



FATS AND PROTEINS RESEARCH FOUNDATION, INC.

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

Docket No. 2002N-0273
RIN 0910-AF46

Dear Madam/Sir:

This document is submitted on behalf of the Fats and Proteins Research Foundation, Inc. (FPRF). It references the Food and Drug Administration (FDA) Document No. 2002N-0273, proposed rule, "Substances Prohibited From Use in Animal Food or Feed, published in the Federal Register, Vol. 70, No. 193, October 6, 2005 with the request for comments.

FPRF is a not-for-profit, non-lobbying, scientific foundation established in 1962 and registered in the State of Illinois. Its primary mission is to coordinate the financial support and conduct of grant established research projects conducted by university, private and public research institutions. The foundation is privately funded primarily by North American independent renderers with support from the meat, poultry, seafood packing/processing industry and other allied industries as supporting members from international origins. Via this support, over 550 research projects have been completed. The majority of which have been published in peer reviewed, international journal documents.

Research objectives while focusing on the use of animal byproduct feed ingredients defining their nutrient and disease prevention properties also concentrate on new use alternatives for non-feed/non-food utilizations. The objectives have included biofuels, biodiesel, soil amendments, fibers and films, and phase change material applications. The biosecurity validation studies of rendering procedures and processes have been numerous. As author of this document, I have been the foundations President and Director of Technical Services for the past twelve years. Previously, I have been an accredited, practicing food animal veterinarian, as well as former Director of Research and Development/Technical Services for a major, midwest farm/feed cooperative. As such the proposed rule is of interest due to the fact that various components of the document provide potential unexpected and negative consequences to animal production, animal and public health risks and our environment.

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The foundation appreciates the opportunity to provide comments and commends FDA for providing the opportunity.

Preamble

Experience and science have demonstrated the 1997 feed rule (21CFR 589.2000-1997) to be an effective fire-wall component for the prevention and amplification of bovine spongiform encephalopathy (BSE). The agency is discouraged from implementing additional rulemaking, many of which as proposed have potential unexpected and negative consequences.

The Current Rule

The 1997 feed rule and numerous others developed and implemented regulations based on science while incorporating numerable precautionary principles are in existence. Certainly, as the need exists to enhance or even exempt these firewall components based on new science or risk analysis parameters, the agency is encouraged to alter the regulatory agenda. The knowledge, research, surveillance data, regulatory compliance data and science currently do not further regulatory change in the feed rule. Current regulatory compliance of the feed rule has been documented for the feed and rendering industry. In perspective, the compliance has exceeded nearly every other FDA regulation promulgated. A statistic that needs to be promoted but similarly requires constant validation. The proposed rule references a primary concern for an intentional or unintentional misfeeding of justify ruminant prohibited protein to ruminants. The removal of brain and spinal cord tissue from the tissues permitted in rendered animal proteins and subsequently labeled "Do not feed to Cattle or other Ruminants", that are derived from a cattle population documented as having a low-risk BSE status, when applied to a risk assessment perspective provides minimal reduction in transmission risk. Surveillance of the US cattle herd, has approached 600,000 individual animals representing a demographic and geographic cross-segment. Two positive cases have been identified within U.S. boundaries. One that originated from Canada and a subsequent June 2005 diagnosis in Texas. Both animals were suspected of being infected prior to either the FDA or Canadian feed rules. Despite noble attempts in both cases to document epidemiological evidence for any conclusion of a feed related transmission remains as totally speculative and assumptive. It is unfortunate that cohort animals, both young and aged, from each of these origin herds were not used as a follow-up research project under the controlled security of the USDA Ames, Iowa facility. Certainly the BSE disease process is complicated and missing science to explain numerous facets of the process to include any abiogenetic qualities. Further research is obviously indicated.

The guidance provided by epidemiologists of the Harvard Center of Risk Analysis (HCHA) at Harvard University and the Center for Computational Epidemiology (CCE) at Tuskegee University provides risk assessment analyses that indicate minimal risk of BSE amplification even when using infection rates several times that have been documented by actual surveillance. The HCHA/CCE model has been re-assessed following the North American positive cases but with the re-affirmation for a very low risk of transmission and amplification of BSE in the US with current regulations. Though a hypothetical simulation for the removal of brain, spinal cord and other specific risk material (SRM's) from the feed chain slightly lowered the transmission risk, however the reduction was mathematically insignificant when compared to the alternative proposals for processing and disposal of those SRM's.

SRM Removal

SRM removal becomes a significant potential animal and public health threat. Threats are created via the disposal options for the SRM tissue, the inadequate disposal of fallen stock and the potential closure of rendering facilities. The proposal document referenced disposal options for cattle materials

prohibited in animal feed (CMPAF). Two of the proposed options, landfilling and composting, are not viable options consistent with responsible animal and public health prevention. Both options can be defined as intentional contamination of the food/feed supply and the reservoir for human/animal pathogens. Many states and localities prohibit or do not have access to hazardous disposal sites and certainly unregulated composting and burial are not appropriate disposal methods. The removal of brain and spinal cord and other SRM tissue can be accomplished but not under all conditions nor at the proposals referenced estimated cost of removal. During summer months in central and northern climates and most of the year in southern states it has been estimated that only 10% of brain and spinal cord tissues can be extracted from autolyzed fallen animals. The remaining 90% will not be rendered and must be disposed of by burial, landfilling, composting, carrion or other environmentally or microbiological compromising methods. Other extenuating circumstances can delay the rendering process and even under ideal conditions the removal of brain and spinal cord from fallen animals is difficult and will not be possible in a high percentage of fallen animal carcasses. Workers may also be exposed to infective tissue in the removal process. It is also important to note that 1 mg of CNS tissue is not 1 mg of the finished rendered protein when referencing potential risk for BSE transmission. Inedible byproducts resulting from animal production and processing are heavily laden with microorganisms many of which are human/animal pathogens or foodborne pathogens. The pathogens have greater health risk potential than BSE in the United States. This fact was validated by a study conducted by Dr. Fred Troutt, University of Illinois Veterinary College, Urbana, Illinois and is summarized in the following table.

Efficacy of the U.S. Rendering System in the Destruction of Pathogenic Bacteria¹

Pathogen	Raw Tissue ²	Post Process ²
<i>Clostridium perfringens</i>	71.4	0
<i>Listeria</i> species	76.2	0
<i>L. monocytogenes</i>	8.3	0
<i>Campylobacter</i> species	29.8	0
<i>C. jejuni</i>	20.0	0
<i>Salmonella</i> species	84.5	0

1. Troutt et al. (2001) Samples from 17 different rendering facilities taken during the winter and summer.

2. Percent of the number of samples found to be positive for pathogen out of the total samples collected.

The data illustrates the high incidence and content of foodborne microorganisms within raw animal by-product material. The data demonstrates the efficacy of the rendering process in inactivating these groups of foodborne pathogens.

The potential infectious microbiological inoculation of our soils, water, air are problematic and defy all animal and public health protection principles. Additionally the inoculation of possible infectious forms of prion material as environmental reservoirs of transmission is irresponsible. The human/animal health risks are greatly reduced under the current regulated and, compliant regime of 21CFR 589 2000-1997. Scrapie infected tissue has been shown to retain infectivity exceeding a three year entombment. Infective premises have been correlated to the transmission of scrapie and chronic wasting disease. BSE has been shown to be even more resistant to inactivation procedures than either scrapie or CWD. The proposed regulations have not considered the economic, environmental, human and animal health consequences for these possibilities and which are entirely possible in many regions due to their implementation and the complete closure of rendering facilities and their services. The proposed regulations are laden with unresolved, unexpected and negative consequences. The agency is encouraged to carefully review these consequences and reference heavily the minimal benefits

provided by the proposed regulations when compared to those currently in effect and providing effective prevention.

Tallow

The proposed amendments of tallow, either that derived from cattle materials prohibited in animal feed (CMPAF) or as an exemption if such tallow contains no more than 0.15% insoluble impurities, is not justified basis current and available science. Justification was stated as necessary based on new preliminary data suggesting a 1 mg of infectious raw CNS tissue requirement for transmission of BSE. There have been no scientific data presented to incriminate tallow, tallow derivatives and insoluble impurities derived from tallow as being a significant risk of BSE transmission irrespective of its raw material deviation. Dr. David Taylor and associates have completed epidemiological studies that failed to demonstrate BSE infectivity from tallow rendered from BSE spiked raw material and offered orally as crude unfiltered tallow. The 1 mg infective dose proposed minimum requirement of raw unprocessed CNS tissue for oral transmission of BSE cannot be extrapolated into a risk comparable to impurities from processed tallow that consist principally of free fatty acids, sterol glucoids, phosphatides, mucilaginous material and precipitates from processing and transport equipment and the fragments of the refining and bleaching process.

Tallow is used for a variety of economic purposes that include feed. But its use as an alternative fuel for deriving bioenergy is rapidly emerging. A requirement as proposed would substantially increase the economic structure for tallow for all uses via the necessity for an additional infrastructure investment and the associative assay requirements. Tallow rendered from CMPAF as one of the five proposed disposition alternatives would require an expenditure for the exclusive handling. An economic impact not considered in any of the current economic projections.

The agency is commended for altering the ANPR proposed assay for insoluble impurities from the Food Chemicals Codex methodology to the proposed AOCS Official Method Ca 3a-46 method. Appreciation is expressed to Rebecca Buckner, Paul Kuznesof and Burt Pritchett for their assistance in recognizing the burden proposed in requiring the Codex method and evaluating acceptable alternatives. However the agency is requested to evaluate the economic burden of requiring any insoluble impurity analysis for domestic used tallow for feed purposes. It is an unnecessary economic burden that is not supported by scientific evidence and lacks a defined regulatory procedure for compliance.

Environmental Interest

The proposed rule presents numerous indirect, incomplete assessments for of the potential negative environmental impacts derived thereof. This fact necessitates an environmental impact assessment study be completed that collaborates with industry, US Department of Agriculture, Environmental Protection Agency, and the Homeland Security prior to the implementation of the proposed FDA regulations. The potential hazardous consequences to public health, animal health, and environmental risks are alarming and very poorly addressed or assessed in the proposal document. Hazardous material will be diverted from a regulated utilization to a multitude of unregulated disposal options that create a carcass disposal and a potential comprehensive inedible animal raw material disposal crisis

Dr. Tsegaye Habtemarian, a renown Computational Epidemiologist at Tuskegee Institute – ([334-724-4438](tel:334-724-4438)-habtemant@tusk.edu) and Dr. Fran Kremer, Senior Science Advisor, Office of Research and Development, US Environmental Protection Agency have been consulted for the preparation of a protocol to address a number of these potential unexpected and negative consequences. The agency is encouraged to collaborate with the Fats and Proteins Research Foundation Inc. and the appropriate scientists in pursuing this required assessment.

Compliance

The proposal directs the burden and responsibility for compliance to the rendering industry. The suggested primary compliance methodology is record keeping. As stated there is no current way to reliably test for the presence of the BSE agent or the presence of CMPCF. The focused responsibility to the rendering industry and void of adequate means to validate compliance creates an onerous burden on the rendering industry that creates an uncertain liability exposure.

The proposal that requires renderers that manufacture, process, blend or distribute cattle materials to establish and maintain records to sufficiently demonstrate that rendered material for use in animal feed was not manufactured from, processed with or does not otherwise contain cattle materials prohibited in animal feed, cannot be scientifically accomplished in respect to brain, spinal cord or tissues derived from animals over 30 months of age. The agency and the industry are ill equipped to provide enough resources to initiate and enforce a "bad" regulation or a regulation without appropriate compliance procedures. The proposed regulation is a "bad" regulation and certainly lacks a scientific based compliance procedure. The current rule, though lacking definitive and precise compliance validation procedures is one that has provided a regulatory procedure accepted and universally adopted by the feed and livestock sectors to effectively prevent transmission and amplification of BSE in our country based on all risk assessment criteria.

Economics

It is knowledgeable that extensive economic data will be provided via a number of submitted comments. It is suggested however that many of the projections will be under stated as were those presented in the proposed regulations. FDA is strongly encouraged to do an indepth environmental and subsequent economic impact study based on representative data and the real potential for the animal and human health and environmental negative consequences.

Summary

A 1997 feed rule is in effect. The rule provides scientific, sensible control but still contains adequate precautionary principles for preventing transmission and amplification of BSE in our domestic cattle herd. The agency is discouraged from implementing additional rulemaking, many of which as proposed have potential unexpected and negative consequences. The threat of so many other diseases both domestic and foreign derived, affecting both human and animal patients command much greater challenges and resources when compared to the need for additional BSE rulemaking as proposed.

Respectfully Submitted,



Gary G. Pearl, D.V.M.
President and Director
of Technical Services

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