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U.S. Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket Number: 98P-0151/CP1

Dear Sir or Madam:

On behalf of The Humane Society of the United States and its over 7 million constituents, I am writing to request that the FDA grant the petition to label all downed livestock as adulterated, as argued on behalf of Farm Sanctuary and its members in its May 10, 1998 amended petition. Specifically, The HSUS agrees with petitioners that there is sufficient evidence to treat "downed" livestock – non-ambulatory livestock who collapse for unknown reasons and who are unable to stand – as adulterated food and therefore prohibited from entering the domestic food supply.

Food, Drug and Cosmetic Act and Adulterated Food

As cited by petitioners, section 342(a)(4) of the Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. 331, provides that, "A food shall be deemed to be adulterated... if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." For purposes of subdivision (4), it is not necessary for the FDA to determine that a specific item of food is actually contaminated or injurious to health in order to be treated as adulterated. Rather, food is considered adulterated if it has been prepared or held under conditions that may have resulted in its becoming injurious to health. *United States of America v. Nova Scotia Food Products Corp., et al.*, 417 F. Supp. 1364, 1369 (1976). (emphasis added) (See also, *United States of America, v. King's Trading, Inc.*, 724 F. 2d 631 (1983): "Section 342(a)(4) does not require actual contamination of food, only conditions that may result in contamination.")

98P-0151

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Risk of Mad Cow Disease

After the first case of bovine spongiform encephalopathy (BSE) was discovered in the United Kingdom in 1986, BSE quickly became an epidemic in cattle herds there. (Center for Veterinary Medicine Update, 1/10/2001) Eleven years later, in response to the epidemic, regulations were implemented in the United States to prohibit the feeding of mammalian protein to ruminant animals in most cases. More than three years after the implementation of the regulations, however, different segments of the feed industry are showing varying levels of compliance. In fact, as reported by your own agency, "large numbers of companies involved in manufacturing animal feed are not complying with regulations meant to prevent the emergence and spread of mad cow disease in the United States." ("Makers of US feed fail to heed rules on mad cow disease", *New York Times*, 1/11/2001)

Nor is testing at current levels an adequate assurance against mad cow disease. The USDA reports in its March 25, 1999 denial of Farm Sanctuary's "downer" petition that, since 1990, nearly 6,500 specimens, from animals in 43 states, have been laboratory tested by a BSE surveillance system in the U.S. Therefore, on average, the USDA tests less than 650 specimens a year for BSE. Recognizing that every year over 100 million livestock are slaughtered in the United States, if even a *tiny* percentage of untested animals are falling victim to BSE or a similar disease, this could have a devastating impact on the safety of the United States food supply. Moreover, Creutzfeldt-Jakob Disease (CJD), the human equivalent of BSE, is not required to be reported in the United States and thus there are no accurate figures on the number of cases here. (*BBC Radio*, 5/20/1999) Without adequate testing or regulatory enforcement, our food supply is put at risk and consumers will not be reassured to know that: "As long as an animal, even a diseased animal, depending upon the disease, has been passed for slaughter, it is possible that the carcass, or a portion of it, may be inspected and passed for human food." (3/25/1999 USDA letter)

Mad Cow and "Downers"

Downed cow syndrome is a major problem especially among dairy cattle in the U.S., with tens of thousands of cows collapsing for largely undetermined reasons every year.¹ Although no U.S. downed cow has yet exhibited symptoms matching those of Britain's mad cows, spongiform encephalopathies can emerge as variant forms, with different disease patterns. For example, to determine if sheep scrapie agents in the United States would induce a disease in cattle resembling BSE, scientists inoculated 18 newborn calves intracerebrally with brain specimens from 9 sheep with scrapie. (Many scientists believe BSE spread in Britain when sheep infected with scrapie were fed to cattle.) All calves kept longer than 1 year became severely lethargic and demonstrated clinical signs of motor neuron dysfunction that were manifest as progressive stiffness, posterior paresis, general weakness and permanent recumbency.² Symptoms created in these scrapie inoculated calves are the same as typically seen in downer cows and suggest that "downed" animals in the dairy industry may, in fact, be infected with scrapie.³

¹ D.J. Middleton and R.M. Barlow, "Failure to Transmit Bovine Spongiform Encephalopathy to Mice by feeding then with Extranuclear Tissues of Affected Cattle," *Veterinary Record* (May 29, 1993): 545-5467

² *J Infect Dis* 1994 Apr; 169(4): 814-20

³ *Journal of Infectious Diseases* 1994; 169:814-20

Adulterated Food

Again in its March 25, 1999 denial of Farm Sanctuary's "downer" petition, USDA argues that *some* disabled or non-ambulatory animals are not diseased. (emphasis added) However, section 342(a)(4) of the Food, Drug and Cosmetic Act does not require that each and every downed animal be determined to be injurious to health in order that downed animals in general be deemed adulterated. Instead, the law provides for an adulteration label when conditions exist that *may* result in downed animals being injurious to health.

This was the case when your agency determined that clams from certain foreign waters were prepared, packed or held under unsanitary conditions whereby they may have been contaminated and therefore adulterated within the meaning of 21 U.S.C. § 341(a)(4). *Goodwin v. United States*, 371 F. Supp. 433 (1972). The court held that the FDA was not required to find that each shellfish is actually contaminated; rather, it is sufficient that the shellfish appear to have been grown or processed under unsanitary conditions. *Id.* at 435. Otherwise, the FDA would be required to inspect each and every clam and such a burden on the agency would severely minimize the power of the FDA to protect the U.S. food supply – as it would if the FDA or USDA were required to test each and every downed animal before determining they posed too great a risk to American consumers.

Summary

Based on the above, downed animals should be deemed adulterated because they are raised in conditions where they may have been "rendered injurious to health". 21 U.S.C. § 342(a)(4) First, as the FDA reported to the *New York Times*, large numbers of companies involved in manufacturing animal feed are not complying with regulations meant to prevent BSE in the United States. In addition, the USDA is currently failing to test more than a miniscule percentage of the U.S. livestock population for the presence of the disease. Inadequate regulatory compliance and testing is especially alarming considering recent evidence that a strain of the disease may in fact manifest itself in symptoms more typically characterized as downed animals. Moreover, most dairy cows in the U.S. are slaughtered after just a few years in production, possibly long before they would show symptoms of BSE.

As Europe has discovered, the stakes with BSE are huge. If even a seemingly insignificant portion of the tens of thousands of downed animals in the United States are indeed exhibiting signs of BSE, a health crisis with devastating consequences could be on the horizon. Contrast that risk with the relatively small economic impact of not allowing downed animals into the domestic food supply and the choice is clear. The HSUS believes that downed animals pose an unacceptable risk to the health of the American meat-eater and urges you to grant the petition as argued by Farm Sanctuary.

Sincerely,



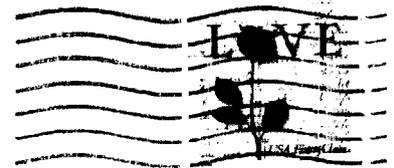
Patricia Forkan
Executive Vice President

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OF THE UNITED STATES**

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