specific) or species specific tissues based on analysis. The stakeholder industries should become privy to the proposed regulatory compliance procedures to include the analytical record keeping and other processes that will be utilized in the compliance validation process. The uncertainty that exists in the scientific confidence related to the sensitivity and specificity of all analytical procedures currently available for determining compliance is certain to initiate

an array of litigation. Attention that will undermine the food safety, and public relations efforts while providing few benefits to the overall safety of human or animal health.

- 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?**

This section is beyond science and technology and must be addressed by the legal community. The timeframe provided was not sufficient for the involved industries to research and pursue adequate legal interpretation of the agencies legal authority. It has been some six months between the public statement announcements and the publishing of the ANPR. It is facetious to assume that the legal influence was not or more as demanding of the agency as was the interpretation of science and technology in the development of the proposed documents. Thus without the required time and resources to research opinions relative to the legal authority for each and every point within the published documents, this section cannot be appropriately addressed. One can project that legal interpretations will be made and required. As previously stated, precise analytical determinations of adulteration for each specific banned SRM and animal species tissue will be required to establish compliance and will likely be submitted to legal scrutiny.

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

As per Section 30.

FSIS welcomes comments on the following:

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

The complete listing of in-plant food and feed safety practices that are already in place could be provided as an answer to this question. Preventing cross-contamination whether a microorganism or a toxic compound is based on the same principles. The principles for controlling foodborne pathogens is of greater and documented importance to the consuming public when compared to the scientific base relating those of BSE. Any specific requirements promulgated for SRM removal should first evaluate the over-all affect it poses to the more important risk factor of foodborne pathogen transmission.

- 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?**

Slaughterhouse environments and processes in the U.S. are designed and operated with food safety as the utmost priority. To institute requirements and regulations based on "abundance of precaution" that compromise food safety principles that are known and documented as human health threats (foodborne pathogens) is counterproductive. The removal of designated tissues as SRMs certainly has the potential to violate food safety principles and exacerbate food safety concerns. The complete evaluation of this question is highly dependent upon the specific identification of the SRM tissue. Each referenced SRM tissue and the separation of the edible and inedible tissue fraction presents the need for a specific evaluation relative to food safety principles throughout the entity of the slaughter processes and the slaughterhouse facility.

The evaluation, implementation of the requirements and the effects will differ by facilities. The smaller, custom and locker plant type facilities will undoubtedly be impacted. This type of slaughtering, though declining, is the heart of rural America. Additional requirements will only enhance their decline. Economic projections and costs compared to the additional assets derived from "abundance of precaution" most certainly must be developed and evaluated.

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

Recognizing that trade issues are extremely important, primary concern are the current domestic issues. The same regulations that are imposed on the U.S. meat industry and its production and processing infrastructure should be required and validated as from any foreign source.

First, "BSE Free" apparently has several connotations and interpretations that are not only scientifically established but trade maneuvered. The OIE has surveillance guidelines that establish respective country status. Even though the U.S. exceeds these requirements, their sufficiency was not accepted as adequate. Following December 23, 2003 and the initiation of an intensified surveillance, the call from some trading countries that ask for all bovine animals to undergo testing. The document to which we are responding references innumerable questions and proposals that are difficult to address from a domestic perspective none the less for all other countries.

Perhaps some further questions should be posed.

- a) Is FSIS confident in the BSE status of respective countries? Which ones? And by what criteria?
- b) How is FSIS now validating that the appropriate surveillance, diagnostic procedures and equivalent sanitary measures are followed for all involved foreign trade countries?
- c) If SRM removal is required domestically, how will international suppliers be monitored for compliance for their products if we do not have technology capable for monitoring ours?

- d) If exemptions of the current rule are altered, how will the agencies monitor the feeding practices, cross-contamination and errors for imported animals and meat products for meeting those same standards?
- e) What demands will be implemented for SRMs removal from products in respect to labeling for imports?
- f) Considering the concern for poultry litter, cross-contamination and errors serving as a source of BSE transmission, how will the gastrointestinal tracts of imported live animals be monitored?
- g) Will the import of young animals be prohibited on the "possibility" that the distal ileum is infected but without procedures for a confirming diagnosis?
- h) Will imported young animals be required to be subjected to a 5 to 8 year isolation period?
- i) The list of "possible inquiries" is endless. It is the nature of the complexity of the TSE diseases. The timeframe for articulating and developing an expanded list was not sufficient to do so.

Summary: There are numerous unanswered questions. However the U.S. agencies have the responsibility of determining the standards and precautions to be mandated to countries exporting into our country. The U.S. agencies must develop our own standards for determining risk analysis as it relates to BSE risk and potential human and animal health hazards. The standards, regulations and compliance verifications must be equivalent to that imposed on our domestic production and cannot be delegated or compromised.

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?

As per several previous sections, specific criteria/questions must be posed to promulgate preventive controls, based on U.S. credentials and data in order to provide assurance that equivalency meets or exceeds those same criteria to prevent BSE and amplification in our country.

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?

It is the responsibility of the agencies to perform the functions associated with the context of the questions posed. The U.S. must conduct its own evaluations! Qualified and certified third party evaluations contracted to perform certain tasks in an option. The OIE cannot perform this function beyond providing generalized standard recommendations and global oversight. But all of the comprehensive assessments, validations, verifications, certifications required in assuring that our standards are being met for equivalency or beyond is our responsibility. Only then can the decision-making process be consummated.

Summation

The Fats and Proteins Research Foundation, Inc. appreciates the opportunity to present comments and facts brought forth concerning the complexities of BSE. It is those complexities combined with a restricted time frame permitted for response and the drastic changes that are proposed which differ significantly from past communications, press releases and announcements from all of the agencies referencing this subject that make responses that are difficult to completely address all of the issues.

Of particular significance is the removal of SRM's from all animal feed, which presents a new issue to every facet of the food animal and companion animal industries. Impacts that present unestablished consequences to the economic, environmental, ecological and human and animal health status for numerous industries. The requirement for dedicated facilities, equipment and transportation vessels for handling, storing feed and ingredients present a re-structuring of numerous industries. The prohibition of materials from non-ambulatory disabled cattle and deadstock from use in all animal feeds presents unestablished risks to human and animal health, environmental tragedies and economic impacts that threaten the sustainability of animal agriculture. These specific and numerous other concerns and referenced impacts are responses brought forth as a result of a document that has been proposed without supportive, published science and risk analyses that warrant adoption.

There is no evidence that risks of BSE have changed within the United States. With the exception of a single cow, without confirmation of having received feed containing prohibited ruminant material, there is not data to support anything other than the scientific conclusion that the United States does not have any of its cattle population infected with BSE or it is of very, very, very low prevalence. The negative surveillance data for nearly 20,000 high-risk cattle during each of the years of 2001, 2002 and 2003 and the over 28,000 since June 2004 is scientific documentation.

The purported possibility that cross contamination or feeding errors, based on inferences from the U.K. experiences, negates past risk assessments cannot be supported with data. The industries (rendering, feed and livestock feeders) have committed to implementing the 1997 regulation and by both FDA, industry and third party certifications have documented exemplary compliance. Not to repeat the complete data base from the July 29, 2004 FDA compliance report, it must be pointed out that 159 active rendering firms handling prohibited ruminant material reported 0 firms (0%) with violations of Official Action Indicated (OAI) which are FDA sanctioned inspections that report significant conditions or practices that cannot assure that ruminant feed is contaminated with prohibited material and requires prompt re-inspection. Further only two firms (1.3%) were reported as Voluntary Actions Required (VAI) in which inspections result in the finding for the need to voluntarily correct violations such as minor regulatory conditions involving non-ruminant feeds. The July 29, 2004 FDA compliance report for FDA inspected and licensed feed mills included 339 active firms handling prohibited material stated one firm (0.3%) classified as OAI and 7 firms (2.2%) as VAI. These data confirm compliance within the risk analysis parameters for concluding that on the basis of a low incidence rate and compliance to the current feed regulations that amplification risks are extremely unlikely.

Suggestions from the IRT have referenced cross contamination and feeding errors based on the past experiences primarily within the United Kingdom. Please compare the United States compliance documentation to that supplied by the IRT for the U.K. to correspond in time intervals following the implementation of respective directives to assess risk analysis. The U.K. conditions cannot be taken in respect to disease prevalence, feeding practices, regulations and their compliance thereof and apply unilaterally to the United States. There has been a 15-year proactive history for BSE preventative measures. And compliance to those preventative measures have been monitored to include the complete traceability of all imported animals that have all tested free of BSE.

The agencies have not presented any data or scientific evidence that warrants the adoptions of the proposed regulations. Regulations that if implemented have even greater human and animal health risk potential. The uncontrolled and unregulated dispersion of human pathogens, animal pathogens and foodborne pathogens associated with the implementation of the regulations pertaining to deadstock, non-ambulatory cattle, SRM removal and their disposal are counter to effective disease control and food safety initiatives. Documented evidence is available to conclude that those same animal tissues are being abusively disposed of in various manners conducive to transmission of microorganism, parasitic and protozoal diseases. Scientific evidence is available to document the effectiveness of rendering the predominant foodborne pathogens, parasitic, protozoal and other pathogenic microorganisms incapable of surviving a carefully controlled rendering process. The abuse will only be exacerbated with the implementation of the proposed rule. Thus the Fats and Proteins Research Foundation has and continues to be dedicated to a science and risk analysis decision making process as the basis for regulatory procedures to be formulated to control all human and animal diseases and the safety of our food. I on behalf of FPRF encourage the respective agencies to do so. It is our understanding that the mandated *modus operandi* is to do so.



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