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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Docket No. 2004N-0264, "Federal Measures to Mitigate BSE Risks: Considerations for Further Action"

On behalf of The Humane Society of the United States (HSUS) I would like to take this opportunity to submit comments regarding the Advance Notice of Proposed Rulemaking "Federal Measures to Mitigate BSE Risks: Considerations for Further Action." As the country's largest animal protection organization with more than 8 million supporters nationwide, we are deeply concerned about the potential impact of transmissible spongiform encephalopathies (TSEs) on animal health. We are disappointed with the lack of progress made by the Food & Drug Administration (FDA) in closing loopholes in animal feed rules which could allow the spread of TSEs through contaminated feed.

Upon discovery of a Washington State cow suffering from Bovine Spongiform Encephalopathy (BSE), the U.S. Department of Agriculture (USDA) immediately announced prudent changes such as banning non-ambulatory disabled cattle (downers) from the human food supply.¹ On January 26, 2004, the FDA also announced that it would strengthen its animal feed rules because "we must never be satisfied with the status quo where the health and safety of our animals and our population is at stake." It has yet to follow through with these changes. Secretary Thompson publicly pledged to close identified loopholes in the FDA feed ban regarding the use of blood, poultry litter, and plate waste, and to require dedicated production and transportation equipment to minimize risks of cross-contamination – all to be effective "immediately upon publication" of an interim final rule.² The subsequent publication in July of this Advance Notice of Proposed Rulemaking – a much more tentative step that may never yield a final rule – is an alarming set-back. Any further delay needlessly puts animal (and human) health at risk.

The FDA has an opportunity to show true leadership by moving forward and acting on the premise that BSE is likely circulating in North American cattle and that we are likely to find more cases. It has been suggested that for each clinically affected animal identified, many animals are infected or exposed.³ This notion is supported by the USDA Foreign Animal and Poultry Disease Advisory Committee's Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy (hereafter referred to as 'the subcommittee').⁴ The FDA's Dr. Crawford was quoted as saying that the subcommittee had "convinced us that there is a greater risk of amplification, than previously believed."⁵

The U.S. General Accounting Office's (GAO) 2002 report on "Mad Cow Disease" concluded that "federal actions do not sufficiently ensure that all BSE-infected animals or products are kept out or that if BSE were found it would be detected promptly and not spread to other cattle through animal feed or enter the human food supply."⁶

We are concerned that FDA may be waiting for another case of BSE to surface in the U.S. before acting decisively to tighten the feed rules.⁷ The animal and human health implications as well as the impact on consumer confidence of another BSE case are too serious to be merely reactive; rather a proactive approach is needed. We therefore urge the FDA to implement quickly changes as follows: 1) ban specified risk materials (SRMs), dead stock, downers, and cattle showing signs of a central nervous system (CNS) disorder and/or testing negative for rabies from all animal feed, including pet food; 2) ban all mammalian and poultry proteins with the exception of milk (including blood, plate waste, and poultry litter) immediately from ruminant feed, and as soon as possible from all other farm animal feed; 3) require dedicated facilities and equipment so that animal feed is not contaminated with prohibited material; and 4) strengthen enforcement of the feed rules with more frequent inspections of facilities, more direct testing of feed content and less reliance on industry self-reporting, and more meaningful sanctions for non-compliance. The need for these changes is explained in the following sections.

1) Ban use of high-risk materials in all animal feed, including pet food

We agree with the subcommittee's approach that preventing potentially infective tissues from ever entering the animal feed chain is crucial. Therefore, as the subcommittee suggests, prohibiting SRMs (the brain, skull, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and vertebral column of cattle 12 months or older and the tonsils and distal ileum of the small intestine of all cattle), in which the abnormal prions that cause BSE are concentrated, is a sensible first step.⁸ SRM removal from the feed supply is further supported by the 2003 Harvard Risk Assessment which found that a ban on SRMs from both human food and animal feed reduces the predicted number of BSE cases, following introduction of ten infected cattle, in cattle by 90% and the potential human exposure by 95%.⁹ Also, both the World Health Organization (WHO) and the United Nation's Food and Agriculture Organization (FAO) recommend that SRMs not be permitted to enter any food chain (human or animal).^{10,11}

The removal from animal feed of downers, dead stock (animals that have died on the farm), cattle showing signs of a CNS disorder, and cattle who appear rabies-suspect but test negative would add another important layer of protection since these animals have a greater incidence of BSE than the general population. A Swiss study (one of several cited by USDA) found that downer cattle are 49 to 58 times more likely to have BSE than cattle identified through passive surveillance (i.e., those reported to veterinary authorities as BSE-suspect based on clinical observation).^{12,13} Hence, the USDA has imposed a complete prohibition on use of downed cattle in the human food supply, regardless of the reason an animal is non-ambulatory (in recognition of the difficulty of correctly determining why the animal is downed and the fact that injury and illness are often

interrelated). The Harvard Risk Assessment found that prohibiting the rendering of animals that die on the farm would remove a great deal of potential contamination in the animal feed chain and reduce average predicted cases of BSE following introduction of ten infected cattle by 80%.¹⁴ Preventing the entry of the highest-risk animals (downers, dead stock, CNS-suspect, and those that test negative for rabies) into the animal and pet feed supply is also sound policy because the FDA has acknowledged the lack of adequate infrastructure at many rendering plants for effective removal of SRMs. Given those limitations, it makes sense to prohibit the highest-risk animals from feed altogether. Also, a ban on these animals is important because, although cattle muscle has not yet been shown to contain the infectious prions, recent studies have found them in the muscle of other species. In 2002 the abnormal prions that cause TSEs were found in mouse muscle, and in 2004 researchers found them (albeit at much lower levels than in the brain) in sheep muscle several months before clinical disease onset.^{15,16} This raises the real possibility that increasing sensitivity and sophistication of testing procedures could reveal infectious prions in cattle muscle. In light of this concern, prohibiting only SRMs does not provide adequate protection and it is prudent to keep the high-risk animals altogether from animal feed and pet food.

There is strong evidence that cats are susceptible to BSE and we therefore urge FDA to prohibit immediately the use in pet food of any SRMs, downers, dead stock, or cattle showing signs of a CNS disorder or testing negative for rabies. There have been confirmed cases of Feline Spongiform Encephalopathy in approximately 100 cats in Europe. More than a third of U.S. households own at least one cat and there are approximately 77.6 million pet cats nationwide, according to a 2002 survey. As a testament to the importance of these cats to their owners, the top-rated benefit of cat ownership is identified as companionship, love and company by almost nine out of ten cat owners.¹⁷ Since the FDA is charged with ensuring the safety of the food cats consume, we feel it would be reckless not to prohibit the inclusion of the high risk materials enumerated above in pet food. FDA has recognized the necessity of prohibiting these materials in human food, dietary supplements, and cosmetics, through its Interim Final Rule published on July 14, 2004. This same protection must be extended to our nation's pets. Furthermore, it is reckless to allow high risk materials in pet food given the potential for cross-contamination with ruminant feed during processing, distribution, and use on the farm. We note that the pet food industry appears to be moving in this direction, as they are increasingly demanding protein that is free of SRMs.¹⁸ Iams, one of the largest pet food companies, makes a point of claiming on its website that "We do not use any head (including brain), spinal column, tonsils or intestines from beef in any of our Iams or Eukanuba formulas."¹⁹ But there must be an across-the-board rule for all manufacturers in order to ensure safe pet food production.

The measures discussed above are consistent with measures introduced by the Canadian Food and Inspection Agency (CFIA). The CFIA intends to require the removal and redirection of SRM and dead stock and downer cattle from all animal feed, including pet food. Its risk analysis found that removing SRM from animal feed will hasten a reduction in BSE incidences in North America by preventing future disease spread.^{20,21} Considering

the large amount of trade between Canada and the U.S., it would seem sensible to have similar feed regulations in order to reduce confusion and trade barriers.

We recognize that the ban on use of high-risk cattle for animal feed and pet food could have some financial impacts associated with alternative, environmentally sound disposal. But these concerns must be weighed against the potentially enormous costs to industry and society of allowing feed contamination, with resulting BSE cases and possibly human infections. Moreover, it is hoped that industry is beginning to take extra care to prevent animals from becoming non-ambulatory as a result of the USDA and FDA bans. Temple Grandin – advisor to the American Meat Institute, McDonald’s, and others – long ago explained in *Meat & Poultry Magazine* that “Ninety percent of all downers are preventable.” With improved handling and animal husbandry practices, industry can reduce the already relatively small percentage of downer cattle (estimated by USDA in January 2004 to be 0.4 percent to 0.8 percent of the total number of cattle slaughtered).

2) Ban use of any mammalian and poultry protein in ruminant feed, then in all farm animal feed

FDA should immediately prohibit the use of all mammalian and poultry protein (except milk) in ruminant feed, including blood and blood products, plate waste, and poultry litter. We find it disturbing that FDA has backtracked on its January 2004 promise to issue a final rule to close the loopholes on blood, plate waste, and poultry litter, and we strongly urge the agency to go forward expeditiously with these important prohibitions. Blood from cows, which is routinely fed to calves as part of their milk formula, poses unwarranted risks. FDA’s January 26th press release noted that “recent scientific evidence suggests that blood can carry some infectivity for BSE.”²² There is growing support for this contention. For example, one study found that it is possible to transmit BSE to a sheep by transfusion with whole blood taken from another sheep that was infected with BSE but in the symptom-free phase.²³ And a recent human case of variant Creutzfeldt-Jakob disease (vCJD) has been linked to a blood transfusion from a donor who died of vCJD.²⁴

Allowing the continued use of plate waste (uneaten meat and other scraps from restaurants) confounds FDA’s ability to determine the content of animal feed and ensure it is free of prohibited material.²⁵

Feeding poultry litter to ruminants is also risky – as well as unnatural and offensive. It is a practice that is met with widespread revulsion when it receives public attention. Recycled poultry litter often contains spilled feed that may have prohibited proteins. So chickens are fed ground up cow parts and cows, in turn, are consuming left-over chicken feed with cow parts in it. Poultry litter also contains large quantities of manure, which may contain infectious prions. Experiments with mice that were infected with scrapie (a TSE affecting sheep) showed that a detectable amount of infectivity passes through the gut.²⁶ In addition, using poultry manure in animal feed poses other risks because it contains pathogens, drugs and their metabolites, and minerals and heavy metals.²⁷

The FDA should ban the use of all mammalian and poultry protein from ruminant feed in short order. According to WHO, the digestive contents and fecal material from livestock or poultry being fed with meat and bone meal (which may be contaminated with BSE) should not be used as feed ingredients.²⁸ Furthermore, rendered porcine products should be prohibited because pigs have been shown to be capable of contracting a TSE in a laboratory setting.²⁹ We note that the Harvard Risk Assessment did not consider the feeding of rendered swine to cattle because this practice is considered expensive and uncommon; therefore, it should be little or no burden on industry to have this practice prohibited.³⁰ There are also concerns that livestock could be silent carriers. A study of mice with infectious prions acquired from hamsters found the mice did not become sick but instead accumulated prions that could infect other mice. This raises the possibility that livestock such as swine, fed with BSE-contaminated animal protein, could remain healthy but accumulate prions in their CNS.³¹ While this research is in its preliminary stages, it illustrates that our knowledge of TSEs is still evolving and raising new possibilities for the spread of these diseases. In light of this, FDA should err on the side of caution and prohibit all mammalian and poultry protein from ruminant feed immediately.

We further urge FDA to phase out the feeding of mammalian and poultry protein to all farm animals (not just ruminants) as soon as possible. Such a blanket rule would help prevent cross contamination and allow better enforcement. There is a well-documented risk of cross contamination at feedmills and on farms in countries where meat and bone meal (MBM) is fed exclusively to pigs and poultry. In the European Union, cross contamination of ruminant feed with MBM destined for pigs and chickens probably sustained the spread of BSE.³² In recognition of this, the use of mammalian MBM to feed any farm animal has now been prohibited in the United Kingdom.³³ The European Union has also introduced a ban on the feeding of processed animal protein to animals kept for food production.³⁴ This approach makes even more sense because other illnesses besides BSE can also result from high-risk feed with animal proteins in it, such as foot and mouth disease.

3) Require dedicated equipment and facilities for handling and storing feed and ingredients during manufacturing and transportation

Cross contamination of ruminant animal feeds, which can occur during production and distribution, as well as on farm due to inappropriate use, is a real concern. We therefore strongly urge the FDA to require that feed manufacturers and distributors maintain dedicated equipment and facilities. This is a necessity given how little BSE agent is required for infection. Recent research shows that as little as 0.01 grams of the BSE agent can be an infectious dose, and researchers believe additional studies may uncover a still lower dangerous dosage.³⁵ The abnormal prions that cause BSE are highly resistant to destruction, so equipment cannot be readily decontaminated.³⁶

4) Strengthen enforcement of feed rules

We commend the FDA for its commitment to increasing inspections of feed mills and rendering plants. However, the GAO's 2002 report seriously called into question the efficacy of the FDA's enforcement of the feed ban. Among the flaws cited were too infrequent inspections, use of warning letters for violations without meaningful follow-up, and an inadequate database.³⁷ We are also concerned that FDA relies too heavily on industry self-reporting without direct testing of feed supplies for prohibited proteins. And we are concerned that FDA cedes too much oversight responsibility to state government entities whose budget constraints may result in corner-cutting. Without strong federal enforcement and penalties the feed rules offer little protection. We encourage FDA to take steps, through administration budget requests and improvements in utilization of resources, to ensure the strongest possible enforcement of these important rules.

In conclusion, we urge the FDA to ban immediately high-risk materials (SRMs, downers, dead stock, and cattle suspected of CNS disorders) from all animal feed including pet food, and all mammalian and poultry protein including blood, plate waste, and poultry litter from ruminant feed, with a goal of eliminating all such protein from non-ruminant farm animal feed in the near future. We also urge FDA to require immediately dedicated facilities and equipment to reduce risks of cross contamination, and to improve inspections and other enforcement efforts. We appreciate the opportunity to provide our comments on this urgent matter and hope you will move forward quickly on these recommendations. The health and welfare implications for all animals, including humans, make this issue an extremely important one. Thank you for your time and consideration.

Sincerely,



Wayne Pacelle
President and CEO

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Docket No. 2004N-0081, "Use of Materials Derived from Cattle in Human Food and Cosmetics"

On behalf of The Humane Society of the United States (HSUS) and the more than 8 million supporters of our organization nationwide, we would like to take this opportunity to submit comments regarding the Interim final rule "Use of Materials Derived from Cattle in Human Food and Cosmetics." One of the most prudent measures taken by the United States Department of Agriculture (USDA) to mitigate bovine spongiform encephalopathy (BSE) risks was the banning of all non-ambulatory disabled cattle (downers) from the human food supply. The HSUS strongly supports this policy as it helps to protect animal welfare and the safety of the food supply. We therefore strongly urge the Food and Drug Administration (FDA) to extend the prohibition on non-ambulatory disabled cattle to all the human food and cosmetics under its regulation.

Animal Welfare

Downed animals suffer terribly. Firstly, they suffer as a result of the illness and or injury that incapacitates them. A study on disabled cattle found their cortisol levels (a physiological indicator of stress) were nearly triple that of normal healthy cattle.¹ The researchers concluded that the cows were suffering from severe stress. Furthermore, because they need special processing, downed animals may be left in this condition for hours or days without food, water, or veterinary care as they await slaughter.

Transporting downers in inhumane ways compounds this suffering. Non-ambulatory disabled animals are difficult, if not impossible, to transport humanely. Investigations by The HSUS and other animal protection organizations have revealed that animals too sick or injured to stand or walk are routinely kicked, dragged with chains, shocked with electric prods, and pushed by bulldozers in efforts to move them at auction and slaughter facilities. A national study by industry expert Temple Grandin, Ph.D., found that at some plants the most common handling problem associated with downers was dragging them while they were conscious.²

Some animals may be non-ambulatory due to broken legs. Anyone who has broken a bone knows the need for handling with the utmost care to minimize pain. To be dragged by chains, and perhaps even pulled by the very limb that is broken, is abhorrently cruel. As Dr. Grandin has also noted, "Ninety percent of all downers are preventable."³ It is precisely the cases that involve broken bones and other injuries that are the most preventable with improved animal husbandry and handling practices. Prohibiting use of these animals for human food will encourage greater care to keep them from becoming downers in the first place.

Promoting the protection of all animals

2100 L Street, NW, Washington, DC 20037 ■ 202-452-1100 ■ Fax: 202-778-6132 ■ www.hsus.org

Food Safety

Allowing downers to be processed for human food threatens the safety of the food supply. Non-ambulatory disabled cattle are understood to be at heightened risk for BSE. A Swiss study (one of several cited by USDA) found that downer cattle are 49 to 58 times more likely to have BSE than cattle identified through passive surveillance (i.e., those reported to veterinary authorities as BSE-suspect based on clinical observation).⁴⁵ Given the terrible and devastating nature of new variant Creutzfeldt-Jakob disease (vCJD) in humans, thought to be caused by eating meat contaminated with the abnormal prions that cause BSE, keeping downer cattle out of the U.S. food supply makes eminent sense.

Animals unable to stand or walk are not only at a higher risk of suffering from BSE but also have been shown to have a higher prevalence of *Escherichia coli*, *Salmonella*, and other dangerous pathogens that can transmit disease to consumers. In particular *E. coli* O157: H7 is a significant public health concern because it has been implicated in more than 70,000 human infections and around 61 human deaths each year in the U.S.^{6,7} Cattle are the primary reservoir for *E. coli* O157:H7⁸ and a study on the subject found downer cattle were more than 3 times more likely to have this deadly pathogen than healthy cattle.⁹ Downer cows can also shed more salmonella.¹⁰

Public Support

When the USDA announced its interim ruling prohibiting the processing of non-ambulatory disabled cattle for the human food supply, there was an outpouring of public support. Major retailers, consumer groups and other nonprofits, and some agricultural organizations and individual ranchers expressed strong support for the ban as well. In fact, of approximately 22,000 comments submitted to the USDA, more than 99 percent strongly support the ban. Details on this and more are in the included HSUS report "[Public Comments on USDA's Downed Animal Ban: Major Retailers and the Vast Majority of Americans Support No-Downer Policy; Some Industry Groups Reverse Their Support for the Ban](#)". The massive support for the ban was not only based on food safety concerns but also humane concerns, and is in line with a 2003 Zogby poll that showed a majority of Americans oppose the use of downed animals for human food. According to that poll, more than three-fourths of the U.S. population feels it is unacceptable to use downed animals for human consumption (77%). An even larger majority of the U.S. population is concerned that sending downed animals to slaughterhouses could put human consumers at risk for mad cow disease (81%).¹¹ The FDA should heed this strong and unwavering support for the prohibition on non-ambulatory disabled cattle and extend the ban to the human food and cosmetics it oversees.

In conclusion, we urge the FDA to prohibit the use of non-ambulatory disabled cattle in the human food and cosmetics under its regulation. Animals that are unable to stand and walk are suffering and their meat and meat byproducts should be entirely kept out of the food supply. Thank you for your time and consideration.

Sincerely,



Wayne Pacelle
President and CEO

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