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January 31, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 12061
Rockville, MD 20852

Re: Document No. 02N-0273
Substances Prohibited from Use in Animal Food or Feed;
Animal Proteins Prohibited in Ruminant Feed;
Advanced Notice of Proposed Rulemaking

Dear Madam/Sir:

The opportunity to offer comments in reference to Docket No. 02N-0273, a request by the agency to solicit information, comments and opinions with specific emphasis on five specific questions regarding the current rule "Substances Prohibited From Use in Animal Food or Feed: Animal Proteins Prohibited in Ruminant Feed" is appreciated. These comments are being made on behalf of the Fats and Proteins Research Foundation, Inc. (FPRF). The initial comments will amplify the significant scientific facts and knowledge in respect to the preventative regulations formatted and implemented here-to-fore since 1986 in response to a foreign disease of which has not been diagnosed in any North American native cattle.

FPRF is organized to serve the research needs of the rendering and its allied industries. Its completion of over 525 peer reviewed projects in its 40 years tenure is a testament to the sincerity that science should dictate the actions of an industry that is so vital as rendering. The rendering function and its infrastructure is that of recycling the co-products resulting from food animal production. This industry has very effectively, efficiently and with biosecure initiatives processed up to 50-54 billion pounds of annually generated animal byproducts in the ancillary support of animal food production. They have performed this biosecure function for over 100 years.

The FPRF, the rendering industry, the feed and ingredient industries and many other animal food producing stakeholders have appreciated the dialogue afforded in the

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development of the current regulations initiated upon the diagnosis of BSE in 1986. Additionally many of these stakeholders initiated additional voluntary measures to supplement the regulations. The primary stakeholders have supported the 21CFR§ 598.2000 (Federal Register, June 5, 1997) regulation that prohibits specified animal proteins in ruminant feed. The specifics of that prohibition incorporated the current best scientific information but with an interpretation that instilled enhanced precautionary principle as added safety while knowing of the BSE free status in the US as validated by extensive surveillance testing. As one evaluates the current status, the scientific facts can only reference and document that the regulatory network has been effective. Contrary to any indications for additional regulations, the evidence strongly indicates that focus should be directed at the compliance and enforcement of all the previously instated regulations.

The agency and the stakeholders have embraced an intensive compliance program. The stakeholders have implemented third party certification programs. Of importance are those of the American Protein Producers Industry directed at the rendering industry and the Facility Certification Institute developed for the feed manufacturing industry. Both have resulted in validation of facilities to assure compliance to the prohibited protein regulation. These programs are directed at facilities that produce a very high percentage of all animal proteins and feed manufacturers that produce a significant tonnage of all US mixed feeds. Additionally these stakeholders have implemented Hazard Analysis Critical Control Point programs at all levels. The facts are that a very high level of compliance exists for the handling of prohibited protein material (21CFR§589.2000). The agency is encouraged to vigorously ensure compliance and aggressively pursue enforcement.

The scientific facts are available to reference that the nations risk to the establishment and amplification of the infectious agent of BSE is extremely low. Based on the preventative regulations already established the risk has been described as the lowest since the first diagnosis of BSE in the UK in 1986. The Harvard Center for Risk Analysis report to the Department of Agriculture on November 26, 2001 evaluated the various risks, potential exposure and amplification potential for US cattle to BSE. This very comprehensive study concluded that: "Our analysis finds that the US is highly resistant to any introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the U.S." The direct quote enforced with the opportunity to attend seminars and presentations by both Dr. G. Gray, Principle Investigator, and Dr. J. Cowhan, Epidemology Modeler for the Harvard University study[1][2] provides confidence and comfort that the current control measures combined with near absolute compliance are not in need of any further regulatory action. In fact the same five questions referenced in the agencies request in Docket No. 02N-273 were mathematically modeled and assessed in the Harvard University study. Any interpretation of the scientific data in this study or data or information from any other existing scientific study that the agency has or that was provided via any of the public hearings should be made publicly available for scientific scrutiny.

The respective agencies responsible for the regulations developed here-to-fore should be extremely concerned and diligent for their compliance and the surveillance efforts. It is

understood that the scientific base has not provided easy diagnostic procedures for BSE. Nor have analytical procedures been developed for high sensitivity, high specificity, rapid, inexpensive tissue testing. The 21CFR§598.2000 regulation introduced regulations without analyses to analytically confirm compliance. The agencies should promote 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 pre clinical procedures, (4) detection procedures for specific tissues and individual species protein in meat and ingredients/feed and (5) epidemiology of the respective TSE's. With the recognition of fragmentary research contributions filling few voids, in composite most of the outlined priorities remain without conclusive answers or agency direction. There is insufficient scientific evidence to alter the regulatory plan established, initiated and validated for compliance as outlined in the final rule of August 1997. In summary the 21CFR§589.2000 regulation instituted as a "fire wall" regulatory adjunct to a series of precautionary practices is not in need of any modifications or changes until such time science and research findings dictate. This statement is applicable to the agencies request for information specific for the following five questions:

(1) Excluding Brain and Spinal Cord from Rendered Animal Products –
In the absence of any indications of BSE in the U.S. despite an intensive surveillance monitoring of the U.S. cattle population with concentration on the high risk segments and the knowledge of very low risk probability of any amplification it is not warranted. Again the agency should concentrate on those activities and scientific based surveillance data to attain a BSE status and classification (OIE – Category I) in collaboration with all other U.S. governmental agencies.

(2) Use of Poultry Litter in Cattle Feed –
In the absence of BSE in the U.S., the limited and demonstrated potential for spilled feed into poultry litter having been quantified as miniscule and not an enforceable regulation, the absence of associative risk assessment data, and the FDA contention and anecdotal evidence that "the agent that causes BSE would not survive the chicken intestinal tract", regulatory action is not warranted.

(3) Use of Pet Food in Ruminant Feed –
The use of recycled, distressed or salvaged pet food as feed ingredients must be considered as prohibited protein in ruminant rations. Under 21 CFR§589.2000, label requirements must state "Do not feed to cattle or other ruminants". Retail companion animal food are labeled for specific species usage. Label directions not warning labels effectively control the specialized pet food market. The Pet Food Institute has conducted a survey to determine the consumer impact of the proposed label statement. This survey documented a significant negative consumer reaction to a FDA required label that at a minimum would result in a $2 billion loss of market. In the absence of BSE in the U.S. and the current regulation prohibiting by label requirement of salvage or distressed pet food in ruminant feed further labeling requirements are not warranted.

(4) Preventing Cross Contamination –
The 21CFR§389.2000 mandates compliance requirements that include the handling of prohibited and non-prohibited material with written procedures to include sequencing, flushing, clean-out and the use of dedicated equipment for both ingredient and feed. Good manufacturing practices (GMP), Hazard Analysis Critical Control Point (HACCP), third party certification programs (FCI, APPI) are all adjuncts to the regulatory compliance network. The absence of BSE and the concentration on compliance and enforcement of the current regulatory procedures outlined for the handling of prohibited and non-prohibited material is not warranted.

(5) Elimination of the Plate Waste Exemption –
The inference that food produced, prepared and served to the American consumer could be potentially hazardous to animals creates unnecessary apprehension. Based on evidence that the agency possesses that the U.S. is considered to be free of BSE, the meat processing and inspection surveillance domestically and the scrutiny that imported meat and animal products should be receiving do not warrant further actions of exemption eliminations. Resources should be directed to assuring that these functions receive the highest priorities.

On behalf of FPRF, we thank the agency for the opportunity to submit these comments. The agency is encouraged to vigorously ensure compliance and aggressively pursue enforcement. Surveillance, "border patrol", and the assurance/documentation/promotion of the BSE free status- Category I status should receive highest priority from all regulatory agencies. Resources should be directed to these priorities while directing research to satisfy the scientific voids that exist. FPRF on behalf of the rendering industry, is committed to assist with these objectives in anyway possible.

Respectfully Submitted,

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

(1) Cowhan, J – Animal, Dairy and Meat Sciences; Professional Society Meetings, Quebec City 2002

(2) Gray, G. – University of Minnesota – 63rd Nutrition Conference – St. Paul, MN 2002