1-2-2004

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**Presence of “Mad Cow” Disease in United States Raises Significant Questions Concerning U.S. Food Safety Policies**

— by Roger A. McEwen* and Neil E. Harl**

The detection of a Holstein cow infected with Bovine Spongiform Encephalopathy (BSE) (commonly known as “mad cow” disease) at a dairy in Washington state raises significant questions about the effectiveness and validity of existing food safety regulations and the ability of the federal government to detect the presence of the disease under current procedures.\(^1\) Likewise, the presence of BSE in the U.S. will almost certainly force the Congress to reconsider legislation that addresses the safety of the U.S. meat supply.

### BSE Basics

BSE is a fatal disease in cattle that causes degeneration of the brain and is evidenced by staggering and weight-loss of the infected animal.\(^2\) BSE was first detected in the United Kingdom in 1986, and has since spread to over 23 countries. To date, over 180,000 cases of BSE have been detected worldwide, and approximately 150 human deaths have occurred from the human version of the disease. Scientific findings in recent years have revealed that feeding cattle the rendered remains of sick animals spreads the disease. Consequently, the USDA has imposed various import controls and has adopted a feed ban prohibiting the use of most animal-derived proteins in cattle feed. The USDA also collects and analyzes brain samples from adult cattle with neurological symptoms and adult animals that were non-ambulatory at slaughter.\(^3\) However, current U.S. law does not require that cattle be tested before slaughter\(^4\) or that the tissues that harbor the disease (brain and spinal cord) be banned from possible human consumption.\(^5\)

### Legal Challenge to USDA Regulations

Before the USDA’s announcement of the presence of BSE in the United States, an administrative challenge had been filed against USDA regulations that permit downed livestock to be used for human consumption after passing a post-mortem inspection.\(^6\) The plaintiff, a beef consumer, claimed that the USDA policy violated the Federal Meat Inspection Act (FMIA)\(^7\) and the Federal Food, Drug, and Cosmetic Act (FFDCA).\(^8\) The FFDCA prohibits the manufacture, delivery, receipt or introduction of adulterated food into interstate commerce,\(^9\) and provides that any food that is “in whole or part, the product of a diseased animal” shall be deemed “adulterated.”\(^10\) USDA regulations define “dying, diseased or disabled livestock” as including animals displaying a “lack of muscle coordination” or an “inability to walk normally or stand.”\(^11\) Thus, the consumer argued that the agencies should label all downed livestock as “adulterated,” and that the

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consumption of downed animals created a serious risk of disease transmission (particularly the risk that humans will contract a fatal disease by eating BSE-contaminated beef products) and that elimination of downed cattle from the human food stream was necessary to protect public health.¹²

On May 25, 1999, the USDA’s Food Safety and Inspection Service (FSIS) denied the petition on the basis that FSIS was bound by the definition of “adulteration” set forth in the FMIA for all livestock slaughtered at a federally-inspected slaughterhouse, and that the FMIA does not classify all products from diseased animals as adulterated. The FSIS also took the position that its regulations were consistent with the FMIA which permits the carcases of diseased animals to be passed for human food if an FSIS veterinary officer determines that the carcass is safe for human consumption.¹³ The plaintiff sought judicial review under the Administrative Procedure Act,¹⁴ and the USDA motioned to dismiss the complaint on the basis that the consumer lacked standing to sue because no allegation was made that BSE had ever been detected in the U.S. and, as a result, any asserted injury was merely speculative.¹⁵ The Federal District Court for the Southern District of New York granted the USDA’s motion to dismiss on the basis that the alleged harm was “too remote” to support standing.¹⁶

On appeal, the Second Circuit vacated the district court’s opinion and remanded the case.¹⁷ The Second Circuit pointed out that a beef consumer, to establish standing, must allege and prove an injury-in-fact (not merely conjecture) that is fairly traceable to the challenged action of the USDA which is likely to be redressed by the requested relief.¹⁸ According to the court, enhanced risk of disease transmission due to the USDA’s position of allowing the meat from downed livestock to be used for human consumption constitutes injury-in-fact in the context of food and drug safety statutes.¹⁹ The court noted that the purpose of the FMIA and the FFDCA (the statutes USDA is alleged to have violated) is to ensure the safety of the nation’s food supply and to minimize the risk to public health from potentially dangerous food and drug products.²⁰

Thus, the court found a direct connection between the type of injury alleged and the fundamental goals of the statutes the lawsuit was based upon. The court also stated that standing is not to be denied simply because numerous people (here, consumers of beef) may suffer the same injury.

As to whether the plaintiff had successfully alleged a non-conjunctural risk of harm by asserting an enhanced risk of disease due to the USDA policy of allowing the meat from downed cattle to be used for human consumption, the court noted that even a moderate increase in the risk of disease may be sufficient to confer standing.²¹ While the USDA maintained that there was no evidence of the presence of BSE in the U.S. (and that it was never likely to enter the U.S.),²² the court noted that a General Accounting Office (GAO) report in January of 2002 challenged the basis for the USDA position by raising concerns about the effectiveness of current federal BSE prevention and detection efforts.²³ The GAO report also noted that an FDA advisory committee had recommended that the “FDA consider taking regulatory action to ban brains and other central nervous system tissue from human food because of the potential risk of exposure to BSE-infected tissue.”²⁴ The court also pointed out that the USDA’s FSIS, in a Think Paper, had acknowledged that BSE-infected animals may pass the required post-mortem examination and be offered for human consumption.²⁵ Consequently, the court held that the plaintiff had alleged a credible threat of harm from downed cattle, and had standing to challenge the USDA regulation.

**Defeat of Proposed Legislation**

In July 2003, the United States House of Representatives defeated by a vote of 202-199 an amendment to the Fiscal Year 2004 Agricultural Appropriations bill (enacted thereafter as the Consolidated Appropriations Act of 2004)²⁶ which would have prohibited meat packers from passing through inspection any “nonambulatory livestock.”²⁷ The legislation was earlier proposed as an amendment to the Farm Security and Rural Investment Act of 2002,²⁸ but was later offered as an amendment to the Fiscal Year 2004 Agricultural Appropriations bill. Although the amendment had been passed by the Senate, the Conference Committee on December 9, 2003, stripped the provision from the Agricultural Appropriations bill which then was passed.

The proposed legislation, entitled the “Downed Animal Protection Act,”²⁹ in addition to prohibiting an establishment covered by the FMIA from passing nonambulatory livestock through inspection, would also have prohibited an entity covered by the legislation from moving nonambulatory livestock while the livestock was conscious and would have required covered entities to humanely euthanize such livestock.³¹ Nonambulatory livestock would have been defined to mean “any cattle, sheep, swine, goats, or horses, mules or other equines, that are unable to stand and walk unassisted.”³² The Secretary of Agriculture would have been directed to promulgate regulations to provide for the humane treatment, handling and disposition of nonambulatory livestock by a covered entity, including the requirement that nonambulatory livestock be humanely euthanized.³³ The term “covered entity” would have included a stockyard, a market agency a dealer, a slaughter facility and an “establishment.”³⁴ The term “establishment” would have been defined to include any firm covered by the FMIA.³⁵

**Future Developments**

The discovery (and later confirmation) of BSE in the U.S. in December 2003 is likely to lead to the invalidation of the existing USDA regulations that allow meat from downed livestock to enter the human food supply when the merits of Baur and other policy steps (including increased testing, if not required testing, for all cattle; tightened rules on the feeding of animal by-products to bovine; a system for tracing livestock; Country of Origin Labeling; and legislation that gives the federal government power on a...
FOOTNOTES

1 It is noted that the infected cow was not tested because of the presence of outward symptoms of BSE, but because the cow had become a “downer” cow due to an injury to her pelvic canal after giving birth to an unusually large calf. See “Mad Cow Case In U.S. Shows Gaps in System,” The Wall Street Journal, December 26, 2003, p. A1.

2 The disease appears to be caused by misfolded proteins known as prions that fold themselves into alternative shapes containing lethal properties and trigger reactions in tissues of the nervous system. As the number of misfolded proteins accumulate, nerve cells are destroyed.

3 Because FSIS has determined that downed animals are at particular risk for neurological illnesses such as BSE, it has focused its testing efforts on downed cattle which currently account for over 90 percent of the animals tested in the federal BSE surveillance program.

4 Of the approximately 35 million cattle slaughtered in the U.S. in 2003, only slightly more than 20,000 were tested for BSE. Proposals to increase the number of cattle tested have been met with stiff opposition by the meatpacking industry.

5 Such materials are commonly included in processed meats, including bologna, hot dogs and sausages. Another point that has received relatively little attention is that the cooking of meat, regardless of the temperature, does not remove the presence of BSE.

6 Baur v. United States Dept. of Agriculture, administrative petition filed Mar. 4, 1998, challenging 9 C.F.R. § 311.1. The petition was amended in May of 1998 requesting the agencies to label all downed livestock, not just downed cattle, as adulterated under the FFDCA and that they be banned from potential use for human consumption.

11 9 C.F.R. § 301.2.
12 The petition claimed that current BSE surveillance efforts, including slaughterhouse inspection procedures, only provided limiting screening based on the fact that the required post-mortem inspection of downed cattle commonly takes five minutes or less (making the identification of central nervous system symptoms difficult) and that BSE has a long incubation period during which time there may be no observable symptoms of BSE.
13 9 C.F.R. § 311.1. FSIS also maintained that “BSE does not exist in this country.”
14 5 U.S.C. §§ 701 et. seq.
15 The USDA defended the adequacy of its regulation and current inspection policies by noting that 6,500 specimens from animals in 43 states have been laboratory-tested for BSE since 1990 without finding any evidence of BSE or related transmissible diseases.
18 Id.
19 Id.
20 Id.
21 Id.
23 See United States General Accounting Office, Rep. No. GAO-02-183, Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts (2002). The report noted that while BSE had not been found in the U.S., federal actions did 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.
24 Id.
25 FSIS Think Paper (no date given). The paper states, “the typical clinical signs associated with BSE cannot always be observed in downer cattle infected with BSE. Thus, if BSE were present in the U.S., downer cattle infected with BSE could potentially be offered for slaughter and, if the clinical signs of the disease were not detected, pass ante-mortem inspection. These cattle could then be offered for human food.” Baur v. Veneman, No. 02-6249, 2003 U.S. App. LEXIS 25297 (2d Cir. Dec. 16, 2003).
29 H.R. 2519, supra, note 27.
31 H.R. 2519, Sec. 2(a), supra note 27.
32 Id., Sec. 2(a).
33 Id., Sec. 2(a).
34 Id., Sec. 2(a).
36 See note 17, supra.
37 See note 27, supra.