January 31, 2003

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

Re: Comments on Docket No. 02N-0273 (Advance Notice of Proposed Rulemaking on Substance Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed)

Dear Sir or Madam:

This letter is in response to the Federal Register Notice on Docket No. 02N-0273, regarding the Advance Notice of Proposed Rulemaking (ANPR) on possible changes to the current rule "Substances Prohibited From Use in Animal Food or Feed: Animal Proteins Prohibited in Ruminant Feed" [21 CFR Part 589].

Smithfield Foods Inc. is the largest pork processor in the world. In addition to our pork operations here and abroad, we also own and operate a number of beef processing and rendering facilities across the country. We offer the following comments to the above referenced notice for the agency's consideration.

In 1997 the FDA adopted the current feed restrictions. While this regulation was completely supported by animal agriculture, including Smithfield Foods, as necessary to create a safety zone around the US beef industry; it came at considerable expense to the livestock, meat and rendering industries. We continue to believe the existing FDA animal feed regulations are appropriate, but seriously question the need to change the rule given the current level of science on the issue and the well documented, low-level of risk of BSE occurring in the United States. Thus, we believe the current facts suggest no regulatory changes are warranted at this time.

We believe the FDA's goal should not be to change the current regulation, but to achieve 100 percent compliance with the existing rule. According to recent FDA publications, compliance with the BSE ruminant feed rule (21 CFR § 589.2000) has been excellent, approaching 100 percent. This is a better compliance record than any other FDA rule or program of which we are aware. We urge the agency to focus its efforts on compliance rather than modifying an already good rule for a extremely small amount of risk reduction at considerable expense to an already burdened industry.

02N-0273 C26

BSE prevention in the U.S. involves multiple programs that can best be described as a "triple firewall" strategy. This includes: (1) a ban on the importation of ruminants and ruminant products from countries with BSE; (2) a statistically sound and comprehensive animal surveillance program to continually monitor for the presence of the disease; and (3) ruminant feeding restrictions to prevent the amplification and spread of the infective agent in the unlikely event BSE occurs in our domestic cattle. The current BSE feed rule, as part of this triple firewall strategy, is more than adequate to meet the objectives stated in the preamble to the final rule.

The Harvard Center for Risk Analysis completed a three-year study on the potential ways that U.S. cattle could be infected with BSE. This report was released on November 26, 2001. The following quotation is from the executive summary of this report: "Our analysis finds that the US is highly resistant to any introduction of BSE or a similar disease." We believe the conclusion of the report is that due to the control measures that are in place the risk to US cattle and US consumers from BSE is extremely low. Therefore the current science does not support an expansion of the rule at this time.

The regulated industries and government have worked diligently to provide a preventive approach to a perceived problem, and have been involved in this effort for the past 16 years. It is not in the best interests of animal agriculture, to continue to raise doubts about a proactive program that has proven that it is working. The health and safety of the human and animal population in the US should be advertised world wide, rather than be held up, for inspection, to cause additional concerns to be raised.

Please see below our comments regarding the five specific questions outlined in the notice:

1. Excluding Brain and Spinal Cord from Rendered Products.

The first consideration should be that BSE has not been found in the US. Further, various variety meats such as brain, tongue, and intestines from cattle have been, and are, used and considered to be edible products for humans. If these tissues are safe for human consumption, we cannot understand why the FDA would be considering a ban for animal feed if properly rendered. Although the Food Safety Inspection Service may be considering some regulatory restrictions of certain brain and spinal tissues in meat, it is our understanding that they are not doing this because of concerns about BSE, rather for other reasons.

We should not forget we do not have BSE in this country. In fact, the US government has stated this in a number of official publications. We do not understand why the FDA now suggests that it may be necessary to introduce additional regulations as if BSE does exist in this country. We cannot believe it is because of significant changes in the science.

We believe changing the regulation at this time would be carrying the "precautionary principle" far beyond what the professional risk studies have indicated is necessary. The regulated industries, under [21 CFR Part 589] have proven their desire and ability to conform to this regulation, and as a result have borne a huge financial burden.

At this time the Animal and Plant Health Inspection Service (APHIS) is diligently working with the European Union (EU) and other third countries to assure them that the US is free of BSE. Therefore, the US should be permitted to ship its ruminant animal protein products without the removal of specified risk materials (SRM).

Also the US is working to convince the EU and the Office of Internationale des Epizooties (OIE) that the US deserves a category 1 ranking on the EU Geographical BSE Risk (GBR) scale. A regulation requiring removal of these tissues from the rendering stream is certainly going to send a negative signal to our trading partners worldwide.

2. Use of Poultry Litter in Cattle Feed.

The Harvard Risk Study covered a three-year period; it is certainly logical to assume that if the epidemiologists considered this to be a viable way to transfer the prohibited material to ruminant feed, this issue would have been addressed at that time.

It must be remembered that ruminant meat and bone meal represents only a small portion of the rendered animal protein incorporated in poultry diets. In feed producing companies it is becoming an increasing practice to use "conditioner systems" prior to the pelleting process. This process operates with live steam, heat and pressure to gelatinize the feed ingredients, an additional heat treatment step.

A policy statement from CVM in June 1998 implied that litter/manure could be fed to ruminants: "FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract." Poultry producers are going to make every effort to reduce the amount of feed going into litter, for the obvious reasons of lowering their production costs. There have been no scientific studies to indicate a valid reason for banning the use of poultry litter in ruminant diets.

3. Use of Pet Food in Ruminant Feed.

The cost of pet food rations will dictate that only salvaged or distressed materials will be considered for use in ruminant rations. This possibility is already covered under 21 CFR Part 589, which requires labeling "DO NOT FEED TO CATTLE OR OTHER RUMINANTS."

There is no benefit to requiring such labeling for retail pet food products. This will serve to unnecessarily raise the cost of manufacture, raise the cost to consumers, and cloud the issue with foreign buyers, all without a corresponding safety benefit.

4. Preventing Cross Contamination.

Rule 21 CFR Part 589 provides the regulated industries with specific procedures to assure that cross contamination will not occur. To add new requirements to the regulation will be a tremendous financial burden to all segments of U. S. animal feed production. The first line of defense in the prevention of cross contamination is the feed producer. This industry has been using proper and adequate separation measures for years. "Licensed medicated feed mills" are a proven part of this program.

The rendering industry, and protein blenders, established an independent procedure for audit and verification of compliance through the firm Cook and Thurber. The program found renderers and protein blenders to have a 99% compliance rate with Rule 21 CFR Part 589.

The checks and balances already in place would virtually preclude cross contamination. In order to have cross contamination occur would require a simultaneous breakdown in established procedures by all parties involved in the feed manufacture/delivery cycle.

5. Elimination of the Plate Waste Exemption.

By its very definition, plate waste is a human food product that has undergone inspection by FSIS or a similar state inspection agency. The Harvard Risk Study makes the following conclusion: "Plate waste consists of little mammalian protein, and the tissues that are included in this waste are unlikely to contain BSE infectivity."

Plate waste, by the very nature of the raw material, must be treated by a high-temperature processing step in order to reduce moisture content to a level that will allow grinding of the cooked material. It is highly unlikely that plate waste is going to be included in ruminant rations due to the various and inconsistent odors which would be unacceptable to ruminants, with their highly developed olfactory senses.

Summary

Since the enactment of 21 CFR Part 589 the US rendering industry has supported this regulation, and as result has sustained a tremendous loss of market share for its products. *Feed Management* magazine conducts an annual survey of US feed mills, covering a variety of feed mill related issues. In the

January 2003 issue it reports that in 1998 meat and bone meal was used in 67.7% of the feed mills responding. By the 2002 reporting period that figure had declined to 39.3%. It is obvious that the US rendering industry has paid a huge price to support and comply with a feed ban rule that cannot be justified by science alone, but rather for prevention. To go further would be a tremendous financial burden on an industry that has already contributed greatly for extremely miniscule reductions in the level of risk. Such small levels of risk reduction simply are not worth the costs we will bear.

We believe the FDA has been diligent in carrying out its responsibilities to reduce, as much as possible, the risk of BSE being introduced and amplified in the US. Our risk of BSE in domestic cattle is not zero, nor can it ever be, but our risk today is the lowest it has ever been since the disease was first recognized as a threat to the US cattle population. All involved in animal agriculture, including Smithfield Foods, will continue our commitment to a goal of 100 percent compliance and assuring that relevant federal and state agencies have the necessary resources to achieve that goal.

We thank the agency for the opportunity to submit these comments and for the agency's consideration of them.

Sincerely,

Smithfield Foods Inc.

DOUG ANDERSON
Vice President, Rendering

Smithfield Foods, Inc.
200 Commerce Street
Smithfield, Virginia 23430
Phone (757) 365-3003
Fax (757) 365-3073
E-mail. douganderson@smithfieldfoods.com