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**FATS AND PROTEINS RESEARCH FOUNDATION, INC.**

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October 30, 2001

Dockets Management – Center for Veterinary Medicine

HFV-12  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855

RE: Docket No. 01N-0423

This opportunity to offer comments for the Food and Drug Administration's solicitation of information pertaining to its animal feeding regulation as referenced in the Federal Register October 5, 2001 (Volume 66, Number 194) is very much appreciated. The comments are being made on behalf of the Fats and Proteins Research Foundation, Inc. (FPRF). FPRF is organized to serve the rendering and its associated industries. The rendering function is that of recycling the co-products resulting from food animal production. The rendering and its ancillary support industry has ecologically, economically and via the most biosecure procedure processed the more than 50 billion pounds of inedible animal tissue generated annually into products of value for a variety of useful purposes. Rendering represents the collection of animal raw material from slaughter, packing, processing, food preparation and fallen animal sites for transport to process controlled facilities, heated to a temperature higher than required for sterilization, which also removes moisture. The fat is extracted from the protein. The fat and protein are then used as animal feed ingredients or other industrial uses.

Edible tallow and lard are used in all food groups to include bakery products and cooking compounds. Inedible animal by-products are utilized as important energy and protein components for animal nutrition, a multitude of industrial uses that in part includes biodiesel, biofuels, fertilizers, soap, rubber and plastics. This important recycling function currently is accomplished by approximately 260 North American facilities.

The Fats and Proteins Research Foundation, Inc. was organized in 1962 to serve the animal agriculture industry. FPRF's purpose is to provide an institution, which will direct and manage a research process that results in an enhanced current usage and the

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development of new uses for rendered animal products. FPRF is a nonprofit, non-lobbying organization as defined in 501-C Illinois statutes. Approximately 100 industry members voluntarily support and contribute in a cooperative effort to focus research resources to the individual research projects. Over a hundred and twenty-five projects have been assigned and completed since 1994. All researchers are strongly encouraged to publish the results in respected peer reviewed journals, with nearly 90% of the projects resulting in being published for public knowledge usage.

Though there are seventeen specific questions posed in the October 5, 2001 document, these comments will not address each question directly but such will be supplied within the written comment period to follow. The 21CFR, 589.2000 (Federal Register, June 5, 1997) regulation has functioned within its objectives to prevent the establishment or amplification of the infectious agent of bovine spongiform encephalopathy (BSE) in the U.S. cattle population. Thus in a composite review of the questions there is little need to duplicate the process initiated in 1996 and resulting in a June 5, 1997 prohibition of specified animal proteins in ruminant feed. The specifics of that prohibition incorporated the best scientific information available but interpreted it by instilling a degree of precautionary principle as added safety knowing of the BSE-free status in the U.S. as validated by extensive testing.

The intensive compliance program accompanying the establishment of the rule has now been supplemented with the development and implementation of third party certification programs. Of importance are those of APPI (Cook and Thurber) directed at the rendering industry and the Facility Certification Institute at the feed manufacturing industry. Both have resulted in validation of facilities that produce a very high percentage of all animal proteins and feed manufacturers producing a significant tonnage of mixed feeds. These and other voluntary actions have been taken to insure compliance with government regulations while demonstrating an active commitment to feed/food safety and animal/public health.

Surveillance initiatives and numerous associative regulations initiated in 1986 and enhanced throughout this subsequent fifteen year period have provided no evidence that an enhanced risk for the emergence of BSE has been altered. This foundation has been promoting the research attention to the identified priorities established by the agency and referenced in the August 1997 regulation. Among those were (1) inactivation of the causative agent (2) transmission among inter and intra species (3) diagnosis with emphasis on preclinical procedures (4) detection procedures for individual species protein in meat and ingredients/feed and (5) epidemiology of the respective TSE's.

With the recognition of fragmentary research contributions filling a few voids, in composite most of the outlined priorities remain, without conclusive answers. These priorities were essentially restated in the summary comments resulting from a USDA/ARS BSE Workshop held March 15, 2001. There is not sufficient scientific evidence to alter the regulatory plan established, initiated and validated for compliance as outlined in the final rule of August 1997.

Additionally this foundation has since its inception retained a focus on the biosecurity principles provided by the rendering procedures. Recent validation that proper time/temperature processing inactivates viral and the primary foodborne pathogens (Salmonella spp., Listeria monocytogenes, Clostridium perfringens and Campylobacteria jejuni) in byproducts derived from slaughter of animals for food purposes. This assurance is not available for the other alternatives for rendering and certainly becomes increasingly important as we face new biosecurity challenges.

Animal agriculture has and now more than ever depends upon the sanitary, biological secure, ecological and environmental processing and infrastructure of the rendering industry as a vital synergistic means of utilizing approximately one half of all livestock and poultry produced each year.

In summary the 21CFR, 589.2000 rule instituted as a "fire wall" regulatory adjunct to a series of precautionary practices is not in need of any extensive modifications or changes until which time science and research findings dictate.

Gary G. Pearl, D.V.M.  
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of Technical Services