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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, Advance Notice of Proposed Rulemaking, Food
and Drug Administration, HHS**

The American Association of Meat Processors (AAMP) is submitting the following comments concerning the proposed **Advance Notice of Proposed Rulemaking (ANPR)** by the U.S. Food and Drug Administration (FDA) concerning federal measures to mitigate BSE risks, and considerations for further action.

The Association is an international organization that represents the meat and poultry processors, slaughterers, wholesalers, retailers, caterers, home food service companies, suppliers and consultants to the meat and poultry industry. Most of its members are small and very small plants, and most are family-owned and operated.

While the ANPR seeks preliminary comments about the issue at hand, and there will likely be further opportunities to comment during actual rulemaking, AAMP has great concerns about what the FDA is suggesting in this proposal: the removal and ban some animal feed ingredients currently that are being used, particularly **Specified Risk Materials (SRMs)** from the entire animal feed chain. These new feed regulation ideas would propose prohibiting mammal and poultry protein from being fed to ruminants, as well as a total ban on SRMs in animal feed. They would remove SRMs from pet food, allegedly to control the risks of cross contamination throughout feed manufacture and distribution on the farm due to mis-feeding. It would also require dedicated equipment or facilities for handling and storing feed and ingredients during manufacture and transportation, for the same reason.

Such a ban has no basis in scientific fact. It would have a massive negative financial effect on the meat industry. This proposal to ban specified risk materials from animal feed in animal feed regulated by FDA would fail both tests. It will put tremendous economic hardships on both meat processors and producers. The total estimated cost to comply with this regulation is estimated at \$300 million. At the same time, FDA has no real "proof" that the new burden it is proposing would result in any benefit to anyone involved in the industry.



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At the same time, the **American Association of Meat Processors (AAMP)** believes that the existing FDA guidelines for feed rules already provide protection against BSE. Two studies have already examined existing controls in the United States. These studies have

evaluated the controls statistically, and the level of compliance measured by FDA, which the Agency continuously claims is very high. The results are that any BSE that exists anywhere in the U.S. should disappear and not spread.

There are really two issues here: (1) Whether a complete SRM ban in animal feed would eliminate the risk of BSE in the United States, and (2) How would meat processors and producers be affected by such a ban. It seems as if it would lower the risk by an infinitesimal amount, while at the same time cost a lot of money. It will hurt renderers as well, because it will require them to make significant changes in the way their industry operates. We are concerned that as a result of those changes, renderers will be even less inclined to visit and pick up materials from small processors.

All the evidence that exists up to now shows that current FDA feed restrictions, if fully enforced the way the Agency has been doing it, will prevent the increase and spread of BSE, as well as get rid of the disease if it currently exists anywhere in the United States.

The questions that FDA raises concerning the use of non-ambulatory disabled cattle in animal feed again renews concerns about whether non-ambulatory animals that have merely suffered physical injuries, rather than central nervous system disease or similar problems, need to be removed entirely from the human food chain. The FDA plan would prohibit SRMs from these animals, as well as "dead stock," animals that die on the farm or that are killed for humane reasons, from use in all animal feed. FDA notes that little if any infrastructure is in place for the removal of SRMs from cattle that are not slaughtered as part of the routine process that occurs at government-inspected slaughter establishments.

FDA asks if SRMs can be effectively removed from dead stock and non ambulatory disabled cattle so that the remaining materials could be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled animals from use in all animal feed? It would not be necessary to prohibit the entire carcass from non-ambulatory disabled animals that merely suffer physical injuries. And if that is true at the animal feed level, it again raises the question as to whether SRMs can be removed from non-ambulatory animals that have merely suffered physical injuries, and not nervous tissue problems.

It is also important to remember that FDA feed rules are designed to protect animal health, while USDA's direction for removal of SRMs is geared toward the protection of human health from BSE. It should also be noted that the **Harvard Center for Risk**

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Analysis has conducted a large assessment of the risk of BSE in the United States over a period of years. The study has concluded that the measures taken so far by the industry and government show that the U.S. has great defenses against the spread of BSE to animals and humans, if it should get into this country.

So far, more than 100,000 animals have been sampled for BSE as part of the **Animal & Plant Health Inspection Service (APHIS)** surveillance program. If there is any BSE in the American cattle herd, its prevalence is extremely low. When you pair that factor with the FDA feed ban that's been in existence for the past seven years, the odds are that the disease is on its way to extinction. Also, FDA's figures show a compliance rate of 98-1/2 percent with the feed ban.

As a result of all these factors we've named above, AAMP does not think that the FDA plan to expand its BSE prevention as part of this ANPR is justified. Instead, it seems to be more "added layers of protection" that sound good in the media and in the public arena, but don't necessarily do anything to improve the "public safety." "We'll make a strong system even stronger," Agency officials said. In other words, "piling on," like in football, won't really accomplish anything, but it looks good.

In its comments to other regulatory agencies concerning BSE, AAMP has asked a number of times why animals that are sampled for BSE and found to be OK aren't released for use as human food. The regulatory agencies never answer the question, because they don't have a viable answer. But the economic impact of moving huge amounts of valuable meat and bone meal from use now as feed supplements is going to hurt the beef industry greatly. It gives renderers the incentive to pick up and process cattle that die before they are slaughtered. Removing these feed supplements will hurt the industry. Doing so won't improve public health. But it would impress the public!

What would happen to all those dead carcasses? Right now, almost half are picked up by renderers. Instead, they'll either be buried on farms or go to landfills – if they'll be taken there. Of course, there's no regulation of on-farm burial. In fact, these buried animals spread out in the fields could end up being fed to cattle, which is exactly the opposite of what the government is trying to do.

AAMP also wonders why the **Food and Drug Administration** gave commenters such a short period of time (30 days) to formulate reactions to this important proposal. Even though it is preliminary rulemaking, the Agency took quite a long time to publish the ANPR following the release of the **International Review Team** report on the issue. We wonder why the Agency didn't extend the comment period to at least 60 or even to 90 days. That way, interested parties could submit sound, scientific and well-thought-out comments to the Agency ANPR.

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Please let us know if you have any questions, or if we can submit additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Bernard F. Shire". The signature is written in a cursive, flowing style.

Bernard F. Shire
Director of Legislative & Regulatory Affairs

cc: Scott Cunningham, AAMP President