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August 10, 2004

Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0264; Federal Measures to Mitigate BSE Risks:
Considerations for Further Action

To Whom It May Concern:

The following comments are submitted on behalf of Farm Sanctuary on the advanced notice of proposed rulemaking on Federal Measures to Mitigate BSE Risk, published in the Federal Register on July 14, 2004 (Volume 69, Number 134).

We wish to comment on three topics addressed in the notice: Human Food Supply, Animal Feed, and Non-Ambulatory (Downed) Cattle.

Human Food Supply

The Harvard-Tuskegee Study identified three pathways that could allow transmission of the BSE agent to humans: 1) Non-compliance with the FDA ban on ruminant to ruminant feed, 2) rendering of animals who die on the farm and use of the rendered product in ruminant feed, and 3) inclusion of high-risk tissue from cattle in products for human consumption. In commenting on the FSIS interim final rule for Specified Risk Materials (SRM) for Human Food, Farm Sanctuary recommended that the following SRM be excluded from both human and animal foods: brain and spinal cord of all cattle, skull and vertebral column of all cattle, and intestines from pylorus to anus from all cattle.

A total ban on SRM, regardless of age of the animal, would best protect the public since a blanket ban would significantly improve enforcement of the prohibition and eliminate the need to determine the age of each animal. The intestine should be considered a primary source of infectivity since infection with BSE has come from cattle ingesting contaminated feed, according to the Scientific Steering Committee of the European Union. In classifying the entire intestine as SRM, the EU Steering Committee noted that because slaughterhouse contamination of other intestinal areas with matter from the ileum can't be avoided, it is prudent to remove the entire small and large intestine.

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Animal Feed

According to the advanced notice of proposed rulemaking, the FDA has reached a preliminary conclusion that it should propose to remove SRM from all animal feed. We urge the FDA to go further and ban all animal protein except milk and eggs from use in feed for any animal that enters the human food chain, an action that has already been taken by the European Union. It is suspected that TSE diseases may be capable of crossing the species barrier and, in fact, some scientists theorize Britain's BSE outbreak occurred when cows ate feed containing parts of sheep and goats infected with scrapie. In addition to stopping the practice of feeding mammals to other mammals, it should also be illegal to feed cattle remains to chickens and then feed the chicken litter back to cows. It is not known whether prion infectivity is reduced or eliminated by passage of infected feed through the chicken's intestinal tract.

Even if the feeding of ruminants to non-ruminants, or of feeding non-ruminants to ruminants or other non-ruminants, doesn't pose a risk of direct transmission of BSE, the practice should be banned to prevent accidental feed contamination. Chicken feed containing cattle protein may spill on the barn floor and then become mixed with poultry litter that's fed back to cattle. The Report on Measures Relating to BSE in the United States, produced by the international panel of experts convened by the USDA, noted that ruminant derived protein contained within the lumen of porcine or avian intestines at slaughter may be included in ruminant feed. [p. 6] Furthermore, the rendering process is not exact. Prohibited cattle feed can be mixed with other feed at the rendering plant, or in feed mills, ranches, and other facilities where mixing takes place. With animals routinely being rendered and fed to other animals, there is no certainty that intentional or accidental contamination won't take place somewhere in the process. The only sure way to guard against accidentally feeding poultry or pig-feed to cattle, or vice versa, is to not allow any avian or mammal meat or bone meal to be processed into feed.

Farm Sanctuary also supports prohibiting the use of animal blood in animal feed and milk replacer. Currently in the U.S. cow's blood collected at the slaughterhouse is used to supplement the colostrum replacer given to young calves. A majority of dairy producers use milk replacer made from cattle blood protein as a cheaper alternative to milk. This practice enables intensive farming operations to remove calves from their mothers immediately after birth, causing physical and behavioral problems for the animals. Cattle blood may also be sprayed directly on the feed of weaned calves and young pigs to save money on feed costs. A number of published studies have shown prion transmission through blood, and the European Commission report on the assessment of BSE risk in the U.S. specifically condemned the practice of "intraspecies recycling of ruminant blood and blood products."

An extension of the current animal feed ban must be accompanied by the enforcement of measures to prevent cross contamination. The USDA's panel of international experts on BSE have recommended enforcement through an inspection program including sampling and testing of feed. [p. 6] The advance notice states that current compliance with the 1997 feed ban rule by feed mills, renderers, and protein blenders is very high. However,

we understand that this assessment is based on feed businesses' reporting of their own practices and not on on-site government inspections and testing of animal feed. Concerns regarding the FDA's inspection methods have resulted in three investigations by the General Accounting Office in the past four years. According to FDA statistics published by the *Sacramento Bee*, of 13,798 feed-handling companies in the United States, 7,725 (or 56%) have not been inspected since December 31, 2002. We encourage the FDA to include on-site inspections and feed testing in any new regulations related to animal feed.

One question posed in the advance notice of proposed rulemaking is whether an exemption should be included in future rulemaking to take into account the future development of new technology or testing that would establish that feed does not present a risk of BSE to ruminants. We oppose the inclusion of such an exception. Cattle and other ruminants are herbivores and do not eat other animals in nature. Even if it were possible to establish with certainty that ruminant proteins are not ingested by ruminants, the risk of interspecies transmission of the disease still exists. And even if it were possible to establish with certainty that non-animal ruminant proteins do not present a risk of BSE to ruminants, other zoonotic diseases may be found to be transmitted in this manner.

Non-Ambulatory (Downed) Cattle

It is generally agreed that non-ambulatory cattle are more likely to be infected with BSE than healthy cattle and therefore pose a greater risk to public health. As a result, the USDA has implemented a ban on the slaughter of downed cattle, which Farm Sanctuary strongly supports. The Harvard-Tuskegee Study has also suggested that the risk of BSE transmission could be further reduced by prohibiting the rendering of animals who die on the farm, an approach we support.

The report prepared by the USDA's international panel of experts notes that steps must be taken to allow for collection of samples from non-ambulatory cattle and for the proper disposal of carcasses. The report observed, "This most likely would involve expending resources to assist with costs associated with sampling, transport and disposal." [p. 4] If a decision is made to increase on-farm sampling of non-ambulatory animals, we request that two concerns be taken into consideration and addressed by any on-farm surveillance program. First, it is important that examination of live animals be conducted in as timely a manner as possible so that animal suffering is minimized. Second, following sample collection, animals must be humanely euthanized by properly trained personnel and only by approved methods.

Thank you for providing the opportunity for Farm Sanctuary to comment on these issues.

Sincerely,



Gene Bauston
President, Farm Sanctuary