Journal of Food Law & Policy

Volume 2 | Number 2 Article 3

2006

Animal Identification and Traceability Under the US National Animal Identification System

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ANIMAL IDENTIFICATION AND TRACEABILITY UNDER THE US NATIONAL ANIMAL IDENTIFICATION SYSTEM

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This article is based on work supported by the Cooperative State Research, Education and Extension Service, US Department of Agriculture, under Project No. ILLU-470-309. The author thanks David Holesinger and Annvi Shah for their research assistance and John F. Wiemers, DVM, MS, for his participation in the 2006 AALA symposium on NAIS and for his helpful review of this article.

I. INTRODUCTION

The identification of animals has a long history in the United States. Since the late nineteenth century, livestock producers have used brands to mark their animals. Ear tags and other marks now identify individual animals or animals from a specific producer, but not all livestock are identified to facilitate traceability.

Recent developments have enhanced the need for both reliable identification of animals and the ability to trace those animals from premises of origin to slaughter. These include discovery of transmissible Bovine Spongiform Encephalopathy (BSE) in the United Kingdom (UK) in 1986 and the epidemic of foot and mouth disease in the UK and elsewhere in Europe in 2001. More recent international outbreaks of other contagious livestock diseases, including avian influenza and bluetongue virus, are added causes for concern. Moreover, since 2001, fears of bioterrorism—especially an attack on

the agriculture and food system–have increased in the United States (US), and the ability to trace animal disease will be an important component of a national system designed to minimize the impact of a biological attack.[1]

The discovery of BSE in Canada and the US in 2003 made a dramatic impact and triggered several important developments.[2] Bans on US beef in a number of nations followed the discovery and had economic impacts for the meat industry. Indeed, during 2006, some level of trade ban or restriction on US cattle or beef products continues in sixty-five nations.[3] Both the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) enacted regulations to prevent transmission of BSE and to protect human health. In addition, the USDA intensified its efforts to develop a comprehensive system to trace food animals, the National Animal Identification System (NAIS).

Animal identification and traceability are important elements in a system of measures designed to protect the safety of the nation's food supply and to ensure that the US can offer products acceptable to trading partners. Meat is an important component of the American diet, so meat safety is critical. Per capita consumption of beef in 2005 was 42.8 kilos; pork, 29.3 kilos; broiler meat, 45.4 kilos; and turkey, 7.6 kilos. Similar consumption patterns are forecast for 2006 and 2007.[4]

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1. Press Release, USDA, Mike Johanns, Transcript of Remarks to the International Symposium on Agro-terrorism, Kansas City, MO (No. 0386.06, 27 Sept. 2006). *See* the Animal Enterprise Terrorism Act, Pub. L. No. 109-374, 120 Stat 2652 (2006) (to be codified as 18 U.S.C. § 43, Force, violence, and threats involving animal enterprises).

2. *See* Michael B. Abramson, *Mad Cow Disease: An Approach to its Containment*, 7 J. HEALTH CARE L. & POL'Y 316, 317 (2004) (identifying several developments, including enhanced consumer and public awareness of BSE).

3. *See generally* Kenneth H. Mathews, Jr., Monte Vandeveer, & Ronald Gustafson, An Economic Chronology of Bovine Spongiform Encephalopathy in North America (USDA, LDP-M-143-01, June 2006).

4. Foreign Agriculture Service (FAS), USDA, Livestock and Poultry: World Markets and Trade 20-22 (Cir. DL&P 2-06, Oct. 2006). Data for 2005 are preliminary. Only Argentina, among reported countries, leads the US in per capita beef consumption. *Id.* at 20.

A recent USDA publication examined retail beef purchases in light of the US discovery of BSE. The study found that "the magnitude of responses in the market was difficult to estimate precisely, but the duration was clear: within 2 weeks, consumers were behaving exactly as they had before the announcements" about BSE. FRED KUCHLER & ABEBAYEHU TEGENE, DID BSE ANNOUNCEMENTS REDUCE BEEF PURCHASES? (USDA, ERS Rep. 34, Dec. 2006).

Exports of meat continue to be significant for US trade. For 2007, exports of pork are projected to reach 1.4 million tons; poultry, 2.5 million tons.[5] The US had an 18% share of the global beef and veal market in 2002 and 2003.[6] As a result of BSE, however, beef and veal exports dropped dramatically after 2003,[7] leaving only a 3% share in the 2004 global market. Because major trading countries have now lifted some of their restrictions on US beef, trade has now improved, and beef exports for 2007 may reach 680,000 tons, a 30% increase over the estimate for 2006.[8]

Animal identification and traceability can help to protect the livestock industry and its global markets from BSE and from contagious diseases like foot and mouth disease. Because the discovery of BSE in the US focused the need for a reliable system of animal identification and traceability, this article discusses NAIS in the context of BSE. The article first discusses BSE in cattle and its impact on humans, followed by a discussion of USDA efforts to test cattle. A summary of regulatory responses to BSE by the USDA and the FDA follows. Turning to the subject of traceability, the article discusses the importance of traceability, both in general and for animals, and look briefly at traceability in Canada and Australia.

The article then describes the US National Animal Identification System, developed by the USDA. The system, according to USDA, offers important benefits to producers, whose participation will help to protect premises and livelihoods, reduce hardships caused by disease outbreak, and protect access to markets.[9] The article discusses development of the components of NAIS and raises important issues[10] connected with NAIS. Should the system be mandatory or voluntary? Does NAIS affect liability of producers? Can NAIS protect the confidential business information of producers?

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5. FAS, *supra* note 4, at 1.

6. *Id.* at 3.

7. *See* Charles E. Hanrahan & Geoffrey S. Becker, Mad Cow Disease and U.S. Beef Trade 1, CRS Report RS21709 (updated 30 Mar. 2006).

8. FAS, *supra* note 4, at 3.

9. Animal and Plant Health Inspection Service (APHIS), Top Reasons to Participate in NAIS, http://animalid.aphis.usda.gov/nais/about/top_reasons.shtml (last visited 26 Mar. 2007).

10. An important issue is "how to address consumer concerns about food safety related to BSE effectively without drastically disrupting the current domestic meat production and processing systems." DeeVon Bailey, James Robb, & Logan Checketts, *Perspectives on Traceability and BSE Testing in the U.S. Beef Industry*, 20(4) CHOICES 293, 293 (2005).

II. BSE - SOME BACKGROUND

A. BSE

1. Prevalence

"BSE is a transmissible, slowly progressive degenerative disease of the [central nervous system] of adult cattle. This disease has a prolonged incubation period in cattle following oral exposure (two to eight years) and is always fatal."[11] BSE is a type of transmissible spongiform encephalopathy (TSE).[12] TSEs are fatal "progressively degenerative central nervous system . . . diseases of man and animal."[13] TSEs occur in several animal species, e.g., BSE in cattle, scrapie in sheep and goats, transmissible mink encephalopathy in mink, and chronic wasting disease in elk and deer.[14]

BSE is considered transmissible rather than contagious, though infected cows sometimes deliver calves with BSE.[15] Epidemiologists

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11. FDA, Proposed Rule, 62 Fed. Reg. 552, 556 (3 Jan. 1997). *See also* WHO, Bovine spongiform encephalopathy, Fact Sheet No. 113 (Nov. 2002), http://www.who.int/mediacentre/factsheets/fs113/en/ [hereinafter WHO, BSE].

12. According to the WHO,

> The nature of the TSE agent is being investigated and is still a matter of debate. According to the prion theory, the agent is composed largely, if not entirely, of a self-replicating protein, referred to as a prion. Another theory argues that the agent is virus-like and possesses nucleic acids which carry genetic information. Although strong evidence collected over the past decade supports the prion theory, the ability of the TSE agent to form multiple strains is more easily explained by a virus-like agent.

WHO, Variant Creutzfeldt-Jakob disease, Fact sheet No. 180 (Nov. 2002), http://www.who.int/mediacentre/factsheets/fs180/en/ [hereinafter WHO, vCJD]. A recent publication identified viral particles and suggested that "a virus, rather than prion proteins, is the cause of mad cow disease in animals and Creutzfeldt-Jakob disease in humans." Misha Milhailova, *Yale M.D. makes leap in mad cow research*, YALE DAILY NEWS (7 Feb. 2007. *See* Laura Manuelidis et al., *Cells infected with scrapie and Creutzfeldt-Jakob disease agents produce intracellular 25-nm virus-like particles*, 104(6) PROC. NAT'L ACAD. SCI. 1965 (6 Feb. 2007).

A USDA Agricultural Research Service project evaluated cattle that were genetically modified to be free of prions. Preliminary results observed no adverse effects on the health of the cattle. Jürgen A. Richt et al., *Production of cattle lacking prion protein*, NATURE BIOTECHNOLOGY, advance online publication, 31 Dec. 2006 (doi:10.1038/nbt1271), http://www.nature.com/nbt/.

13. 62 Fed. Reg. 552, at 552.

14. *Id.* at 554. Feline spongiform encephalopathy is another TSE.

15. WHO, UNDERSTANDING THE BSE THREAT 11, WHO/CDS/CSR/EHP/2002.6, http://www.who.int/crs/resources/publications/bse/BSEthreat.pdf (last visited 26 Mar. 2007) [hereinafter WHO, UNDERSTANDING].

in the UK suspected that BSE in cattle was linked to feed that contained rendered protein from sheep infected with scrapie and cattle infected with BSE.[16] The World Health Organization (WHO) agreed, stating that consumption of contaminated feed transmits BSE.[17] Infectious products include "rendered animal proteins and compound animal feed containing meat-and-bone meal,"[18] sometimes described as "ground-up slaughterhouse waste."[19] Only a small amount of infectious material, perhaps as little as a gram of brain tissue, can transmit BSE.[20] Unfortunately, as international experts have noted, "[m]aterials potentially infected with BSE have been distributed throughout the world through trade in cattle and certain cattle products and by-products."[21]

In 1986, BSE was first identified in the UK as a neurological disease in cattle. Though BSE has been reported in a large number of countries, the majority of confirmed cases have occurred in the UK.[22] As of July 2007 in Great Britain, the Department for Environment Food and Rural Affairs (DEFRA) indicated that under passive (scanning) surveillance, used for animals with clinical signs, 179,176 head of cattle on 35,413 farms had been confirmed to have BSE, and 214,409 cattle had been slaughtered, most since July 1988. Active (targeted) surveillance of slaughtered and other animals confirmed another 1868 cases since 1999. Since 1996, the number of cases confirmed each year has declined significantly, with only 15 confirmed in 2006 and 3 so far in 2007 through passive surveillance and 89 in 2006 (of 598,666 tested) and 25 so far in 2007 through active surveillance.[23]

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16. *See* 62 Fed. Reg. at 560, 562.

17. WHO, UNDERSTANDING, *supra* note 15, at 11.

18. JOINT WHO/FAO/OIE TECHNICAL CONSULTATION ON BSE: PUBLIC HEALTH, ANIMAL HEALTH AND TRADE: CONCLUSIONS AND KEY RECOMMENDATIONS 4 (OIE Headquarters, Paris, 11-14 June 2001), http://whqlibdoc.who.int/publications/2001/9290445556.pdf [hereinafter WHO/FAO/OIE].

19. Dennis Normile, *First U.S. Case of Mad Cow Sharpens Debate Over Testing*, SCIENCE 156, 156 (9 Jan. 2004).

20. WHO, UNDERSTANDING, *supra* note15, at 3, 14.

21. WHO/FAO/OIE, *supra* note 18, at 4.

22. WHO, BSE, *supra* note 11. Other European countries with the most cases are France, Germany, Ireland, Portugal, Spain, and Switzerland. *Id.*

23. Animal Health and Welfare, DEFRA, BSE-GB weekly cumulative statistics, 27 July 2007, www.defra.gov.uk/animalh/bse/statistics/weeklystats.html. Another source indicated that as of 1 September 2006, 183,139 cases had been confirmed in the UK. DEFRA, BSE: Frequently Asked Questions, www.defra.gov.uk/animalh/bse/faq.html (last visited 26 Mar. 2007).

In the European Union (EU), an expanded monitoring program started in 2001 has tested over 51 million cattle. In 2005, the first year that all 25 Member States participated in monitoring, more than 10 million cattle were tested, and 561 tested positive for BSE; 87% of these were among high-risk animals and healthy slaughtered cattle tested by active surveillance.[24] Infected cattle were found in 16 of the then-25 Member States.[25]

Regulators in the US and Canada responded to the BSE crisis by implementing protective measures, including bans on ruminant proteins in feed.[26] Nonetheless, BSE was discovered in North America when an infected cow was diagnosed in Canada in May 2003.[27] In December 2003, the US discovered BSE in a 6½-year-old cow located in Washington, but imported in 2001 from Canada. Subsequently, the US confirmed that a 12-year-old Texas cow (June 2005) and a 10-year-old Alabama cow (March 2006) tested positive for BSE.[28]

Since May 2003, Canada has confirmed BSE in ten animals. In February 2007, Canada identified its ninth case, a six-year-old bull in Alberta. The bull, born after Canada's 1997 implementation of a ban on ruminant proteins in animal feed, is likely to have been infected early in life.[29] Canada's eighth case of BSE, identified in August 2006, was an eight-to-ten year old beef animal in Alberta, probably exposed before or shortly after the 1997 feed ban.[30] The seventh cow, also from Alberta, was diagnosed in July 2006. The dairy cow did not show clinical signs of BSE and had died from mastitis, but at 50 months old, she was the youngest Canadian animal to

24. DIRECTORATE-GENERAL FOR HEALTH & CONSUMER PROTECTION, REPORT ON THE MONITORING AND TESTING OF RUMINANTS FOR THE PRESENCE OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) IN THE EU IN 2005, at 1 (2006). In addition, 2906 sheep (of almost 350,000 tested) and 989 goats (of 265,000) had TSEs. *Id.*

25. *Id.*

26. *See infra* text accompanying notes 108-110, 127-138.

27. For a detailed chronology of BSE-related events, from Nov. 1986 to 27 July 2006, see Geoffrey S. Becker, Bovine Spongiform Encephalopathy (BSE, or "Mad Cow Disease") in North America: A Chronology of Selected Events, CRS Rep. RL32932 (updated 27 July 2006).

28. USDA, BSE Chronology: Key USDA Actions Related to Canada (July 2006) http://www.aphis.usda.gov/newsroom/hot_issues/bse/content/printable_version/BSE_Chronology_Canada_Final.pdf.

29. Canada Confirms Ninth Case of Mad Cow Disease, Informa Econ. Pol'y Rep. (9 Feb. 2007). The bull did not enter the food chain. The tenth animal was a mature dairy cow. Canadian Food Inspection Agency, BSE Case confirmed in British Columbia (2 May 2007), http://www.inspection.gc.ca.

30. Press Release, USDA, Statement by Agriculture Secretary Mike Johanns Regarding Canada's Eighth BSE Case (No. 0314.06, 23 Aug. 2006).

be diagnosed with BSE. Canadian officials believe that the animal was exposed by the contamination of a batch of cattle feed shipped to the farm of origin of the infected animal.[31] Canadian cases, ten since 2003 with five of those in 2006, were identified through its national surveillance program, which tested over 117,500 cattle since 2003.[32] Six of the ten Canadian cows were born after the 1997 feed ban.[33]

BSE has had a significant effect on US beef trade. Beef exports had increased since 1992, and in 2003, exports of beef and veal totaled $3.9 billion. US exports of beef totaled about ten percent of production.[34] After the December 2003 discovery of BSE, most important importers of US beef (e.g., Japan, South Korea, Mexico, Canada, which accounted for 90% of beef exports) banned imports.[35] As already mentioned, the US market share of beef and veal declined from 18% in 2003 to 3% in 2004.[36] Loss of exports cost the beef industry $3.2 - $4.7 billion in 2004, according to estimates, but early safeguards against BSE meant that its economic impact in the US was less serious than in the UK, for example.[37] Some improvement has occurred. For example, Japan now accepts US beef, but only from cattle 20 months or younger.[38] South Korea decided to end its ban in September 2006, and to accept boneless beef from cattle younger than thirty months. The first shipment of boneless beef arrived at the end of October, but a small bone fragment resulted in its rejection. In late November, a second shipment was

31. Canadian Food Inspection Agency (CFIA), BSE Investigation Reaches Conclusion (24 Aug. 2006), http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060824e.shtml. The entire batch was shipped to the animal's farm of origin, and the animal did not enter the food supply. See also Pete Hisey, Canadian BSE case may indicate testing regimes are missing infections (31 Aug. 2006), http://www.meatingplace.com/MembersOnly/webNews/details.aspx?item=16464.

32. CFIA, BSE Confirmed in Alberta (23 Aug. 2006), http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060823e.shtml.

33. Centers for Disease Control, BSE (1 Aug. 2006), http://www.cdc.gov/ncidod/dvrd/bse/.

34. Hanrahan & Becker, *supra* note 7, at 1; Mathews et al., Economic Chronology, *supra* note 3, at 7.

35. One report indicated that the immediate effect of the discovery of BSE in the US was a loss of about $200 million in beef products left in foreign ports or at sea. Johanna Neuman & Evelyn Iritani, *USDA Defends Its 'Mad Cow' Disease Efforts*, LA TIMES, 1 Jan. 2004, at A18.

36. FAS, *supra* note 4, at 3.

37. Hanrahan & Becker, *supra* note 7, at 5-6. *See also* APHIS, USDA, BSE Trade Status as of July 28, 2006, http://www.aphis.usda.gov/newsroom/hot_issues/bse/bse_trade_ban_status.shtml.

38. *See* BSE Trade Status, *supra* note 37.

rejected for three small bone fragments (7, 13, and 22 mm) in 3.2 tons of beef; in early December, a third shipment with small bone chips was rejected Many Korean retailers plan to continue to sell Australian, rather than US, beef.[39]

In 2006, the US applied to the World Organization for Animal Health (OIE) for a "country classification" for BSE risk.[40] Three categories are available: negligible, controlled, and undetermined. After a review of the US application and supporting documents, including the "science-based mitigation measures" used to manage BSE, the OIE recommends a risk classification, which is adopted by the OIE General Assembly.[41] In March 2007, USDA officials announced that both an OIE expert panel and its Scientific Commission have recommended that the US be classified as a "controlled risk," with effective and interlocking regulatory controls to ensure safe trade in beef.[42] Adoption of this classification by the General Assembly at its May 2007 meeting is expected to facilitate US trade in cattle and beef products.[43]

2. BSE and Human Health

BSE has been linked to variant Creutzfeldt-Jakob disease (vCJD), a rare and invariably fatal disease first described in the United Kingdom in March 1996. vCJD, like BSE, is a TSE characterized by a "spongy degeneration of the brain and its ability to be transmitted."[44] Clinical signs of the disease include psychiatric symptoms (e.g., depression), followed by neurological signs that include "unsteadiness, difficulty walking and involuntary movements," end-

39. South Korea to Resume Imports of U.S. Beef, Informa Econ. Pol'y Rep., 11 Sept. 2006, at 9; South Korea Admits U.S. Beef, Ending Three-Year-Old Ban on Imports, Informa Econ. Pol'y Rep., 31 Oct. 2006, at 6; Little bone, big problem, Informa Econ. Pol'y Rep., 28 Nov. 2006, at 1; South Korea beef rejection underscores U.S. trade rift, Informa Econ. Pol'y Rep., 1 Dec. 2006, at 1; Johanns Exasperated With South Korea's Rejections of U.S. Beef, Informa Econ. Pol'y Rep., 8 Dec. 2006, at 6-7.

40. USDA, Press Release, Statement by Dr. Ron Dehaven Regarding OIE Risk Recommendation (9 Mar. 2007).

41. *Id.*

42. *Id.* The OIE also recommended controlled risk status for Canada. OIE recommends favorable mad cow rating for Canada, U.S., Informa Econ. Pol'y Rep. (28 Feb. 2007).

43. USDA, *supra* note 40. See USDA, Press Release, Statement by Secretary Mike Johanns Regarding U.S. Classification by OIE (no. 0149.07, 22 May 2007).

44. WHO, vCJD, *supra* note 12.

ing with immobility and muteness.[45] Victims of vCJD have succumbed to the disease at an average age of twenty-nine, after an illness with a median duration of fourteen months.[46]

Several types of TSEs occur in humans, including inherited diseases (e.g., fatal familial insomnia,[47] and Gertsmann-Sträussler-Schenker syndrome), kuru (a disease from Papua New Guinea, found in a tribe that practiced ritual cannibalism), and the most common, Creutzfeldt-Jakob disease (CJD). CJD is a neurological syndrome that has occurred throughout the world; it often claims victims in middle age (average age of sixty-five), most within one year of onset of the disease.[48] Several types of CJD have been recognized: sporadic (the majority of cases), with no known causes; familial, which result from a gene mutation; and iatrogenic, transmitted through transplants or contaminated surgical instruments.[49] The discovery of vCJD adds a new form of CJD to that list.

The first patient with vCJD developed symptoms in January 1994, and most victims of the disease are from the UK or have lived there for significant periods of time.[50] Epidemiologists in the UK first reported the link between BSE and vCJD in 1996.[51] The Department of Health indicated that 158 deaths from confirmed or probable vCJD had occurred between 1995 and 3 November 2006.[52]

After some initial uncertainty, the link between BSE and vCJD, first suspected because of "the association of these two TSEs in time and place,"[53] seems clear. A WHO consultation in 1996 suggested that "[a] link has not yet been proven between V-CJD in the UK and the effect of exposure to the BSE agent. The most likely hypothesis for V-CJD is the exposure of the UK population to BSE."[54] A later

45. *Id.*

46. *Id.*

47. *See generally* D.T. MAX, THE FAMILY THAT COULDN'T SLEEP: A MEDICAL MYSTERY (2006) (tracing fatal familial insomnia in an Italian family).

48. 62 Fed. Reg. 552, 557-58; WHO, vCJD, *supra* note 12.

49. WHO, vCJD, *supra* note 12.

50. *Id.*

51. Kenneth H. Mathews, Jr., Jason Bernstein & Jean C. Buzby, *International Trade of Meat/Poultry Products and Food Safety Issues* 48, 54, chapter 4 in INTERNATIONAL TRADE AND FOOD SAFETY, ERS, USDA, AER 828 (Jean C. Buzby ed., 2003).

52. Department of Health, UK, Monthly Creutzfeldt-Jakob Disease Statistics, 6 Nov. 2006, linked from http://www.dh.gov.uk/PublicationsAndStatistics/Statistics/fs/en. Six suspected patients were still alive, bringing the total to 164.

53. WHO, vCJD *supra* note 12.

54. *Id.* at 561, citing WHO, Report of a WHO Consultation on Public Issues Related to Human and Animal Transmissible Spongiform Encephalopathies 4,

WHO publication is more definitive: "Considerable epidemiological, neuropathological, and experimental data are consistent with the hypothesis that the agent that causes BSE in cattle also causes vCJD in humans. The most plausible route of human exposure is through the consumption of food contaminated with the BSE agent, although this has not been conclusively proven."[55] Tissue from the central nervous system of infected cattle is the most likely food contaminant.[56]

B. USDA Surveillance Testing

1. USDA Testing

In 1990, USDA started a limited active surveillance program for BSE, testing brain samples from "adult cattle with neurological symptoms and adult animals that were nonambulatory at slaughter."[57] In the following years, testing focused increasingly on nonambulatory cattle; in 2001, these cattle provided over 90% of the 4,870 brains tested.[58] The discovery of a BSE-infected cow in the US in December 2003 triggered more intense surveillance.

In June 2004, USDA's Animal and Plant Health Inspection Service (APHIS) implemented an enhanced BSE surveillance plan, designed to discover the presence (and level) of BSE in the US cattle population by testing high-risk cattle—that is, nonambulatory or dead cattle, as well as those with central nervous system or other symptoms of BSE—and a random sample of aged cattle that appear normal.[59] The surveillance program was not a food safety program;

WHO/EMC/DIS/96.147, 2-3 April 1996, http://whqlibdoc.who.int/hq/1996/WHO_EMC_DIS_96.147.pdf.

55. WHO, UNDERSTANDING, *supra* note 15, at 10.

56. WHO, vCJD, *supra* note 12.

57. U.S. GEN. ACCOUNTING OFFICE, MAD COW DISEASE: IMPROVEMENTS IN THE ANIMAL FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S. PREVENTION EFFORTS 20, GAO-02-183 (2002). An APHIS chronology, however, indicates that surveillance began to examine downer cows only in 1993 and expanded this focus on downers in 1999. USDA Actions to Prevent Bovine Spongiform Encephalopathy (BSE) (21 Jan. 2004), http://www.aphis.usda.gov/lpa/issues/bse/bsechron.html.

58. U.S. GEN. ACCOUNTING OFFICE, *supra* note 57, at 20-21. Few cattle that died on farms, also considered high risk, were tested. *Id.* at 21.

59. USDA, Bovine Spongiform Encephalopathy (BSE) Surveillance Plan, March 15, 2004, http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf [hereinafter 2004 Surveillance Plan]. USDA believed that testing of 268,500 high-risk cattle would allow detection of BSE (at the rate of 1 case per 10 million adult

instead, it was planned as a one-time effort to provide information to USDA about BSE in the US.[60] Between 1 June 2004 and 20 August 2006, 787,711 animals had been tested under the enhanced surveillance program.[61]

Testing costs between June 2004 and July 2006 were $157.8 million.[62] An analysis of BSE surveillance data released in April 2006 and finalized in July 2006, including data from the enhanced surveillance plan since June 2004, estimated that among 42 million adult cattle, only 4-7 animals (fewer than 1 per million standing adult cattle) are likely to have BSE.[63]

In July 2006, APHIS announced a change from enhanced surveillance to its ongoing BSE surveillance program,[64] intended to as-

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cattle) at a 99% confidence level. *Id.* at 1. USDA estimated that the population of high-risk adult dairy and beef cattle was about 446,000. *Id.*

60. *Id.* at 1. The Surveillance Plan gave details of targeted population, sample collection, and other technical components. For an evaluation of USDA testing for BSE, *see generally* Gregory L. Berlowitz, Note, *Food Safety vs. Promotion of Industry: Can the USDA Protect Americans from Bovine Spongiform Encephalopathy?*, 2006 U. ILL. L. REV. 625 (2006).

61. APHIS, USDA, BSE Enhanced Surveillance Program: Monthly Test Results, http://www.aphis.usda.gov/newsroom/hot_issues/bse/surveillance/enhanced_surv_results.shtml (last visited 26 Mar. 2007). Between May 1990 and 30 April 2004, 72,500 brains were tested. APHIS, USDA, Surveillance May 1990 - FY 2004 (through 4/30/2004), http://www.aphis.usda.gov/lpa/issues/bse/surveillance/figure2f.html (last visited 26 Mar. 2007).

62. Press Release, USDA, USDA Announces New BSE Surveillance Program (No. 0255.06, 20 July 2006). In May 2006, USDA investigated overpayments (alleged alteration of records to pay amounts not allowed by USDA) identified during an audit. Pete Hisey, USDA vet reassigned over BSE test program overpayments (11 May 2006), http://www.meatingplace.com/MembersOnly/webNews/details.aspx?item=15929.

63. Press Release, USDA, *supra* note 62. Centers for Epidemiology and Animal Health, An Estimate of the Prevalence of BSE in the United States (20 July 2006), http://www.aphis.usda.gov/newsroom/hot_issues/bse/downloads/BSEprevestFINAL_7-20-06.pdf. *See also* Sumeet Patil, Peer Review of the Estimation of Bovine Spongiform Encephaolpathy (BSE) Prevalence in the United States, Final Report (May 2006), http://www.aphis.usda.gov/peer_review/content/printable_version/BSE_Prevalence_Report.pdf (agreeing with the USDA estimated BSE prevalence of 1 per million live cattle).

Another important study is JOSHUA T. COHEN & GEORGE M. GRAY, HARVARD RISK ASSESSMENT OF BOVINE SPONGIFORM ENCEPHALOPATHY UPDATE: PHASE IA (31 Oct. 2005) [hereinafter 2005 HARVARD RISK ASSESSMENT], http://www.fsis.usda.gov/PDF/ BSE_Risk_Assess_Report_2005.pdf. The original HARVARD RISK ASSESSMENT was completed in 2001 and revised in 2003.

64. Veterinary Services, APHIS, Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan (20 July 2006) [hereinafter Ongoing Plan], http://www.aphis.usda.gov/newsroom/hot_issues/bse/content/printable_version/BSE_ongoing_surv_plan_final_71406%20.pdf. *See also* Sumeet Patil, Peer Review

sess and monitor change in BSE status and to detect BSE prevalence in case of increase above one case per million adult cattle.[65] Ongoing surveillance will facilitate decision-making and policy development for future surveillance, help to develop contingency plans for BSE control, evaluate the effectiveness of regulatory measures to reduce BSE risk, and reassure consumers and trading partners.[66] Surveillance continues to be an animal health measure, rather than a food safety measure.[67]

The ongoing surveillance program is designed to reduce the number of animals tested, but to maintain a testing level ten times higher than the World Animal Health Organization (OIE) recommendation. International scientific consensus, reflected in the OIE Terrestrial Animal Health Code,[68] indicates that the most effective BSE surveillance tests targeted populations, rather than all adult cattle.[69] Therefore, approximately 40,000 animals from all sections of the US will be tested each year, with focus on a targeted population of cattle with clinical signs of central nervous system disorders, other symptoms of BSE, nonambulatory cattle, and dead cattle that had shown clinical signs of BSE. During the months of September and October 2006, 3860 cattle had been tested.[70] The ongoing surveillance program announced in July 2006 will cost about $17 million per year.[71]

The Food Safety and Inspection Service (FSIS), another USDA agency, had issued guidelines for collection of brain samples for the APHIS ongoing surveillance program. FSIS personnel would collect samples from cattle condemned due to signs of CNS disease and

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of the Estimation of the Ongoing Surveillance Plan for Bovine Spongiform Encephalopathy in the United States, Revised Final Report (July 2006), http://www.aphis.usda.gov/peer_review/content/printable_version/BSE_peer_review_report.pdf (two of three reviewers agreeing that 40,000 samples per year exceeds OIE surveillance requirements).

65. Veterinary Services, Ongoing Plan, *supra* note 64, at 5.

66. *Id.* at 5.

67. Veterinary Services, APHIS USDA's BSE Surveillance Efforts, Fact Sheet, July 2006.

68. OIE, Terrestrial Animal Health Code (2006), Appendix 3.8.4: Surveillance for Bovine Spongiform Encephalopathy, http://www.oie.int/eng/normes/Mcode/en_chapitre_3.8.4.htm.

69. Veterinary Services, *supra* note 67. For detail on the targeted population, see Veterinary Services, Ongoing Plan, *supra* note 64, at 6-8.

70. APHIS, USDA, BSE Ongoing Surveillance Program: Monthly Test Results, http://www.aphis.usda.gov/newsroom/hot_issues/bse/surveillance/ongoing_surv_results.shtml (visited 27 Nov. 2006).

71. Press Release, USDA, supra note 62.

those thirty months or older condemned for other conditions from selected establishments.[72] Before that provision could take effect, however, FSIS issued a temporary suspension, which limited testing to "cattle of any age that are condemned on ante-mortem for central nervous system (CNS) disease."[73] The animals are to be tagged "U.S. condemned," humanely euthanized, and kept on the premises; an APHIS veterinarian (rather than FSIS personnel) is to collect the brain sample.[74] The FSIS notice that implemented this policy did not provide a rationale.

USDA surveillance testing has been criticized for its limited scope, perhaps due to the use of surveillance for epidemiological, rather than food safety, purposes. Though many animals (nearly 800,000 by October 2006) have been tested, some nations test all slaughtered animals, or at least those over thirty (or even twenty-four) months of age.[75] Japan, which tests all animals slaughtered for food, has identified BSE in cows only twenty-one and twenty-three months old.[76]

2. Private Testing

The USDA has been reluctant to allow private testing for BSE.[77] USDA's reluctance is explained, in part, by the risk of false positives, which would harm the meat industry, and by the fear that meat from animals that have not been tested would be considered unsafe simply because it had not been tested. Moreover, USDA asserts that

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72. Food Safety and Inspection Service (FSIS), USDA, FSIS Notice 51-06, 23 Aug. 2006, effective 27 August 2006, http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/51-06.pdf. Under prior procedures FSIS had collected brain samples from *all* cattle condemned before slaughter. *Id.*

73. FSIS, USDA, FSIS Notice 52-06, 25 Aug. 2006, effective 27 Aug. 2006, http://www.fsis.usda.gov/regulations_&_policies/Notice_52-06/index.asp.

74. *Id.*

75. Jason R. Odeshoo, Note, *No Brainer? The USDA's Regulatory Response to the Discovery of "Mad Cow" Disease in the United States*, 16 STAN. L. & POL'Y REV. 277, 310-11 (2005). Rapid testing, used in Europe, is faster and less expensive than tests used in the US. Berlowitz, *supra* note 60, at 634-35, describes three types of tests.

76. Normile, *supra* note 19, at 156-57. Japan's feed ban on meat and bone meal came rather late. *Id.*

77. On private testing, *see generally* Stephen R. Viña, The Private Testing of Mad Cow Disease: Legal Issues at 4, CRS Rep. RL 32414 (updated 3 Oct. 2006), http://www.nationalaglawcenter.org/assets/crs/RL32414.pdf.

testing young animals is unnecessary, because they do not transmit BSE, "which takes years to develop from exposure to clinical signs."[78]

Scientists have disagreed about the appropriate level of testing. Though some experts assert that every cow slaughtered for food should be tested, others would use testing, as USDA has done, as an epidemiological tool.[79] Meat trade associations support the USDA position. They oppose private testing as unnecessary and fear the expense of testing, should it be necessary to remain competitive.[80] The expense of testing, however, may be justified. Research has indicated that testing for cattle slaughtered in 2004 would have cost $604 million, an amount similar to the revenue gain from getting back only 25 percent of the Japanese and South Korean beef markets lost after 2003.[81]

Some specialty beef producers would like to test their cattle. For example, Creekstone Farms Premium Beef sold Black Angus beef to a large Japanese, South Korean, and EU market. Japanese and South Korean bans on US beef affected Creekstone's sales, so the company planned to test all of its cattle for BSE.[82] Creekstone built a testing laboratory at its processing plant and sent employees to France for training on a rapid screening test.[83]

USDA had licensed several different rapid test kits for BSE, including the French-made Bio-Rad test that Creekstons planned to use, under the Virus Serum Toxin Act of 1913 (VSTA).[84] USDA's licensing of the kits, according to an official, is for "animal health surveillance purposes."[85] As required by the VSTA, Creekstone sought USDA permission to use a rapid test kit to test its animals.[86]

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78. USDA, 2004 Surveillance Plan, *supra* note 59, at 1. *See* Odeshoo, *supra* note 75, at 312-13. But how young may be a question. A few animals younger than thirty months have tested positive for BSE. *Id.* at 308-08.

79. Normile, *supra* note 19, at 156.

80. Creekstone Lawsuit Could Further Complicate U.S. Mad Cow Program, Informa Econ. Pol'y Rep., 27 March 2006.

81. *BSE-Induced Beef Trade Ban Still Haunts U.S. Market*, 16(3) FOOD SAFETY CONSORTIUM NEWSLETTER 1, 1-2 (Summer 2006), http://www.fsconsortium.net.

82. Gateway Beef Cooperative also sought voluntary testing. *See generally* Berlowitz, *supra* note 60, at 638-40.

83. Creekstone Farms Premium Beef v. USDA, No. 06-0544, 2007 U.S. Dist. LEXIS 22851, at *6 (D.D.C., 29 Mar. 2007). Creekstone lost $200,000 per day while Japan and South Korea banned US beef. *Id.* at *5-6.

84. 21 U.S.C. §§ 151-159; Creekstone, *supra* note 83, at *6.

85. USDA, Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs, Regarding a Request by Creekstone for Private BSE Testing (No. 0141/04, 9 April 2004).

86. Editorial, *A Strange Ban on Testing Beef*, N.Y. TIMES, 18 April 2004.

Invoking its VSTA authority to control licensing and use of the BSE test, USDA refused permission for Creekstone to use BSE tests.[87] Shortly before denial of permission, the USDA had restricted the sale and use of diagnostic test kits for BSE to laboratories approved by state and USDA animal health officials.[88] Creekstone's planned use of the tests for its private marketing program went beyond the surveillance licensing of the kits. Moreover, the agency stated that Creekstone's testing would "have implied a consumer safety aspect that is not scientifically warranted."[89] In March 2006, after two years of seeking permission for testing, Creekstone sued USDA.[90]

VSTA makes it unlawful to "prepare, sell, barter, or exchange, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous producted intended for use in the treatment of domestic animals" except at a licensed facility, and it authorizes the Secretary of Agriculture to enact necessary regulations.[91] In Count I of its lawsuit, Creekstone alleged that USDA regulations exceeded the agency's authority under VSTA. It asserted that VSTA grants authority to govern the preparation, sale, barter, or exchange, but not the *use,* of viruses, serums, toxins, or analogous products,[92] and challenged USDA's authority to include diagnostic kits within its

87. Creekstone, *supra* note 83, at *7-8,

88. Veterinary Services, USDA, Center for Veterinary Biologics Notice No. 04-08 (17 Mar. 2004), http://www.aphis.usda.gov/vs/cvb/notices/2004/04-08.pdf; *see also* Viña, *supra* note 77, at 8. Creekstone had asked that Kansas State University be allowed to designate the Creekstone laboratory as a satellite to the USDA-approved Kansas State facility, but that request, too, was rejected. Creekstone, *supra* note 83, at *8 n.4.

89. USDA, Statement, *supra* note 81; *see also* Donald G. McNeil Jr., *U.S. Won't Let Company Test All Its Cattle for Mad Cow,* N.Y. TIMES, 10 April 2004.

90. Creekstone, *supra* note 83. A judge in an unrelated dispute expressed an opinion about private testing. The case had challenged implementation of a USDA rule that allows import of Canadian beef and cattle by lifting the import ban that followed discovery of BSE in Canada. In dicta, the judge commented on private testing:

> The USDA states that private testing of all slaughter cattle is inconsistent with the USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef. However, this is contrary to rational thinking because any private testing would actually assist in assuring proper testing for animal diseases and increase consumer confidence, both domestically and internationally, in U.S. cattle and beef.

Ranchers Cattlemen Action Legal Fund v. USDA, 359 F. Supp. 2d 1058, 1072 (D. Montana, 2005), rev'd 415 F.3d 1078 (9th Cir. 2005).

91. 21 U.S.C. §§ 151, 154; Creekstone, *supra* note 83, at *9.

92. Creekstone, *supra* note 83, at *9-10; 9 C.F.R. § 102.5(d).

definition of "analogous products" and "treatment."[93] In Count II, Creekstone challenged USDA authority to regulate BSE test kits, because the BSE rapid test is neither a "virus, serum, toxin, or analogous product," nor "intended for use in the treatment of domestic animals," nor "worthless . . . ."[94] Both Creekstone and the USDA moved for summary judgment.[95]

In a memorandum opinion filed 29 March 2007, US District Court Judge James Robertson addressed the motions for summary judgment. Judge Robertson first held that Japan's July 2006 resumption of imports of US beef did not moot Creekstone's claim.[96] Moreover, Creekstone had standing to sue, because its significant loss of revenue was "a concrete and particularized injury that is actual, traceable to enforcement of the USDA's prohibition on BSE testing by private industry, and redressable by this Court."[97]

The court rejected Creekstone's motion for summary judgment on Count I. After analyzing USDA's authority under VSTA and noting the deference due to the agency, the court concluded that USDA has the authority to regulate the use of biological products[98] and also to regulate diagnostic test as "analogous products."[99] Thus, under VSTA, USDA can "regulate the 'use' of 'analogous products' including diagnostic tests,"[100] but only if those products are intended for

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93. Creekstone, *supra* note 83, at *10; 9 C.F.R. § 101.2.

94. Creekstone, *supra* note 83, at *10. Count III alleges that USDA's actions, especially its refusal to allow Creekstone to purchase and use BSE test kits, are arbitrary and capricious. Neither party moved for summary judgment, and they agreed that a decision on Count I or II would dispose of Count III. *Id.* n.5.

A New York Times editorial, printed shortly after Creekstone filed its suit, stated that USDA should

> test every cow that goes to slaughter. The cost is not prohibitive. Fear is the problem. The current testing program for mad cow disease is intended to produce, at best, a snapshot of the likelihood of the disease. . . . The fear is that broad testing may reveal a higher rate of infection and destroy consumer confidence, with a devastating impact on the cattle market.

Editorial, *Stop: Don't Test Those Cows?*, N.Y. TIMES, 6 April 2006. See also *A Beef with USDA*, WASH. TIMES, 2 May 2006.

95. Creekstone, *supra* note 83, at *10 & n.5. *See* Viña, *supra* note 77, at 12, for the view that the outcome of the case might turn on the extent of USDA's regulatory authority under VSTA, and whether its authority, which clearly encompasses the production of biologics, also extends to the use and distribution of those products.

96. Creekstone, *supra* note 83, at *11.

97. *Id.* at *12.

98. *Id.* at *12-16.

99. *Id. at *16-19.*

100. *Id.* at *19.

"treatment" of domestic animals *and* are "worthless."[101] Creekstone's Count II therefore turned on the characterization of BSE test kits.

Although the court deferred to USDA's decision that diagnosis is an aspect of treatment of animals, its did not accept USDA's assertion that BSE test kits are used for treatment: "There is no known treatment or cure for BSE . . . and BSE test kits are used only on animals that are dead."[102] Having concluded that the BSE test kits are not intended for treatment, the court did not need to decide whether they are worthless. Nonetheless, the court suggested that Creekstone's extensive testing could provide important information about BSE.[103] Though Judge Robertson held that the USDA's restriction on private use of BSE test kits is unlawful, he stayed his order to allow USDA to appeal; if no appeal is filed by 1 June 2007, Creekstone (and other meatpackers) can test for BSE. USDA, however, has appealed.[104]

III. REGULATORY RESPONSES

After discovery of BSE in the UK, regulatory agencies in a number of nations took action to prevent spread of the disease. As might be expected, the most restrictive control was enacted in the UK.[105] In England, for example, a 1989 feed ban prohibited feeding of certain mammalian proteins to ruminants; regulations enacted in 1996 provided that cattle over thirty months could not be used for food.[106] Later regulations, the most recent from 2006, permit food

101. *Id.* at *20.

102. *Id.* at *21-22.

103. *Id.* at *23. Though he refused to evaluate worthlessness, the judge suggested that "the consumer issues at the heart of USDA's position cannot be located within the purpose of the VSTA, and appear to lie, not with USDA, but with the Federal Trade Commission, or perhaps the Commerce Department." *Id.* at *24.

104. Phyllis Jacobs Griekspoor, *Creekstone wins testing case; appeal likely*, WICHITA EAGLE, 30 Mar. 2007. See Creekstone Farms Response to USDA Appeal of Summary Judgment (30 May 2007), http://www.3buddies.com/creekstone/news-appeal-response.html.

105. CDC, BSE Control Measures (27 June 2005), http://www.cdc.gov/ncidod/dvrd/bse/prevention.htm

106. The Beef (Emergency Control) Order 1996, SI 1996 No. 961: Article 2, Prohibition of sale of meat from older bovine animals, reads "No person shall sell for human consumption any meat derived from a bovine animal slaughtered after the commencement of this Order which, at the time of slaughter, showed signs of more than one pair of permanent incisors."

use of cattle older than thirty months, but only under stringent conditions.[107]

In 1997 Canada enacted a feed ban to prohibit the feeding of certain mammalian proteins to ruminants. In June 2006, after discovery of BSE in Canadian cattle, Canada's feed ban was made more stringent. Potentially infective tissues, already prohibited in human food, will be banned from all animal feeds, pet foods, and fertilizers, effective July 2007.[108] By now, the EU, the UK, Canada and other nations–including the US–have comprehensive regulatory systems to protect cattle from BSE and to protect humans from the related Creutzfeldt-Jakob disease (vCJD).[109]

In the US, both the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) play roles in the protection of the food and feed supply from BSE. USDA, acting through Animal and Plant Health Inspection Service (APHIS), governs the import of animals and, acting through Food Safety and Inspection Service (FSIS), governs the safety of meat and meat products. FDA governs the safety of food for humans and for animals. Thus, in addition to surveillance discussed above, these agencies have acted to prevent the import of animals and meat products that might be infected or contaminated with BSE, prevent the slaughter and food or feed use of diseased animals, and protect the food and feed supply from specific risk materials. The following sections provide a brief summary of some of the regulations that govern imports, feed, and food.[110]

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107. *See* The TSE (England) (Amendment) (No. 2) Regulations 2005, reg. 4, SI 2005 No. 2633. Current law, enacted to implement EC measures, is The Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006, SI 2006, No. 1228. Schedule 2, Part 1(4) reads "It is an offence for the occupier to use a slaughterhouse to slaughter for human consumption a bovine animal aged over thirty months unless the Secretary of State has approved the Required Method of Operation . . . for that slaughterhouse and that occupier."

108. Canadian Food Inspection Agency, Canada's Enhanced Feed Ban (26 June 2006), http://www.inspection.gc.ca/english/anima/feebet/rumin/enhrene.shtml.

109. In the EU, for example, see Regulation 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, 2001 O.J. (L 147) 1.

110. This survey is not intended to be comprehensive or critical. For a detailed and critical analysis of USDA and FDA regulations, *see* Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 ADMIN. L. REV. 289 (2005); THOMAS O. MCGARITY WITH FRANK ACKERMAN, FLIMSY FIREWALLS: THE CONTINUING TRIUMPH OF EFFICIENCY OVER SAFETY IN REGULATING MAD COW DISEASE RISKS (Center for Progressive Regulation, 2004). *See also* Odeshoo, *supra* note 75, at 290-305 (criticizing government efforts to combat BSE both before and after discovery of the cow in December 2003); Center for Science in the Public Interest et al., Cow Sense: The

A. Control of Imports–APHIS

Soon after BSE was identified as a significant problem in cattle, USDA used its regulatory authority[111] to prevent entry of infected animals and products into the US. In July 1989, APHIS banned the import of all ruminants and their products, including most rendered proteins, from countries where BSE had been discovered.[112] In 1997, APHIS extended the ban to live ruminants and most ruminant products from Europe.[113] Fear of cross contamination led APHIS to prohibit import of rendered ruminant protein from any animal from regions with a BSE risk–that is, with confirmed BSE or with weak import rules or inadequate surveillance.[114]

After BSE was found in Canada, with beef trade closely linked with the US beef industry, APHIS amended its regulatory ban. Instead of regulating imports by characterizing regions as those free of BSE and those presenting a BSE risk, APHIS established a new category, the BSE minimum-risk region.[115] A final rule published in January 2005 lists Canada as a minimal-risk region.[116] From minimal-

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Bush Administration's Broken Record on Mad Cow Disease (April 2006), www.cspinet.org/new/pdf/cow_sense.pdf.

The USDA Office of Inspector General audited APHIS and FSIS measures described below. See Office of Inspector General, USDA, Audit Report No. 50601-10-KC (Jan. 2006) [hereinafter OIG Audit].

111. Among current sources of authority is the 2002 Animal Health Protection Act, 7 U.S.C. §§ 8301-8317, intended to protect animal and human health through the "prevention, detection, control, and eradication of diseases and pests of animals." *Id.* § 8301(1). That law allows the Secretary of Agriculture to prohibit or restrict "the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock." *Id.* § 8303(a)(1). Regulations may restrict import and entry of animals. *Id.* § 8303(b).

112. *See* 62 Fed. Reg. 552, 563 (discussing early USDA and FDA actions against BSE). Before amendment, relevant regulations were at 9 C.F.R. §§ 93.401 (general prohibitions for ruminants and products), 94.18 (restrictions on meat and edible products due to BSE) (2003). USDA purchased the 69 still-living cattle imported from the UK between 1981 and 1989. 62 Fed. Reg. 552, 563.

113. APHIS, Bovine Spongiform Encephaolpathy: Minimal-Risk Regions and Importation of Commodities, 70 Fed. Reg. 460, 462 (4 Jan. 2005), codified at 9 C.F.R. parts 93-96.

114. 70 Fed. Reg. at 462. The current regulation is 9 C.F.R. § 94.18 (2006), amended numerous times between 1991 and 2005.

115. See 70 Fed. Reg. at 462. The BSE minimal risk region is defined at 9 C.F.R. § 90.4.

116. 9 C.F.R. § 94.18(a)(3) (listing only Canada). The rule cited the Animal Health Protection Act, 7 U.S.C. §§ 8301-8017, among other statutes, as authority.

risk regions, the rule allows import of beef products from animals subject to the feed ban and other restrictions, as well as bovines younger than thirty months for slaughter or feeding.[117] Bovines from Canada for feeding had to be branded "CAN" and identified by official eartags and be traceable to the premises of origin.[118] After discovery of the second and third Canadian cows with BSE, however, APHIS delayed applicability of part of the rule, insofar as it allowed the import of meat, meat products, and carcasses from cattle over thirty months of age.[119] As of September 2006, the US continued to ban older cattle from Canada;[120] the July 2006 discovery of BSE in a cow aged fifty months increased concern among regulators.[121]

The minimum-risk rule for Canada was controversial. R-CALF, an association of US cattle producers, sued to enjoin the implementation of the APHIS regulations that would allow import of beef from Canada. The district court found that irreparable harm would occur when "Canadian cattle and meat enter the U.S. and co-mingle with the U.S. meat supply," and that plaintiffs were likely to succeed on the merits; the district court therefore issued a preliminary injunction against the rule.[122] The Ninth Circuit lifted the preliminary injunction, finding neither irreparable harm nor likelihood of success on the merits.[123] As relevant here, the court decided that the Animal Health Protection Act, one of the laws under which the rule was promulgated, did not require the USDA to avoid *all* risk that

117. 70 Fed. Reg. 460 (4 Jan. 2005) (amending sections of 9 C.F.R. parts 93-96).

118. 70 Fed. Reg. at 549, 9 C.F.R. § 93.436(b)(4). (See 71 Fed. Reg. at 45,439 (9 Aug. 2006), with a proposal to allow means of identification other than ear tags.)

119. 70 Fed. Reg. 12,112 (11 Mar. 2005), codified at 9 C.F.R. § 94.19.

120. In August 2006, APHIS published a proposed rule that would remove further restrictions on imports from BSE minimal-risk areas. 71 Fed. Reg. 45,439 (9 Aug. 2006). In January 2007, APHIS published another proposed rule designed to expand the types of allowable imports from minimal-risk countries (now, only Canada). The proposed rule would apply to cattle and other bovines born on or after 1 March 1999, when Canada's feed ban was enforced effectively. 72 Fed. Reg. 1102 (9 Jan. 2007). See Press Release, USDA, USDA Proposes to Allow Additional Imports from BSE Minimal-Risk Countries (No. 0001.07, 4 Jan. 2007). The proposed rule was published before the February 2007 discovery of the BSE-infected bull born in 2000.

121. Bill Tomson, USDA: *Decision on Older Canadian Cattle May Take Months*, Dow Jones Newswires, 6 Sept. 2006, http://www.cattlenetwork.com/content.asp?ContentID=66315.

122. Ranchers Cattlemen Action Legal Fund v. USDA, 359 F. Supp. 2d 1058, 1074 (D. Mont. 2005).

123. Ranchers Cattlemen Action Legal Fund v. USDA, 415 F.3d 1078 (9th Cir. 2005).

BSE could enter the US, but gave the Secretary of Agriculture discretion to enact appropriate measures, of which closing borders is only one possibility.[124] Moreover, the court held that USDA's conclusion that import of ruminants from Canada would not significantly increase the risk of BSE was supported by substantial evidence. The USDA had relied on "multiple, interlocking safeguards" to prevent spread of BSE to livestock and humans.[125] These include a low rate of BSE in Canada; the Canadian feed ban, import restrictions, and feed testing; import into the US of animals under thirty month; the requirement of slaughter before thirty months; the FDA ruminant-to-ruminant feed ban; and FSIS regulations to protect the human food supply.[126]

B. Restrictions on Animal Feed–FDA

The FDA governs animal food and feed under authority of the Food, Drug and Cosmetic Act.[127] One of the early FDA responses to the discovery of BSE, even before its diagnosis in the US, was to amend its feed regulations. Because epidemiologists in the UK had linked transmission of BSE to the feeding of rendered protein from sheep infected with scrapie and cattle infected with BSE,[128] FDA enacted a regulation, effective since 4 August 1997, that prohibits the use of most proteins from mammals in feed for ruminants.[129]

The FDA defined "protein derived from mammalian tissues" to include "any protein-containing portion of mammalian animals," but excluding blood and blood products, gelatin, human food waste ("plate waste") from inspected meat products (heat processed for feed), milk products, and any product with only porcine or equine

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124. *Id.* at 1094-95.

125. *Id.* at 1095.

126. *Id.* at 1095-96. R-CALF continues to litigate. E.g., the appeal is R-CALF v. USDA, No. 06-35512 (9th Cir.).

127. 21 U.S.C. §§ 321, 342, 343, 348, 371 (sections cited as authority for the ruminant feed ban, 62 Fed. Reg. 30,936, 30,976 (5 June 1997)). The FDA is currently modernizing and filling regulatory gaps in its system for animal feed safety. See Center for Veterinary Medicine, FDA, Second Draft: Framework of the FDA Animal Feed Safety System (20 Dec. 2006), http://www.fda.gov/cvm/AFSS2ndDraft Framework.html.

128. *See* FDA, Proposed Rule, 62 Fed. Reg. 552, at 560, 562. *See supra* text accompanying note 12.

129. Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Final Rule, 62 Fed. Reg. 30,936, codified at 21 C.F.R. § 589.2000 (5 June 1997). A similar ban in the UK in 1989 resulted in a dramatic decrease in BSE, beginning five years after the ban. 62 Fed. Reg. 552, at 555.

protein.[130] Under the rule, protein derived from mammalian tissues used for ruminant feed is a food additive, subject to regulation under the FDCA;[131] ruminant feed that includes mammalian protein is adulterated and violates the Act.[132] The feed ban applies to ruminants, and not to hogs, poultry, and pigs, which are not susceptible to TSEs. Further requirements help to ensure that protein from mammalian tissue does not contaminate feed for ruminants.

The feed rule requires separation of mammalian and non-mammalian feed materials, using methods that will avoid commingling or cross-contamination.[133] Protein blenders, feed manufacturers, and renderers must label feed or other products that contain (or may contain) protein from mammalian tissues intended for use in animal feed. The label must read, "Do not feed to cattle or other ruminants."[134] Traceability requirements also apply, through maintenance of records "sufficient to track the materials throughout their receipt, processing, and distribution," which must be made available to the FDA.[135] Exceptions from the labeling and record-keeping requirements apply if the renderer follows requirements to de-activate the agent that causes TSE, uses a test method to detect the agent, controls the manufacturing process to minimize risk, or uses a permanent marking method on the product.[136] Those who feed ruminants must keep copies of purchase invoices and labels for all feeds with animal protein products, and make them available to FDA.[137] The rule makes clear that animal protein products and feeds are considered misbranded under the FDCA if they do not carry the appropriate labels and adulterated if they violate other provisions.[138]

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130. 21 C.F.R. § 589.2000(a)(1) (2006).

131. As the proposed rule states: "The agency is proposing to declare that protein derived from tissue from ruminant animals and mink is not GRAS, by qualified experts, for use in ruminant feed and is therefore a 'food additive' under the law." 62 Fed. Reg. 552, at 553. Mink tissue did not appear in the final regulation, but the WHO indicated in 2001 that it is "essential that fur-bearing animals must not be recycled to food animal species." WHO/FAO/OIE, *supra* note 18, at 15.

132. 21 C.F.R. § 589.2000(b).

133. One risk analysis, however, indicated that "cross-contamination is a relatively minor factor." 2005 HARVARD RISK ASSESSMENT, *supra* note 63, at 6.

134. 21 C.F.R. § 589.2000(c)1)(i) (2006).

135. 21 C.F.R. § 589.2000(c)(1) (2006). Records, however, need only be kept for one year. *Id.* § 589.2000(h)(1).

136. 21 C.F.R. § 589.2000(c)(2),(3) (2006). A protein blender or feed manufacturer is exempt from the traceability requirement if it follows the requirements for renderers or if it purchases products with a certificate of compliance. *Id.* § 589.2000(d).

137. 21 C.F.R. § 589.2000(f).

138. 21 C.F.R. § 589.2000(g).

In a 2002 report, even before the US had discovered its first infected cow, the US General Accounting Office (now called the Government Accountability Office) found significant shortcomings in federal efforts. For example, the FDA did not "compel firms to keep prohibited proteins out of cattle feed and to label animal feed that cannot be fed to cattle."[139] Firms had not been re-inspected promptly after earlier noncompliance, and data from inspections did not reflect compliance accurately.[140] A subsequent report, issued three years later, found improvement in FDA's management of the feed ban, particularly in training of feed inspectors, uniform documentation of inspection results, and reliable data tracking. But shortcomings still existed: not all firms had been identified; re-inspections lagged; feed intended for cattle was not sampled routinely; feed intended for export did not require the cautionary label, "Do not feed to cattle or other ruminants"; no notification was given when cattle have eaten prohibited feed; and transportation firms were not inspected.[141]

In addition to cross contamination and failure to comply with the feed rules, many feed mills did not have FDA licenses and were therefore not subject to federal inspection.[142] Rules enacted under the Bioterrorism Act of 2002[143] require registration of facilities that manufacture, process, pack or hold food for consumption by humans or animals.[144] Registration will facilitate inspection of feed mills to ensure compliance.[145]

Since enactment of the 1997 feed ban, FDA has considered more stringent regulation. In November 2002, the agency asked for comments about several possible modifications aspects of the feed ban, including measures to prevent cross contamination and the

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139. US GAO, *supra* note 57, at 3. USDA and FDA inspection of imports was deficient, and USDA did not test high-risk domestic cattle, especially those that died on farms. *Id.*

140. *Id.*

141. U.S. GOV'T ACCOUNTABILITY OFFICE, MAD COW DISEASE: FDA'S MANAGEMENT OF THE FEED BAN HAS IMPROVED, BUT OVERSIGHT WEAKNESSES CONTINUE TO LIMIT PROGRAM EFFECTIVENESS 5-8, GAO-05-101 (2005). Regarding the label for exported feed, FDA asserts it cannot require the cautionary label without a change in law.

142. Caroline Smith DeWaal & Leora Vegosen, *Bovine Spongiform Encephalopathy: The Importance of Precautionary Measures to Protect the Food Supply*, 58 FOOD & DRUG L.J. 537, 540 (2003).

143. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, tit. IIIA, §§ 301-315, Pub L. No. 107-88, 116 Stat. 594, 662-75 (2002).

144. 68 Fed. Reg. 58,894, 58,895 (10 Oct. 2003), codified at 21 C.F.R. part 1. Authority is 21 U.S.C. § 350d.

145. *See* DeWaal & Vegosen, *supra* note 142, at 540.

feasibility of excluding "specified risk materials" (SRMs) from all rendered products.[146] In August 2003, the FDA announced its intention to develop a modernized Animal Feed Safety System (AFSS), with "risk-based, preventive control measures for ensuring the safety of animal feed."[147] The FDA's regulations to prevent the spread of BSE in ruminants are part of the AFSS, but the new program would make the AFSS "more comprehensive, preventive, and effective in addressing feed hazards that present the greatest risks to animal and human health."[148]

In July 2004, FDA and USDA issued a joint invitation to comment on a number of possible further regulatory actions, some recommended in the report of an international review team that assessed the US response to its first BSE-infected cow.[149] These included, for example, the exclusion of SRMs from all animal feed, including pet food; additional measures to prevent cross-contamination; and prohibition of all mammalian and avian meat and bone meal (MBM) in ruminant feed.[150] Researchers, too, have suggested that precaution may require banning MBM and all mammalian protein from feed for all farm animals, a step taken by both the EU and Canada.[151] A proposed rule published in October 2005 would have prohibited specified cattle material from all animal food

146. 67 Fed. Reg. 67,572 (6 Nov. 2002). In 2001, WHO and other organizations had recommended that ruminant meat and bone meal (MBM) not be fed to ruminants. If ruminant MBM is fed to other food animals, measures must be implemented to avoid cross-contamination. If cross contamination cannot be avoided, no MBM from any animal should be feed to ruminants. In a country with BSE or a BSE risk, even MBM for nonruminants should be prepared from material from which SRMs (specified risk materials) have been removed. WHO/FAO/OIE, *supra* note 18, at 10.

147. CVM, FDA, Animal Feed Safety System (AFSS) (updated 16 Aug. 2006), http://www.fda.gov/cvm/AFSS.htm

148. FDA's Animal Feed Safety System (AFSS) Project Plans Update #1 (Mar. 2006), http://www.fda.gov/cvm/AFSSUpdate.htm. Critical FDA activities will focus on safe ingredients and additives, elimination of risky contaminants, controlling manufacture, distribution and use of feed ingredients for a safe product, and regulatory oversight.

149. Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States (4 Feb. 2004), http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf [hereinafter IRT Report].

150. APHIS & FDA, Federal Measures to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 42,288 (14 July 2004).

151. DeWaal & Vegosen, *supra* note 142, at 541, 542. The EU has taken this precaution. *Id.* at 541. On Canada, see *supra* text accompanying note 108.

or feed.[152] These materials would include brains and spinal cords from cattle thirty months and older and from cattle not inspected and passed for human consumption (including nonambulatory disabled cattle); entire carcasses of cattle not inspected and passed, if brain and spinal cords were not removed; and certain mechanically separated beef (MS(beef)) and tallow derived from prohibited material.[153] As of the 2006 edition of the Code of Federal Regulations, however, the feed ban had not been amended since the 1997 enactment.

C. Food for Humans–FSIS and FDA

1. FSIS

The Food Safety and Inspection Service (FSIS), an agency within USDA, governs safety of meat, eggs, and poultry. The Federal Meat Inspection Act (FMIA)[154] makes it unlawful for anyone to sell adulterated or misbranded meat or meat products[155] and authorizes measures to ensure that meat and meat products are neither misbranded nor adulterated. The definition of "adulterated" under the FMIA includes meat that is "unhealthful, unwholesome, or otherwise unfit for human food."[156] Under the FMIA, the FSIS examines animals before slaughter and conducts post mortem examination of carcasses.[157]

The FSIS Hazard Analysis and Critical Control Point (HACCP) Systems regulations, enacted in 1996, represent part of FSIS's efforts to protect the meat supply under FMIA.[158] The regulations require preventive controls to improve product safety (HACCP), as well as sanitation standards and microbial testing, and they impose per-

152. FDA, Proposed Rule, Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. 58,570 (6 Oct. 2005), to be codified at 21 C.F.R. §§ 589.2000, 589.2001.

153. *Id.* at 58,600-01.

154. 21 U.S.C. §§ 601-659.

155. *Id.* § 610(d).

156. *Id.* § 601(m)(3). On USDA's burden of proof that meat is adulterated, see McGarity, *supra* note 110, at 312-13.

157. 21 U.S.C. §§ 603, 604.

158. FSIS, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (25 July 1996) (codified at 9 C.F.R. pts. 304, 308, 310, 320, 327, 381, 416, & 417). On HAACP, see McGarity, *supra* note 110, at 314-319.

formance standards for reduction of Salmonella. Some of the BSE-specific regulations fit within the HACCP requirements.[159]

After discovery of the first BSE-positive cow in the US, the FSIS took several steps to protect the food supply. First, in light of the positive finding, FSIS ordered that, when cattle are selected for BSE testing by APHIS, meat inspectors should not mark carcasses "inspected and passed" until results of the test are received and the result is negative.[160] This change helps to prevent an infected animal from entering the food chain.

Shortly thereafter, FSIS published three interim final rules that reduce human exposure to BSE.[161] The first[162] focused on two significant factors in BSE infection: nonambulatory (sometimes called "downer") cattle[163] and specified risk materials. European data indicated that cattle that cannot stand up, those with clinical signs of a central nervous system disease, and dead cattle show a higher incidence of BSE. Moreover, the WHO and other organizations recommended in 2001 that "clinically confirmed cases [of BSE] in bovines and any progeny born in the two preceding years to female cases should be destroyed" and that "all animals suspected of being infected with BSE should be destroyed."[164]

Under FSIS regulations in effect before 2004, cattle with clinical signs of CNS disease and those that were dying or had died could not be used for human food. Crippled livestock and downers, how-

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159. McGarity, *supra* note 110, at 315.

160. FSIS, Bovine Spongiform Encephalopathy Surveillance Program, 69 Fed. Reg. 1892 (12 Jan. 2004). Prior to this directive, the FSIS only recommended, but did not require, that carcasses be held until the sample proved negative. *Id.*

161. See also the joint USDA, FDA document, Federal Measures To Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 42,288 (14 July 2004).

162. FSIS, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (12 Jan. 2004), codified at 9 C.F.R. pts. 309-311, 318, 319. *See also* the amendment, FSIS, Prohibition of the Use of Specified Risk Materials for Human Food, 70 Fed. Reg. 53,043 (7 Sept. 2005). FSIS affirmed this rule, with changes, in July 2007. 72 Fed. Reg. 38,700 (13 July 2007).

163. Press Release, USDA, Veneman Announces Additional Protection Measures to Guard Against BSE (No. 0449.03, 30 Dec. 2003). Beef industry organizations, especially the National Cattlemen's Beef Association, are reported to have defeated earlier legislative efforts to ban downer cattle from the food supply, as well as country of origin labeling for beef. Sarah Leuck, *Cattlemen Saddle Up for Duels Over Rules*, WALL ST. J. (Eastern ed.), 8 Jan. 2004, A4.

On issues concerning downed animals, see Kevin Briley, Comment, *Downed Animals: Can Your Steak Stand Up for Itself?*, 15 SAN JOAQUIN AGRIC. L. REV. 39 (2006).

164. Cohort animals of a confirmed case should also be destroyed. WHO/FAO/OIE, *supra* note 18, at 11-12.

ever, could be used for food. They were labeled "U.S. Suspects" and subject to veterinary (instead of FSIS inspector) post-mortem examinations, but on satisfactory inspection, they were slaughtered and entered the food chain.[165]

The 2004 regulations, affirmed with changes, in 2007, require condemnation of downer cattle.[166] Nonambulatory disabled livestock (defined to include those that cannot rise from a recumbent position or cannot walk for any reason) are excluded from the human food chain and must be condemned.[167] Condemned carcasses must be disposed of by "tanking" (inedible rendering), incineration, or an approved denaturing method that makes them inedible.[168]

The FSIS also requires the removal of SRMs from the human food supply.[169] Research has demonstrated BSE infectivity in specified cattle tissue, particularly brain, spinal cord, dorsal spinal nerve root ganglia, and other tissue. Therefore, the FSIS regulation defined infective tissues as SRMs, which "are inedible and shall not be used for human food."[170] Under the rule, SRMs include the tonsils

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165. 69 Fed. Reg. 1862, at 1870 (referring to 9 C.F.R. §§ 309.2, 309.3, 309.4, 311.1 (2003)).

166. See 72 Fed. Reg. 38,700. 9 C.F.R. § 309.2(b) (2005). Earlier attempts to persuade USDA and FDA to prohibit food use of downer cattle had been unsuccessful. *See, e.g.*, Baur v. Veneman, 352 F. 3d 625 (2d Cir. 2004). Baur's suit was filed before BSE was found in the US, and the District Court dismissed for lack of standing. Farm Sanctuary, Inc. v. Veneman, 212 F. Supp. 2d 280 (S.D.N.Y. 2002). The Second Circuit vacated the judgment as to Baur, holding that Baur had standing, at least as to cattle; his increased risk of contracting illness from downer livestock was an injury in fact and the possible transmission of BSE was a credible threat of harm. 352 F.3d at 643.

167. 9 C.F.R. §§ 309.2(b), 309.3(e). The ban does not include disabled cattle that are ambulatory. For criticism, *see* McGarity, *supra* note 110, at 335-36. Though some disagree with the ban, others assert that the risk to human health posed by downer animals made the ban overdue. Odeshoo, *supra* note 75, at 306.

168. 9 C.F.R. § 314.1. *See* 69 Fed. Reg. 1862, at 1871.

169. In 2001, the WHO had emphasized the importance of eliminating specific risk materials from human food. WHO/FAO/OIE, *supra* note 18, at 6-8. The Terrestrial Animal Health Code (2006) of the World Organization for Animal Health (OIE or Office International des Epizooties) indicates that SRMs should not be used in "food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices." Art. 2.3.13.13, http://www.oie.int/eng/normes/Mcode/en_chapitre_2.3.13.htm (last visited 26 Mar. 2007).

170. 9 C.F.R. § 310.22(b). In 2004, USDA announced its intention to establish a loan guarantee program, so that SRMs could be burned to provide a bio-based source of energy. Notice of Funds Availability (NOFA) Inviting Applications for the Specific Risk Materials and Certain Cattle Renewable Energy Guaranteed Loan Pilot Program, 69 Fed. Reg. 28,111 (18 May 2004).

and distal ileum of all cattle.[171] For cattle thirty months of age or older, SRMs also include the "brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column [with a few exceptions], and dorsal root ganglia."[172] Meat slaughter and processing facilities must develop, implement, and maintain procedures for handling SRMs, and document compliance.[173]

The second interim rule addressed advanced meat recovery (AMR) and mechanically separated meat (MS(beef)).[174] AMR allows removal of muscle tissue from livestock bones, but may also leave infective spinal cord and dorsal root ganglia in the meat product.[175] The regulation amends the definition of "meat" to exclude significant portions of bone and components (bone marrow) and "any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia."[176] The products of AMR systems cannot be labeled as meat if they include those four types of nervous system tissue or significant bone solids or bone marrow from any animal, or if they include skulls or vertebral tissue from cattle thirty months or older.[177] Establishments must develop, implement, and maintain procedures to control the AMR process.[178]

MS(beef) results from a process that incorporates bone and its components into the meat food product; earlier regulations had permitted MS(beef) to include spinal cord and dorsal root ganglia. Because of the risk of BSE, FSIS banned the use of MS(beef) for human consumption.[179]

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171. 9 C.F.R. § 310.22(a). The 2004 regulation required disposal of the entire small intestine, 69 Fed. Reg. 1862, at 1873. Amendments in 2005, however, permit use of the small intestine for human food under certain circumstances. Prohibition of the Use of Specified Risk Materials for Human Food, 70 Fed. Reg. 53,043, 53,050 (7 Sept. 2005), (codified at 9 C.F.R. § 310.22(a)(3)). Beef small intestines from countries with BSE risk are subject to APHIS regulations, 9 C.F.R. pts. 94-96; 70 Fed. Reg. at 53,047.

172. 9 C.F.R. § 310.22(a),(e). Cattle are deemed to be thirty months or older, unless proved to be younger.

173. *Id.* § 310.22(d). Procedures can be included in HACCP or other plans.

174. FSIS, Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, 60 Fed. Reg. 1874 (12 Jan. 2004) (codified at 9 C.F.R. pts. 301, 318, 320).

175. 60 Fed. Reg. at 1875-76.

176. 9 C.F.R. § 301.2.

177. *Id.* § 318.24(a). *See also id.* § 318.24(c), which defines measures for determining that AMR products are not meat.

178. *Id.* § 318.24(b).

179. 70 Fed. Reg. at 1882-83, referring to 69 Fed. Reg. 1862, at 1866-67. Evidently, few establishments produced MS(beef). McGarity, *supra* note 110, at 335.

The third FSIS measure prohibited the use of certain stunning devices in cattle slaughter.[180] Under the Humane Methods of Slaughter Act,[181] livestock must be slaughtered humanely; they must be made insensible to pain early in the slaughter process. Slaughter establishments used penetrative captive bolt stun guns, which made cattle unconscious by driving a bolt into the animal's brain, either with compressed air or a blank cartridge. Compressed air guns "can force visible pieces of brain and other CNS tissue into the circulatory system of stunned cattle,"[182] which may then expose humans to BSE through adulterated meat.[183] Therefore, FSIS banned the use of "[c]aptive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle" for stunning cattle.[184] FSIS indicated, however, that US slaughterhouses did not use air-injection stunning.[185]

Though these regulations were intended to remove the risk of infective tissues in the human food chain, some evidence suggests that not all establishments comply adequately. For example, in August 2005, documents released pursuant to a FOIA request indicated that federal meat inspectors had reported more than 1000 instances of noncompliance with food safety rules connected with BSE. One third of these involved improper removal or handling of SRMs; more than half involved inadequate HACCP plans for BSE or SRMs.[186] In response, the FSIS issued a fact sheet to highlight its strong enforcement of HACCP and SRM regulations to protect against BSE.[187] The fact sheet insisted that "FSIS is confident it is successfully carrying out its mission to protect public health by

180. FSIS, Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, 69 Fed. Reg. 1885 (12 Jan. 2004), codified at 9 C.F.R. pts. 310, 313. FSIS affirmed this rule in July 2007. 72 Fed. Reg. 38,700 (13 July 2007).

181. 7 U.S.C. §§ 1901-1906.

182. 69 Fed. Reg. at 1887.

183. *See id.* at 1889, citing as authority 21 U.S.C. §§ 601(m) (defining adulterated) & 621.

184. 9 C.F.R. § 313.15(b)(2)(ii) (2005).

185. 69 Fed. Reg. at 1889.

186. Public Citizen, BSE Noncompliance Record Analysis, http://www.citizen.org/cmep/foodsafety/madcow/articles.cfm?ID=13903 (last visited 26 Mar. 2007). Noncompliance reports dated from January 2004 to May 2005.

187. FSIS, USDA, BSE Rules Being Strictly Enforced (August 2005), http://www.fsis.usda.gov/Fact_Sheets/BSE_Rules_Being_Strictly_Enforced/index.asp.

strictly enforcing safeguards designed to protect Americans from BSE."[188]

A study by the Harvard Center for Risk Analysis evaluated the effect of food safety measures enacted by USDA and concluded that the measures "all reduce potential human exposure to BSE infectivity but have little effect on spread of BSE in the cattle population."[189] Removing downer cattle from the human food supply and prohibiting advanced meat recovery on animals over thirty months reduce human exposure. Removing SRMs from animals older than thirty months "almost completely eliminates potential human exposure."[190] The study also noted that these measures reduce "what is already a small risk in absolute terms."[191]

2. FDA

Though USDA (through FSIS) has primary responsibility for meat and meat products, FDA regulations also apply. FDA and USDA have coordinated their rule making, sometimes publishing related rules in the same issue of the Federal Register. Thus, in July 2004, the FDA published an interim final rule that prohibited the use of certain materials derived from cattle in food and cosmetics for human use.[192] In September 2005, both the FDA and the FSIS amended their July 2004 rules.[193]

Under the FDA regulation, no human food can be manufactured from, processed with, or contain prohibited cattle materials.[194] Prohibited cattle materials are specified risk materials (those in-

188. *Id.* (final paragraph).
189. 2005 HARVARD RISK ASSESSMENT, *supra* note 63, at 6.
190. *Id.*
191. *Id.* The analysis calculated numerical reductions of risk, using a simulation that assumed that 500 infected cattle would enter the US. The study also evaluated proposed measures. Removal of SRM in food and feed from animals twelve months or older would be "extremely effective" in reducing human exposure to BSE; removal of SRMs from rendered animals and removal of animal protein from cattle feed would also be effective. *Id.* at 7.
192. Use of Materials Derived from Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,256 (14 July 2004), codified at 21 C.F.R. pts. 189 & 700. See also the companion regulation on Recordkeeping Requirements, 69 Fed. Reg. 42,275 (14 July 2006). This article does not focus on cosmetics.
193. FDA, Use of Materials Derived from Cattle in Human Food and Cosmetics, 70 Fed. Reg. 53,063 (7 Sept. 2005); FSIS, Prohibition of the Use of Specified Risk Materials for Human Food, 70 C.F.R. 53,043 (7 Sept. 2005).
194. 21 C.F.R. § 189.5 (2006).

cluded by FSIS),[195] material from nonambulatory disabled cattle, material from cattle not inspected and passed, and mechanically separated beef. The small intestine is prohibited unless it is removed according to regulation.[196] Like the FSIS regulations discussed above, the FDA rule also prohibits use of SRMs, nonambulatory disabled (downer) cattle, and MS(beef) as food. Use of the prohibited cattle materials in food for humans makes the food adulterated under the FDCA.[197]

IV. TRACEABILITY

A. In General

Discovery of a food safety issue, like BSE in cattle or, perhaps more commonly, a contaminant like E.coli 0157:H7 in spinach, raises public awareness of the importance of finding the source of the disease or contaminant. Private or government systems of traceability help in this effort. Traceability for a food attribute can occur when "information about a particular attribute of a food product is systematically recorded from creation through marketing."[198]

The European Community's General Food Law, enacted in 2002, recognizes the need for a comprehensive system of traceability within food and feed businesses to avoid disruption in case of food safety problems.[199] Accordingly, the General Food Law requires

195. 9 C.F.R. § 310.22 (2005), discussed *supra* text accompanying notes 170-73.

196. 21 C.F.R. § 189.5(a)(1)(5) (2006). "Prohibited cattle materials do not include [certain] tallow . . . , tallow derivatives, hides and hide-derived products, and milk and milk products." *Id.* (a)(1). The July 2004 regulation listed the whole small intestine as prohibited cattle material, 69 Fed. Reg. at 42,273, but both the FSIS and the FDA concluded that the infective distal ileum could be removed safely from the rest of the small intestine. 70 Fed. Reg. at 53,043 (FSIS), 53,063 (FDA) (7 Sept. 2005).

197. 21 U.S.C. § 342(a)(3),(4). Cosmetics that do not comply are adulterated under *id.* § 361(c).

198. Elise Golan et al., *Traceability for Food Marketing & Food Safety: What's the Next Step?*, AGRICULTURAL OUTLOOK 21, 21 (Jan.-Feb. 2002) [hereinafter Golan et al., *Traceability*]. For a recent review of agri-food traceability, see Jill E. Hobbs, Traceability in the agri-food sector: issues, insights and implications, 2006(1) CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition, and Natural Resources, No. 029, http://www.cabastractsplus.org/cabreviews.

199. Regulation 178/2002, pmbl. (28), 2002 O.J. (L 31) 1, 3. The European Rapid Alert System for Food and Feed (RASFF), authorized by the General Food Law, arts. 50-54, was used in November 2004 to trace dioxin-contaminated potato by-products used for animal feed and to block movement of animals on farms that

farm-to-fork traceability of food, feed, food-producing animals, and other substances used in food. It requires food and feed business operators to implement systems and procedures, including labeling, for traceability.[200] The General Food Law defines "traceability" broadly as "the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution."[201]

The US, in contrast, does not require traceability for all food and feed, and traceability systems are less prevalent than in the European Union. US discussions of traceability in the 1990s may have been "derailed" by a focus on genetically modified organisms (GMOs) and their products. European requirements for traceability of GMOs associated traceability "with locating a negative attribute rather than retaining the value of a positive attribute,"[202] which may have dampened US enthusiasm for required systems of traceability. When US producers and firms establish traceability programs, they often focus on specific food safety goals, defining traceability as "[t]he efficient and rapid tracking of physical product and traits from and to critical points of origin or destination in the food chain necessary to achieve specific food safety and, or, assurance goals."[203]

Both private firms and government food agencies play roles in tracing food in the US. Private firms have several motives for traceability. Some food producers want "to differentiate and market foods with subtle or undetectable quality [or credence] attributes,"[204] which may refer to the food's content or to its process attributes

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used the feed. Press Release, European Commission, Dioxin contamination: EU traceability and alert notification systems work well (IP/04/1343, 5 Nov. 2004).

In 2005, The RASFF received 3158 notifications of food and feed risks (22% more than in 2004). Meat and meat products made up 18% of the products notified. HEALTH AND CONSUMER PROTECTION DIRECTORATE-GENERAL, EUROPEAN COMMISSION, THE RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF): ANNUAL REPORT 2005, at 4, 9, 10 (2006), http://ec.europa.eu/food/food/rapidalert/report2005_en.pdf.

200. Regulation 178/2002, art. 18, 2002 O.J. (L 31) at 11.

201. *Id.* art. 3(15), 2002 O.J. (L 31) at 8.

202. Eluned Jones, *Entity Preservation and Passport Agriculture: EU vs. USA*, 7 DRAKE J. AGRIC. L. 381, 400 (2002). Moreover, the US hasn't experienced a widespread crisis like BSE or foot and mouth disease in the UK. On EC traceability requirements, see Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food, and Feed in the European Union*, 1 J. FOOD L. & POL'Y 43 (2005).

203. FARM FOUNDATION, FOOD TRACEABILITY & ASSURANCE IN THE GLOBAL FOOD SYSTEM 9 (2004), www.farmfoundation.org.

204. Golan et al., *Traceability*, *supra* note 198, at 21. Thus, traceability facilitates traceback.

(e.g., production or stewardship). Other firms use traceability to ensure food safety and quality by reducing the time needed to identify and recall contaminated products (that is, to facilitate traceback).[205] Improvement of supply-side management is another use of traceability systems, which can help to manage production and track sales and inventories (e.g., through bar codes).

Though many traceability systems are voluntary, government-mandated traceability can be used "to facilitate and monitor traceback to enhance food safety; to address consumer information about food safety and quality; and to protect consumers from fraud and producers from unfair competition."[206] Traceability also plays a role in protection of the US food supply from possible bioterrorist threats. Pursuant to the Bioterrorism Act of 2002,[207] the FDA has enacted regulations that require traceability (one step up and one step down) for manufacturers, processors, packers, transporters, and others in the food distribution channel. Farmers, restaurants, and fishing vessels are exempt.[208]

Both USDA and FDA play roles in food safety, and the USDA focuses on meat and poultry. Both agencies rely on private firm documentation for traceability. "A firm's traceback documentation is constructed from its traceability system: the documentation used to trace a food from farm . . . to plate . . . is used to trace a food product back from plate to farm."[209] Moreover, each agency relies on voluntary recall of contaminated foods, because neither has statutory authority for mandatory recall.[210]

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205. *Id.* at 22-23. One example is an Irish supermarket that can trace meat to the animal of origin through DNA testing. *Id.* at 23.

206. *Id.* at 23.

207. The Bioterrorism Act of 2002 is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, tit. IIIA, §§ 301-315, Pub L. 107-88, 116 Stat. 594, 662-75 (2002). Section 306, codified at 21 U.S.C. § 350c, requires record-keeping for traceability and authorizes inspection of records.

208. 69 Fed. Reg. 71,562, 71,651-55 (9 Dec. 2004), corrected at 70 Fed. Reg. 8726 (23 Feb. 2005) (codified at 21 C.F.R. §§ 1.326-.368).

209. Golan et al., *Traceability, supra* note 198, at 24. Golan insists that if markets function properly, firms will provide the optimal level of traceback capacity through their traceability systems. *Id.*

210. Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L. J. 563, 567 (2004). Voluntary recall is motivated by "the implicit threat of regulatory action, liability, and/or adverse publicity." *Id.*

B. Tracing Animals

Animal identification "refers to the marking of individual farm animals, or a group or lot of animals, so that they can be tracked from place of birth to slaughter."[211] It is one part of traceability, which tracks "the movement of identifiable products through the marketing chain."[212] In a discussion of traceability focused on animal disease, the USDA indicated that

> Traceback refers to the ability to track an animal's location over its lifespan and the ability to determine which animals may have been in contact with the diseased animal or shared a contaminated feed supply. Trace forward data provides locations of animals moved out of the premises of concern that may have been exposed to the disease.[213]

US interest in tracing the identity of animals has increased in recent years, particularly after the discovery of BSE (with its link to vCJD) in Canadian and US cattle, the 2001 epidemic of foot and mouth disease in the UK and elsewhere in Europe,[214] and the concern about bioterrorism after terrorist attacks on US soil.[215] Implementation of country of origin labeling (COOL), which has been delayed several times and is still subject to debate, may eventually also require identification and tracing of animals; under COOL,

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211. Geoffrey S. Becker, Animal Identification and Meat Traceability, at 1, CRS Rep. RL32012 (updated 13 July 2006), http://ncseonline.org/NLE/CRSreports/06Aug/RL32012.pdf [hereinafter Becker, Animal ID].

212. *Id.* at 2.

213. APHIS, FSIS, & FDA, Federal Measures to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 42,288, 42,298 (14 July 2004). The Canadian Livestock Identification Agency (CLIA) distinguished between tracking and tracing:

> *Tracking* is the ability to follow an animal or a group of animals from a point of origin in the supply chain to a present location or point of disposal.
>
> *Tracing* is the capacity to follow an animal or group of animals back to the point of origin and link them to contacts or inputs (contaminants or infectious agents) that may have affected their quality or fitness for consumption. Both activities require recording and storage of data on movements through the supply chain.

CLIA, Frequently Asked Questions, http://www.canadianlivestockid.ca/eng/faqs_e.htm (last visited 7 Sept. 2006).

214. *See generally* DEFRA, About Foot and Mouth Disease (updated 16 August 2006), http://www.defra.gov.uk/footandmouth/about/index.htm.

215. Becker, Animal ID, *supra* note 211, at 1.

only meat from animals with a US life cycle can be labeled as meat of US origin.[216]

Identification of animals and the resulting traceability are not new, because livestock owners have strong incentives to identify their live animals. Protection of property from loss or theft, especially in open range grazing, has long been an important motivation for identifying cattle. Other motives for live animal traceability include animal disease control and differentiation of "credence attributes"—characteristics preferred by consumers, but not evident from visual inspection of animals.[217]

Branding, used in the US since the late 1800s, is the traditional method for identifying cattle, but other methods, including tags, were also used.[218] In the 1960s and thereafter, USDA programs to eradicate animal diseases required ear or back tags, tattoos, and face brands on infected animals.[219] The Uniform Eartagging System was used for identification, vaccination, and reactor tags used in programs to eradicate diseases.

Today ear tags and other marks are common, and they use printed numbers, microchips, or machine-readable codes. At cow-calf operations, a majority of cattle of cattle are identified individually or by group. At large commercial feedlots, 98% of cattle are identified individually or by group, and at small commercial feedlots, about 80% are identified.[220] Identification of animals at slaughter allows payment based on carcass quality.[221] Moreover, under FSIS regulations, until completion of post-mortem inspection, the slaughterer must identify the head and specified organs with the rest

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216. *Id.* at 3. COOL has been delayed until 30 Sept. 2008. On COOL, see Geoffrey S. Becker, Country-of-Origin Labeling for Foods, CRS Rep. 97-508 (updated 20 Mar. 2006).

217. ELISE GOLAN ET AL., TRACEABILITY IN THE U.S. FOOD SUPPLY: ECONOMIC THEORY AND INDUSTRY STUDIES 27 (ERS, USDA, AER 830, 2004) [hereinafter GOLAN ET AL., AER 830].

218. Benjamin D. Richey et al., Animal Agriculture and Identification: Historical Significance (National Institute for Animal Agriculture, prepared for US Veterinarian 2005), www.animalagriculture.org/id/AnimalAgricultureandIDHistoricalSignificance.htm (visited 21 Nov. 2006).

219. *Id.*

220. *Id.* at 28-30. Large commercial feedlots, which feed 66 percent of cattle, have at least 8,000 head. *Id.* at 29. Traceability systems for hogs tend to be integrated, because most hogs are produced under contractual arrangements or by integrated operations. *Id.* at 33. For disease control, interstate swine movement requires identification of animals. Becker, Animal ID, *supra* note 211, at 3-4.

221. GOLAN ET AL., AER 830, *supra* note 217, at 30.

of the carcass and retain all identifying tags.[222] After inspection, however, the identity of individual animals may be lost, and meat safety becomes the predominant issue.[223]

An effective system of identifying cattle and tracing their movement is critical to minimize the risk from BSE and numerous contagious animal diseases. In Canada, where a national identification and tracking system was in effect before its first identified BSE case, officials could identify, trace, and test birth cohorts of infected cattle.[224] The lack of an animal identification system contributed to the USDA's "inability to track down most of the other at-risk cows" that entered the US from Canada with a BSE-infected cow.[225] Lack of any identification on the Alabama cow with BSE in March 2006 meant that the cow could not be traced to its herd of origin, even after an investigation of thirty-seven farms.[226] Even so, industry leaders view animal identification as a "potential tool in animal health and food safety assurance programs," rather than a method for preventing BSE.[227]

An animal identification system that records date of birth can also determine the age of cattle sent to slaughter. Removal of SRMs at slaughter is one of the "firewalls" designed to keep SRMs from animals infected with BSE out of the food supply, and additional SRMs must be removed from cattle that are thirty months or older. When age cannot be documented, all carcasses must be treated as thirty months or older.[228] An audit report, critical of slaughter controls, noted that "[w]ithout an animal identification system, APHIS

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222. 9 C.F.R. § 310.2 (2006).

223. GOLAN ET AL., AER 830, *supra* note 217, at 31.

224. CENTER FOR SCIENCE IN THE PUBLIC INTEREST, NAME THAT COW: U.S. BSE PRECAUTIONS AND TRADE WITH CANADA 6 (2005) [hereinafter NAME THAT COW]. A birth cohort is "cattle born on the farm of origin the 12 months before and after the birth of the affected animal." *Id.*

225. Odeshoo, *supra* note 75, at 313. Some could be tracked only because the infected cow came from Canada, which has an animal ID system. *Id.* The US could track only 29 of the 81 cows imported with the infected cow. NAME THAT COW, *supra* note 224, at 6, Table 3.

226. APHIS, USDA, Alabama BSE Investigation, Final Epidemiology Report, May 2, 2006, at 13, http://www.aphis.usda.gov/newsroom/hot_issues/bse/content/printable_version/EPI_Final.pdf. *See also* Scott Kilman, *Mad-Cow Case Frustrates Officials*, WALL ST. J., 4 May 2006.

227. Geoffrey S. Becker & Sara A. Lister, Bovine Spongiform Encephalopathy (BSE, or "Mad Cow Disease"): Current and Proposed Safeguards 43, CRS Report RL32199 (updated 13 Oct. 2005), http://ncseonline.org/NLE/CRSreports/05oct/RL32199.pdf.

228. *See, e.g.*, 9 C.F.R. § 310.22(a)(e).

and FSIS rely on meat establishments to determine the age of cattle slaughtered."[229]

Animal identification and traceability are costly. One USDA estimate of the implementation cost of farm to slaughter traceability for "all program species" is $500 million; a private-sector estimate of initial capital investment is $140 million, plus annual costs of approximately $108 million.[230] Despite the potential cost, however, numerous recent reports and commentaries have emphasized the importance of animal identification. For example, in a 2001 report that focused on international hazards from BSE, the WHO and other organizations recommended that if a case of BSE is confirmed, "all cohort animals, i.e. animals exposed to the same risk, should be destroyed." The report continued, "For this purpose, adequate, individual animal identification and records of movement of cattle must be in place."[231] The report recommended ongoing education of food chain participants to encourage, among other things, traceability of animals, as well as traceability of raw materials and compound feed.[232]

Similarly, after discovery of BSE in the US, a report by international experts assessed BSE-related measures and emphasized the importance of "effective identification and traceability systems, that have value not only for the cost-effective and rapid tracing of animals for culling, but also for containment of contagious diseases."[233] The report encouraged the implementation of an appropriate animal ID system.[234] More recently, the *Safe Food International Guidelines*, developed by international consumer organizations with cosponsorship from WHO and FAO, recommended essential elements for effective food safety.[235] Among these are recall and tracking sys-

229. OIG Audit, *supra* note 110, at 52.

230. Bailey et al., *supra* note 10, at 293. Sparks Companies Inc. estimated the capital investment and annual costs.

231. WHO/FAO/OIE, *supra* note 18, at 12. In some cases, the recommendation continued, more extensive destruction might be considered for "social, political, economic or trading reasons." *Id.*

232. *Id.* at 13.

233. IRT Report, *supra* note 149, at 9.

234. *Id.*

235. Guidelines for Consumer Organizations to Promote National Food Safety Systems (2005), printed in Caroline Smith DeWaal & Gonzalo R. Guerrero Brito, *Safe Food International: A Blueprint for Better Global Food Safety*, 60 FOOD & DRUG L.J. 393, 398-405 (2005).

tems which, "[i]n the case of live animals, may include animal identification systems using ear tags and other devices."[236]

C. *Tracing Meat*

This emphasis on animal identification and traceability illustrates an important impact of BSE, which has influenced the whole food industry: "the shift in emphasis away from risk management at the retail level to implementing quality assurance and traceability throughout the supply chain."[237] In this context, traceability of meat and their products is important, too, both for supply-chain management and for food safety.[238] But farm to fork traceability is difficult and expensive.

Most meat sold at retail can be traced to its slaughter or processing plant, because FSIS regulations require meat that is transferred to be marked with the official inspection legend and the number of the processor or slaughterer.[239] Identifying beef from individual animals, however, raises special difficulties because, unlike manufacturing, the process is a "disassembly process."[240] At the packing plant, where animals are slaughtered, meat cuts from numerous beef carcasses are often packaged together.[241] This large-scale fabrication process, where individual cuts of meat are prepared, makes "tying individual cuts . . . back to animals entering the plant virtually impossible."[242]

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236. *Id.* at 403. Surveillance systems that identify diseases in animals should be part of a system that allows "tracing of causes of foodborne disease from the farm to the kitchen." *Id.* at 400.

Similarly, NASDA emphasized the importance of tracing food in the event of an emergency and noted that the lack of a uniform regulatory system may make tracing difficult. NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE, EMERGENCY RESPONSE PLAN: FOOD EMERGENCY TEMPLATE, at App. B-4 (2006), http://www2.nasda.org/NR/rdonlyres/2EC4F1B6-9732-4187-8A1D-7024C6818CBE/858/NASDAFoodPlanTemplate020906.pdf.

237. Jones, *supra* note 202, at 399.

238. GOLAN ET AL., AER 830, *supra* note 217, at 31, 34.

239. 9 C.F.R. § 316.9 (2006). In addition, some meat includes a processing batch number. GOLAN ET AL., AER 830, *supra* note 217, at 32.

240. Bailey et al., *supra* note 10, at 293. The authors describe the process at a typical meat slaughter and packing operation.

241. *Id.* at 293-94. Perhaps as a substitute for complete traceability, testing protocols are designed to ensure that meat is safe before it leaves the plant.

242. *Id.* at 294. The authors present results of a survey that suggests that a substantial percentage of consumers are willing to pay more for steaks that are traceable from farm to fork.

A two-step process of traceability for animals—separate traceability systems for live animals from farm to slaughter and for meat and meat products from the processing plant—leaves a break in farm to fork traceability. That is, information on the identity of individual animals has generally not been maintained. Recent focus on attributes like animal welfare practices, feed, and use of antibiotics and hormones, as well as diseases like BSE, has increased interest in linking animal and meat tracing systems. Techniques that link animals with their meat products have been developed, but these are often capital or labor intensive and require careful recordkeeping.[243] It is expected, however, that animal-to-meat traceability will become more common as technological advances reduce costs and increase accuracy.[244]

V. ANIMAL IDENTIFICATION

A. Other Countries

A number of countries have implemented some level of tracking and tracing of animals.[245] Member States in the EU must identify their animals under programs enacted pursuant to EC measures. For example, a Regulation enacted in 2000 governs the system for identification and registration of cattle,[246] and a later Regulation governs identification and registration of sheep and goats.[247] Similarly, both Canada and Australia, competitors with the US in beef

243. Ahmed ElAmin, DNA technique developed for meat traceability, Food Navigator USA.com (9 Oct. 2006), http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=71125.

DNA techniques can be used to trace meat, and even products made from meat from more than one animal, back to individual animals. *Id.* These techniques are costly and not yet commonly used.

244. GOLAN ET AL, AER 830, *supra* note 217, at 32.

245. These include, the EU, New Zealand, Japan, Australia, Brazil, and Argentina. CLIA, Frequently Asked Questions, Q. 11, http://www.canadianlivestockid.ca/eng/faqs_e.htm (last visited 26 Mar. 2007).

246. Regulation 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products, 2000 O.J. (L 204) 1 (11 Aug. 2000). *See also* Commission Regulation No. 1083/2003 laying down detailed rules for the implementation of Regulation 1760/2000, 2003 O.J. (L 156) 9 (25 June 2003).

247. Regulation 21/2004 establishing a system for the identification and registration of ovine and caprine animals, 2004 O.J. (L 5) 8 (9 Jan. 2004). For a description of EU measures, see Bernd M.J. van der Meulen & Annelies A. Freriks, *Beastly Bureaucracy: Animal Traceability, Identification and Labeling in EU Law,* 2 J. FOOD L. & POL'Y 317 (2007).

and other agricultural products, have mandatory animal ID systems. Other countries, too, require identification of food animals. The discussion that follows describes these animal identification systems briefly.

1. Canada

In Canada, the Canadian Livestock Identification Agency (CLIA), created in 2005 as an industry-led and government-supported agency, provides leadership for development of a traceability system, including a multi-species database and national standards and criteria for identification and traceability.[248] The CLIA defined livestock traceability as "the ability to trace the history, application, or location of an animal by means of recorded identifications . . . . This requires three key information components: animal identification, premises identification, and the movement of animals between premises that can be applied from birth or import to death or export or what is being termed as 'whole-life'"[249]

Canada's mandatory animal identification system for cattle is operated by a non-profit industry organization, the Canadian Cattle Identification Agency (CCIA).[250] The Canadian Cattle Identification Program is intended to contain and eradicate animal disease. Under the program, begun in 2001 and fully implemented by July 2002, each animal bears a unique tag number[251] from its herd of origin until export or slaughter. Canadian Food Inspection Agency regulations require cattle to be tagged before leaving their farm of origin,[252] and penalties punish non-compliance. Though the CCIA system is a "book end" system, under which the tag from farm of origin is retired at slaughter or death of the animal, a "movement and sighting" (movein, moveout) component has been added, and

248. Canadian Livestock Identification Agency–Spring 2006 Update, http://www.canadianlivestockid.ca/eng/index_e.htm (last visited 26 March 2007).

249. *Id.*

250. *See* Canadian Cattle Identification Agency (CCIA), http://www.canadaid.com/ (last visited 28 Nov. 2006).

251. The Canadian program uses eartags for animal identification. 71 Fed. Reg. 45,439, 45,440 (9 Aug. 2006).

252. CCIA, Producer information, http://www.canadaid.com/Producer/ (last visited 26 March 3007). In February 2007, however, it was reported that many young feeder cattle and dairy cows from Canada reached the US without tags or with tags that do not match their health certificates. Stephen J. Hedges, *Canadian cattle slip past USDA safeguards*, CHICAGO TRIB. (19 Feb. 2007). USDA representatives blamed minor recordkeeping problems. Stephen J. Hedges, *USDA: Mistakes tracing Canadian cattle are 'minor'*, CHICAGO TRIB. (23 Feb. 2007).

movement data can be reported voluntarily.[253] Radio frequency identification devices (RFID) have been used since January 2005, and beginning 1 September 2006, CCIA policy requires cattle leaving their "herd of origin" to wear an RFID tag.[254] Data are maintained in a national database, and CCIA protects the confidentiality of producer information; the Food Inspection Authority has access to data if an animal health issue occurs.[255]

The Canadian Pork Council and various provincial pork organizations have been active in developing the National Hog ID and Traceability System, scheduled to be implemented by Summer 2008.[256] Led by industry, the program will facilitate trace back and trace forward on live hogs from all swine premises to minimize harmful effects of a food safety issue or an outbreak of a foreign animal disease. The program will register swine premises, assign numbers to animals (with "slap tattoo" numbers), and track movement of animals from farm to slaughter and between farms. Collaboration with the Canadian Livestock Identification Agency will ensure that the hog program is compatible with traceability systems for other livestock.[257]

2. Australia

Australia, a large red meat exporter,[258] established itself as a pioneer in livestock tracing when it began its system of tracking cattle

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253. CCIA, Producer Information, Backgrounder, http://www.canadaid.com/Producer/ (visited 3 Jan. 2007). The movement and sighting module, which began in January 2006, is mentioned in CCIA: A Report to the Community 2005/2006, http://www.canadaid.com/CCIA%20Community Report2006.pdf (visited 3 Jan. 2007).

254. CCIA, RFID Tagging Date Arrives, CCIA News (Fall 2006), http://www.canadaid.com/16256%20CCIA%20FallNEWSLETTER.pdf. Enforcement of the RFID requirement begins 31 Dec. 2007. CCIA, Producer Information, *supra* note 253.

255. Canadians, Australians Provide Details of Successful Animal ID Systems, Informa Econ. Pol'y Rep., 20 Sept. 2005. By September 2005, 40 million unique numbers had been assigned to Canadian animals.

256. Canadian Pork Council, National Identification and Traceability System—Spring 2005, http://www.cpc-ccp.com/Traceability/Background.pdf.

257. *Id.*

258. Glynn T. Tonsor & Ted C. Schroeder, Animal Identification: Lessons for the U.S. Beef Industry Learned from the Australian National Livestock Identification System 2 (Western Extension Marketing Committee, FS #13, Summer 2006), http://www.lmic.info/memberspublic/animalID/fs13.pdf#search=%22australia%20animal%20identification%20mandatory%20system%22 [hereinafter Tonsor & Schroeder, Animal ID].

in the 1960s.[259] Initially, the program was designed simply to counter bovine brucellosis and tuberculosis, but soon led to mandatory tail or ear tags for cattle sales.[260] After the detection of excessive chemicals in a number of cattle, Australia added its National Vendor Declaration program[261] to the tracing system, requiring owners to disclose a number of facts about their herds.[262]

Recently, Australia enhanced its ground-breaking tracing systems through the introduction of the National Livestock Identification System (NLIS) for cattle. Originally introduced as a voluntary program that could be adopted on a state-by-state basis, the NLIS has since become mandatory.[263] Unlike Australia's previous tracing programs, the NLIS constitutes a "whole-of-life identification system" taking "individual animals . . . from property of birth to slaughter."[264] Under the NLIS, cattle producers must tag calves before they leave the birth premises and report animal movements between

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259. Animal Health Australia (AHA), National Livestock Identification System (updated 3 July 2006), http://www.animalhealthaustralia.com.au/programs/adsp/nlis/nlis_home.cfm [hereinafter AHA, NLIS]. *See also* Animal Health Australia, Policy Paper, Livestock Identification and Traceability 6 (2003), http://www.animalhealthaustralia.com.au/shadomx/apps/fms/fmsdownload.cfm?file_uuid=F28BC7E5-FB25-566A-70D9-4E62E6C41A6B&siteName=aahc [hereinafter AHA Policy Paper] (tracing the genesis of the national identification system explicitly to the Brucellosis and Tuberculosis Eradication Campaign).

260. AHA, NLIS, *supra* note 259.

261. The program is also known as the National Vendor Declaration and Waybill. Meat and Livestock Australia, About the National Vendor Declaration and Waybill, http://www.mla.com.au/topichierarchy/industryprograms/livestockqualitysystems/nationalvendordeclarations/default.htm (last visited 26 Mar. 2007).

262. Glynn T. Tonsor & Ted C. Schroeder, Australia's Livestock Identification Systems: Implications for United States Programs, 9 Aug. 2004, http://www.agmanager.info/events/risk_profit/2004/Schroeder.pdf. Such facts include

> whether the cattle 1) have been treated with a hormonal growth promotant, 2) were produced at that location with rules consistent with an independently audited quality assurance program, 3) were born and raised on the vendor's property and if not, how long they resided there, 4) in the last 60 days had been fed any by-product stockfeeds and if so a list is required, 5) in the past 6 months had been grazed on any property placed under grazing restrictions because of chemical residue, 6) were still within a holding period for treatment of any drug or chemical, [or] 7) had grazed or been fed fodder at risk for endosulfan spray drift.

Id. at 8-9.

263. Tonsor & Schroeder, Animal ID, *supra* note 258, at 3.

264. Meat and Livestock Australia, About NLIS, http://www.mla.com.au/TopicHierarchy/IndustryPrograms/NationalLivestockId-entificationSystem/About+NLIS.htm (last visited 11 April 2007).

properties.[265] RFID tags allow cattle data to be read electronically during transactions.[266] Producers purchase ear tags either alone or in combination with rumen bolus devices.[267]

NLIS is governed by state and territorial legislation,[268] but the database is managed by industry.[269] Because the database is held by a private company, rather than government, producer information is protected from disclosure.[270] Federal and state authorities may obtain information needed to address an animal health issue,[271] and livestock producers may obtain valuable data about their herds for use in their own operations.[272] Concerns about accuracy of the database, however, have led to an independent audit, to be completed in Spring 2007.[273]

In addition to the NLIS for cattle, a similar system designed for sheep and goats began its phase-in process on 1 January 2006.[274] PigPass, a system for swine traceability, was introduced recently, though this system is a paper version analogous to the National Vendor Declaration that preceded the NLIS.[275]

3. Other Countries

New Zealand currently has three paper-based animal identification systems supported by the Ministry of Agriculture and For-

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265. Todd Andrews, NLIS Cattle: identification and stock movements 1 (NSE, DPI, Primefact 137, Dec. 2005), http://www.dpi.nsw.gov.au/__data/assets/pdf_file/49661/nlis_cattle_-_identification_and_stock_movements_-_primefact_137.pdf

266. *Id.*

267. *Id.* On the rumen bolus, *see infra* text accompanying note 286.

268. Canadians, Australians, *supra* note 255.

269. Specifically, management and implementation responsibilities belong to Meat and Livestock Australia (MLA). AHA Policy Paper, *supra* note 259, at 5.

270. Canadians, Australians, *supra* note 255. By September 2005, 23 million tags were in the Australian national database.

271. *Id.*

272. *See* Tonsor & Schroeder, Animal ID, *supra* note 258, at 3.

273. Meat News, Aussie ID System Audit Outcome Awaited, 1 Nov. 2006, http://www.meatnews.com/index.cfm?fuseaction=article&artNum=12824.

274. Meat and Livestock Australia, NLIS for Sheep & Goats, http://www.mla.com.au/TopicHierarchy/IndustryPrograms/NationalLivestockIdentificationSystem/NLIS+sheep/default.htm (last visited 11 April 2007).

275. PigPass, Questions and Answers, http://www.australianpork.com.au/media/PigPass%20QA%204%20150806.pdf#search=%22pigpass%20australia%22.

estry.[276] In the next few years, however, New Zealand plans to consolidate these various systems into a "single, universal livestock identification system, supported by a core registry of data linking people, property and animals."[277] This new system is designed to track animals from birth to post-mortem inspection. Though the system does not require use of RFID tags, it does permit their use, and the Ministry of Agriculture and Forestry has suggested that RFID tags may become mandatory in the future.[278] Although the first phase of the system, focusing on cattle and deer, was initially planned to begin much earlier, its implementation has been delayed until 2008.[279]

Japan, responding to several food safety crises,[280] began its own mandatory tracing system in 2002, under the Law Relating to Special BSE Countermeasures.[281] The breadth of this system was expanded in 2003 to cover cattle from birth to retail sale, at least for beef muscle meat.[282] Each cow has a ten-digit ID number assigned at birth; tags include, among other information, animal birth date, sex, breed, birth date, transport history, as well as the producer's address.[283] The Individual Livestock Data Control Center receives tracking data and enters it into a central computer.[284] Japan has about 4.5 million cattle; each year about 1.5 million cattle are born, and about 1 million are transferred between farms.[285] As a result of

276. New Zealand Ministry of Agriculture and Forestry, Animal Identification and Traceability, http://www.maf.govt.nz/mafnet/animal-identification-and-tracing.htm (last visited 26 Mar. 2007).

277. *Id.*

278. *Id.*

279. *New Zealand Animal Tagging System Postponed*, RFID TIMES, May 29, 2006, http://rfidtimes.blogspot.com.

280. Roxanne Clemens, Meat Traceability and Consumer Assurance in Japan 1-2 (Midwest Agribusiness Trade Research Information Center Briefing Paper 03-MBP 5, September 2003), http://www.card.iastate.edu/publications/DBS/PDFFiles/03bp41.pdf [hereinafter Clemens, Consumer Assurance]. The series of crises began with BSE, but continued afterwards when several mislabeling schemes were brought to light, including the labeling of imported beef as domestic. *Id.*

281. Roxanne Clemens, *Meat Traceability in Japan*, IOWA AG REVIEW ONLINE, Fall 2003, http://www.card.iastate.edu/iowa_ag_review/fall_03/article2.aspx [hereinafter Clemens, *Meat Traceability*].

282. *Id.*; Meat and Livestock Australia, Red Meat Markets, Japan, *Current Issues*, http://www.mla.com.au/TopicHierarchy/MarketInformation/OverseasMarkets/RedMeatMarkets/Japan/Current+issues.htm (last visited 26 Mar. 2007). Ground beef and processed beef are excluded from traceability. *Id.*

283. Clemens, *Meat Traceability*, *supra* note 281.

284. *Steady Progress in the Creation of a "Family Register" for Cattle*, 20(9) JAPAN AGRINFO NEWSLETTER (Japan International Agricultural Council), May 2003, http://www.jaicaf.or.jp/agrinfo_0305-0504/0305.html#8.

285. *Id.*

these and other transactions, the Control Center handles 25,000 communications per day.[286]

In 2001, Brazil, with 200 million cattle, established the Brazilian System of Identification and Certification of Origin for Bovine and Buffalo (SISBOV), an agency with responsibility for the traceability system for cattle from birth to death. Under the Brazilian system, producers must register their premises and then their cattle, which receive individual ID numbers under SISBOV.[287] Producers disclose various information about the cattle, including birth date and place, breed, gender, current location.[288] Any subsequent sale or transfer, as well as death by slaughter or natural causes, must be reported.[289] This information, stored in a central database, is controlled by the Ministry of Agriculture, Livestock and Food Supply, but certified independent companies may collect data and transfer it to the central SISBOV database.[290] Though any producer can comply voluntarily, SISBOV will be implemented as a mandatory program in phases. In the first phase, producers who exported to the EU had to comply. In 2006, producers in areas affected by foot and mouth disease had to comply, and the system is expected to include all producers in 2007.[291]

Although originally implemented to gain compliance with EU requirements,[292] the SISBOV system received criticism after an in-

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286. *Id.* Most information (15,000 communications per day) comes in by fax, but producers may also use the internet or an automated phone service. *Id.* This system has spawned innovative marketing designed to assuage the concerns of Japanese consumers about meat safety. In particular, the Aeon Company used this data to set up grocery store computers that allow consumers to punch in the 10-digit identification number on a meat package to view the tracing history of the animal that produced the meat and even a picture of the farmer. Clemens, *Meat Traceability*, *supra* note 281; Clemens, Consumer Assurance, *supra* note 280. Although this novel feature gained immediate popularity, few now use it, though it is theorized that the option itself lessens consumer unease. Clemens, *Meat Traceability*, *supra* note 281.

287. WTO, Committee on Sanitary and Phytosanitary Measures, *The Brazilian Bovine and Bubaline Identification and Certification System (SISBOV)*, G/SPS/GEN/503 (25 June 2004), http://www.ipfsaph.org/cds_upload/kopool_data/WTOSPSDOC_0/en_gen503.doc.

288. *Id.*

289. *Id.*

290. *Id.*

291. Certificadora GILGAL, http://www.certificadora.com.br/english.php (last visited 26 Mar. 2007).

292. *See generally* CHRISTOPHER L. DELGADO, CLARE A. NARROD & MARITES M. TIONGCO, POLICY, TECHNICAL, AND ENVIRONMENTAL DETERMINANTS AND IMPLICATIONS OF THE SCALING-UP OF LIVESTOCK PRODUCTION IN FOUR FAST-GROWING

spection by the EU Food and Veterinary Office.[293] In response, Brazil adopted new, stricter legislation that the Food and Veterinary Office will soon examine.[294]

B. Pilot Programs

1. Technology in Brief

Though simple brands and visible ear tags have been used–and are still used–to identify animals, modern systems of animal identification are based on electronic technology. Radio frequency identification (RFID) refers to technology that uses radio waves to identify people, animals, and objects.[295] RFID tags are "tiny computer chips that can be attached to physical items . . . to provide identification and tracking by radio."[296] They work like "supercharged barcodes–barcodes on steroids," because they can be hidden from view (as can their readers), carry a significant amount of information, and operate automatically.[297] An antenna on the RFID tag transmits information to a mobile or stationary reader, which need not be in the line of sight of the RFID tag, and which can read multiple tags simultaneously. Information from the reader is then collected in a database.[298]

The electronic ruminal bolus, using RFID technology, may prove to be accurate and is protected from loss or tampering. The rumen bolus, a capsule or other container inserted into the rumen, has been used to deliver products, including medicines, into cattle. Several companies have developed a ceramic or steel bolus with an integrated RFID tag, which can be read remotely. The bolus, which is administered orally, has a higher retention rate than ear tags, but is more expensive. The rumen bolus may be preferred to an injectable transponder located near the ear, which may not be re-

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DEVELOPING COUNTRIES: A SYNTHESIS § 3.4 (2003), http://www.fao.org/wairdocs/LEAD/X6170E/x6170e00.HTM.

293. European Commission, Press Release, Commissioner Kyprianou visits Brazil to review food safety measures for exports (IP/06/1332, 10 June 2006).

294. *Id.*

295. Patrick Leahy, RFIDs and the Dawning Micro Monitoring Revolution, 150 Cong. Rec. S2989 (23 Mar. 2004).

296. *Id.*

297. *Id.*

298. Laura Hildner, Note, *Defusing the Threat of RFID: Protecting Consumer Privacy Through Technology-Specific Legislation at the State Level*, 41 HARV. C.R.-C.L. L. REV. 133, 134 (2006).

moved properly at slaughter and could enter the food chain, but it is more difficult to remove than an RFID ear tag.[299]

2. Pilot Programs

Some sectors of the animal industry in the US have favored animal identification for decades. In 1977, for example, the US Animal Health Association accepted principles for an animal identification program.[300] These included unique and traceable identification numbers, permanent and tamper-proof identification devices, legal prohibitions on removing or tampering with devices, computerization, cost-effectiveness, confidentiality of producer information, voluntary participation, and some restriction of electronic identification.[301]

The National Farm Animal Identification and Records Program (FAIR), started in 1999 and supported in part by the federal government, can be seen as a pilot program for animal identification and traceability. FAIR uses visible ID tags and optional electronic IDs with radio frequency identification (tested especially in Michigan). To allow both tracking of individual animals and determination of their premises of origin, FAIR uses state premises numbers with the American Identification Numbering system.[302] The FAIR information system can store data about premises, animal IDs, animals at the premises, their movement, and health and performance data, as well as market sale transactions and data from slaughter plants. Data is secured through user logins.[303] As of November 2006, FAIR had enrolled more than 3 million animals (beef and dairy cattle) on more than 16,500 premises in 49 states (most in Michigan).[304] Its experience helped with development of the US Animal Identification Plan.

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299. R.J. Fallon, *The development and use of electronic ruminal boluses as a vehicle for bovine identification*, 20(2) REV. SCI. TECH. OFF. INT. EPIZ. 480, 481 (2001).

300. Report of the United States Animal Health Association Committee on Livestock Identification, Proceedings of the Eighty-first Annual Meeting of the USAHA (1977), cited in Richey et al., Animal Agriculture, *supra* note 218.

301. *Id.*

302. The American ID Numbering system assigns to each animal one lifetime number consisting of a 3-letter country code (e.g., USA) and a 12 alphanumeric character national number. FAIR characterizes the number as a "social security-like" number. FAIR, Farm Animal Identification and Records 6 (2001), http://www.nationalfair.com/pdf/FAIR_resourceGuide_2150001.pdf.

303. National FAIR Program Overview, http://www.nationalfair.com/plan.html.

304. National FAIR Database Statistics (21 Nov. 2006), http://www.nationalfair.com/php/fairstats.php; FAIR, Farm Animal Identification and Records, *supra*

More recently, USDA funded sixteen field trials and pilot projects to test the effectiveness of animal identification in real-world livestock environments. For these trials,

> USDA was particularly interested in projects that provided workable options for collecting animal identification in typical production, market, and abattoir environments without requiring significant change to existing animal handling practices. Projects involving (1) documentation and/or comparison of individual animal identification device effectiveness and (2) the effectiveness of devices for the collection of animals' identification at production, marketing, and harvesting facilities . . . were especially encouraged. Projects that utilized technologies to validate animal identification, to maintain the animal's identity when devices are lost or removed, and to measure accuracy of animal identification were also of special interest.[305]

Fifteen states and one tribe carried out projects to "demonstrate feasibility and document performance" of animal identification technology.[306] A preliminary progress report of the projects indicated that RFID technology is not "a plug-and-play application."[307] Instead, a number of factors, including the application and placement of ear tags and the placement of readers, affect the accuracy and reliability of identification.[308] The report recognized two important observations: RFID technology must be customized for the environment of each livestock operation, and the availability of timely technical service is critical to successful animal identification.[309]

Working with states and livestock organizations, USDA established nine species working groups, with representatives from the livestock industry.[310] The cattle working group, for example, has affiliations with both dairy and beef industry groups; the swine

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note 302, at 8. Over 1.8 million animals had been identified, with more than 500,000 marked with an RFID tag.

305. NAIS, USDA, State and Tribal Field Trial Projects (7 Nov. 2006), http://animalid.aphis.usda.gov/nais/about/projects.shtml.

306. APHIS, Preliminary Progress Report, National Animal Identification System (NAIS): Field Trials and Pilot Projects, 2004-2006, at 1 (7 June 2006), http://animalid.aphis.usda.gov/nais/naislibrary/documents/plans_reports/NAIS_Pilot_Projects_Progress_Report6-7-2006.pdf. USDA released a final report, not considered in this article, in May 2007. USDA, NAIS, Pilot Projects/Field Trials Summary (2007), linked from the NAIS Library at http://www.usda.gov/nais.

307. *Id.*

308. *Id.*

309. *Id.* NAIS permits, but does not require, the use of RFID.

310. NAIS, Species Working Groups, http://animalid.aphis.usda.gov/nais/species _ work_groups/working_groups.shtml#species (last visited 26 Mar. 2007).

working group, with the National Pork Board.[311] Some of the working groups have provided recommendations for NAIS. The sheep and goat working groups, for example, noted that they are already subject to mandatory identification under the National Scrapie Eradication Program and recommended that the existing identification system for scrapie could form the basis for NAIS participation.[312] The cattle working group set out guiding principles (e.g., use of RFID technology, confidentiality of information) and outlined a number of practical considerations (e.g., events to trigger reporting, distribution of tags).[313]

VI. NATIONAL ANIMAL IDENTIFICATION SYSTEM

The Animal Health Protection Act (AHPA) authorizes the Secretary of Agriculture to carry out measures to control or eradicate livestock disease: "The Secretary may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals), including animals at a slaughterhouse, stockyard, or other point of concentration."[314] To carry out its provisions, the AHPA authorizes USDA to cooperate with federal or state agencies, tribes, and others.[315] The law also authorizes USDA to "implement a central automated recordkeeping system to provide for the reliable tracking of the status of animal and plant shipments, including those shipments on hold at ports of entry and customs. . . . [S]uch a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service."[316]

After several years of preliminary work, USDA began to implement the National Animal Identification System (NAIS) in 2004. The goal of the system is to permit animal health officials to identify infected and exposed animals and their premises within 48 hours of disease discovery. This goal is to be accomplished through three interrelated components: premises registration, animal identifica-

311. *Id.* Working groups are cattle, bison, swine, goats, equine, cervids, poultry, camelids, and sheep.

312. NAIS, Sheep Working Group Report, Executive Summary, 6 Sept. 2006; NAIS, Goat Species Working Group Report, Sept. 2006. Both are linked from http://animalid.aphis.usda.gov/nais/naislibrary/plans.shtml.

313. NAIS, Cattle Industry Work Group Report, Executive Summary, 6 Sept. 2006, linked from http://animalid.aphis.usda.gov/nais/naislibrary/plans.shtml.

314. 7 U.S.C. § 8308(a).

315. *Id.* § 8310.

316. *Id.* § 8320(b).

tion, and animal tracking.[317] The system will be phased in as these components are developed with the cooperation of states and tribes, as well as livestock industry groups and private industry.[318] Not all species will be included in NAIS. Cattle, bison, swine, sheep, goats, poultry, horses and other equines, camelids (llamas, alpacas), and cervids (deer, elk) are included. Others are not.[319]

In the process of developing NAIS, USDA issued a number of informational and technical documents that address various components of the system. Most recently, in November 2006, USDA published the draft version of a document called *A User Guide and Additional Information Resources*.[320] The *User Guide* is "the most current plan for NAIS and replaces all previously published program documents."[321] Interestingly, it is descriptive and seems directed to producers, and it omits some of the milestones, benchmarks, and technical requirements established in earlier documents.[322] The *User Guide*, unlike some earlier documents, insists repeatedly that NAIS will be voluntary and that livestock owners and producers may choose their level (or no level) of participation in NAIS.[323] Although the draft *User Guide* explains NAIS, the earlier, now obsolete, documents will be mentioned briefly to indicate the various issues addressed prior to publication of the *User Guide*.

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317. USDA, NAIS: A USER GUIDE AND ADDITIONAL INFORMATION RESOURCES, DRAFT VERSION 5-6 (2006), http://animalid.aphis.usda.gov/nais/naislibrary/userguide.shtml [hereinafter DRAFT USER GUIDE].

318. *Id* at 10. Several tribes participate in NAIS. The discussion that follows often refers to states, rather than both states and tribes. *Id.*

319. *Id.* at 4.

320. *Id.* On the roles of states, industry groups, and the federal government, *see id.* at 13.

321. *Id.*, preface. USDA sought comments on the *User Guide* until 22 Jan. 2007. *Id.* at 16. In a Federal Register announcement published 1 February 2007, however, APHIS announced availability of the Draft User Guide and other documents and asked for comments. APHIS, USDA, National Animal Identification System; User Guide and Technical Documents, 72 Fed. Reg. 4680 (1 Feb. 2007). The other documents are a Program Standards and Technical Reference document and technical specifications for animal tracking databases. *Id.*

322. E.g., USDA, NAIS, Strategies for the Implementation of NAIS (April 2006), available at http://www.iowafarmbureau.com/special/animalid/a11.pdf. [hereinafter USDA, Strategies].

323. DRAFT USER GUIDE, *supra* note 317, at 12-13. In September 2006, a USDA official indicated that NAIS will be voluntary: "I want to clear up any confusion right now, once and for all. At the federal level, NAIS is a voluntary system. And it's going to remain voluntary. That's the final word." Bruce I. Knight, Moving American Agriculture Forward, Remarks to National Association of State Departments of Agriculture, Norfolk, VA, 19 Sept. 2006, http://www.aphis.usda.gov/newsroom/speeches/content/2006/09/nasda9-19-06.shtml.

In April 2005, USDA published documents, developed over a two-year period, that set out the scope of the proposed plan for animal identification and elicited public comments.[324] The *Draft Strategic Plan 2005-2009* presented the outline of NAIS as a mandatory program, under which all premises must be registered and all animals identified by January 2008, with the entire program mandatory, including reporting animal movements, by January 2009.[325] The *Strategic Plan* was accompanied by another document, *Draft Program Standards*, with more technical standards for key components of the proposed system.[326] A later document, published in February 2006, governed animal identification numbers and their use, in conjunction with official identification devices, called AIN tags.[327]

In April 2006, USDA released the NAIS implementation plan, *Strategies for the Implementation of NAIS*,[328] which set out the timelines for establishment of the system, as well as a plan for integrating animal tracking databases. *Strategies* established participation milestones for the operation of various parts of NAIS (e.g., March 2006 for beginning of identification of individual animals; February 2007 for the operation of state and private animal tracing databases).[329] It set benchmarks for the participation needed to achieve the goals of NAIS: 25% of premises registered by January 2007; 70% of premises registered and 40% of animals identified by January 2008; and 100% of premises registered, 100% of "new" animals identified, and movement reporting for 60% of animals under one year of age by January 2009.[330] *Strategies* mentioned the possibility of regulation to compel participation, if market forces did not result in adequate participation.

A guide for small-scale or non-commercial producers appeared in June 2006.[331] The guide assured these producers that the main

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324. APHIS, National Animal Identification System: Notice of Availability of a Draft Strategic Plan and Draft Program Standards, 70 Fed. Reg. 23,961 (6 May 2005).

325. APHIS, USDA, NAIS Draft Strategic Plan 2005-2009, at 2, 17 (2005).

326. APHIS, USDA, NAIS Draft Program Standards: A Discussion Document (2005).

327. NAIS, Administration of Official Identification Devices with the Animal Identification Number (23 Feb. 2006); *see* APHIS, NAIS; Administration of Official Identification Devices with the Animal Identification Number, 71 Fed. Reg. 10,951 (3 Mar. 2006).

328. USDA, Strategies, *supra* note 322. *See* 71 Fed. Reg. 17,805 (7 Apr. 2006).

329. USDA, Strategies, *supra* note 322, at 2, 3.

330. *Id.* at 3.

331. USDA, The National Animal Identification System: A Guide for Small-Scale or Non-Commercial Producers (2 June 2006).

focus of NAIS would be commercial operations, but encouraged all producers to register their premises. In light of the April 2006 threat of regulation, it is interesting that this June 2006 guide states clearly that NAIS is voluntary, with "no enforcement mechanisms or penalties."[332]

A July 2006 document, *Integration of Private and State Animal Tracking Databases with the NAIS: Interim Development Phase*,[333] reviewed the guiding principles for NAIS, which still seem to apply:

> ▪ The system must be able to allow tracking of animals from point of origin to processing within 48 hours without unnecessary burden to producers and other stakeholders.
> ▪ The system's architecture must be developed without unduly increasing the size and role of government.
> ▪ The system must be flexible enough to utilize existing technologies and incorporate new identification technologies as they are developed.
> ▪ Animal movement data should be maintained in private systems that can be readily accessed when necessary by State and Federal animal health authorities.[334]

This document outlined technical standards for animal tracking databases, intended to allow state and private databases to be integrated with NAIS.[335] Those who develop databases will enter a cooperative agreement with APHIS. A form for the Interim Cooperative Agreement sets out the responsibilities of APHIS and the database organization in the animal tracking system. The organization, for example, has the responsibility to "maintain an information system that will provide the traceback and traceforward information for animal health officials to manage the animal disease programs."[336]

By the end of October 2006, USDA had spent almost $85 million on NAIS, with 60% of that amount allocated to states and tribes

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332. *Id.* at 9.

333. APHIS, USDA, Integration of Private and State Animal Tracking Databases with the NAIS: Interim Development Phase (July 2006) [hereinafter APHIS, Integration].

334. *Id.* at 2.

335. *Id.* at 4-6.

336. Interim Cooperative Agreement (1 July 2006), http://www.regulations.gov/fdmspublic/component/main, search for APHIS-2006-0030-0006, posted 28 July 2006 (visited 1 Dec. 2006). See 71 Fed. Reg. 42,795 (28 July 2006) (announcing availability of a revised cooperative agreement). APHIS recently announced the availability of funding for non profit organizations that will conduct outreach to promote NAIS and encourage premises registration. Press Release, USDA, USDA Announces Plans to Expand National Animal Identification System Cooperative Agreements to Nonprofit Organizations (2 Feb. 2007).

for local activities, especially premises registration and education.[337] Preliminary documents had elicited numerous comments and criticisms from producers, industry groups, and others. The November 2006 *User Guide,* developed in light of stakeholder involvement, represents USDA's current plan for NAIS. With reference to the *User Guide* and other documents, the following discussion focuses on the elements of NAIS: premises registration, animal identification, and animal tracing.

A. Premises Registration

Premises registration is the foundation of NAIS, and widespread participation is critical for 48 hour traceability. It ensures that livestock owners can be notified promptly if a contagious disease affects their area or animals of the species they raise.[338] Therefore USDA hopes to have a record of all US premises where livestock or poultry are raised or kept.[339] USDA encourages producers to register their premises by outlining important advantages: more control over animal health, access to critical information in an animal health emergency, protection from slow response to animal disease, and protected market access and trade advantages.[340]

Recent calculations from the National Agricultural Statistical Service indicate that the US has 1,438,280 livestock operations, large and small.[341] For example, the US has approximately 800,000 cattle operations, but 90% of these raise fewer than 100 (and perhaps only five to ten) head, yet almost half of all slaughtered cattle come from small operations.[342] An effective system of animal identification must be comprehensive, including both industrial-scale and small-scale operations.

Therefore the first step in implementation of NAIS is premises registration. A premises is "a unique and describable geographic

337. DRAFT USER GUIDE, *supra* note 317, at 10; Bruce I. Knight, NAIS: Protecting Animals, Livelihoods and Futures, NAIS Community Outreach Event, Kansas City, MO (31 Oct. 2006), http://www.aphis.usda.gov/newsroom/speeches/content/2006/10/nais-outreach10-31-06.shtml.

338. DRAFT USER GUIDE, *supra* note 317, at 5.

339. DRAFT USER GUIDE, *supra* note 317, at 5, 17.

340. APHIS, Why Register Your Premises?, http://animalid.aphis.usda.gov/nais/premises_id/why_register.shtml (last visited 26 Mar. 2007).

341. APHIS, Premises Registration Update, http://animalid.aphis.usda.gov/nais/premises_id/update.shtml (last visited 26 Mar. 2007).

342. Margaret Webb Pressler, *Cattle-Tracing System Will Face Obstacles,* WASH. POST, 3 Jan. 2004, at E1.

location where activity affecting the health and/or traceability of animals may occur."[343] Premises include locations where livestock are "raised, held, or boarded"—farms, ranches, markets, slaughter facilities, veterinary clinics, and other locations.[344]

Producers who register their location will receive a Premises Identification Number (PIN).[345] The PIN is a "unique 7-digit code that includes both letters and numbers"; it is associated with the location and its mailing address or geographic coordinates.[346] The PIN is nationally unique and assigned to a geophysical location; future owners of the property will use the same PIN.[347] Producers who operate in more than one location might want to have more than one PIN, subject to the advice of state officials and veterinary epidemiologists.[348] USDA standards for premises registration require states to collect and maintain basic identifying information, including the PIN, name of the entity and its owner or contact person, the geographic location, phone numbers, and type of operation. States are free to require additional data, but they forward a limited amount of information to the USDA National Premises Information Repository, to ensure rapid response in case of disease outbreak.[349]

Registration of livestock premises is designed to be free to all producers. The process is simple; state programs specify whether producers can register online, by fax, or by mail. The NAIS website provides map-based links to the state agency (or authorized organization) in charge of premises registration in each individual state

343. DRAFT USER GUIDE, *supra* note 317, at 19.

344. *Id.*

345. *Id.* APHIS defined the PIN in an interim rule published in 2004. APHIS, Livestock Identification; Use of Alternative Numbering Systems, 69 Fed. Reg. 64,644. The definition now appears at 9 C.F. R. § 71.1 (2006). The description of the PIN provided by the *Draft User Guide* (at 22), however, omits one PIN alternative (the state's postal abbreviation followed by an assigned number) in the rule. http://animalid.aphis.usda.gov/nais/premises_id/update.shtml

346. DRAFT USER GUIDE, *supra* note 317, at 22. An NPN (non-producer participant number) is available for those who work with NAIS but are not producers. These may include companies that manufacture ID devices or submit information to databases. *Id.* at 24.

347. *Id.* at 23.

348. *Id.* at 20. Having more than one PIN does not necessarily mean the livestock producers should report movement of animals between components of their operation. *Id.* at 21.

349. *Id.* at 23. The USDA Repository will contain the PIN, name of entity and owner or contact person, address information, phone numbers, type of operation, date activited in system, date (and reason) retired from system. In an animal health emergency, additional information can be obtained from state and private databases, if required. *Id.* at 25.

(typically the state Department of Agriculture).[350] In Illinois, for example, premises registration is handled by the Bureau of Animal Health in the Illinois Department of Agriculture. The NAIS website directs the producer to the Illinois Department, and a simple link from the Department of Agriculture website allows livestock owners to register their farms, production sites, feedlots, or markets, without cost.[351] Some states, including Illinois, use a web-based Standard Premises Registration System, developed by USDA and available to states.[352] In designing their registration systems, states have taken a variety of approaches, including state-designed systems or systems developed by a third party.[353]

Registration does not require producers to identify their animals or participate in the animal tracing component of NAIS.[354] Premises registration, however, is the first step in a system that allows producers to protect their animals by exercising more control over animal health, protect their neighbors by reducing "hardships caused by an animal disease event," and protect their access to markets, through participation in a system that works to contain animal disease.[355]

In 2004, states and tribal governments, along with partners from industry, began to implement the premises registration component of NAIS. By mid 2005, nearly all states and five tribes had developed premises registration systems.[356] Federal financial assistance has been provided. In June 2005, USDA announced that it would make $13.5 million available to states, based in part on live-

350. AHPIS, NAIS: How To Register Your Premises, http://animalid.aphis.usda.gov/nais/premises_id/register.shtml (last visited 26 Mar. 2007).

351. Illinois Department of Agriculture, Illinois Begins Voluntary Livestock Premises Registration, http://www.agr.state.il.us/premiseid (last visited 26 Mar. 2007).

352. DRAFT USER GUIDE, *supra* note 317, at 10.

353. *See* National Conference of State Legislatures, State Livestock Identification Programs, http://www.ncsl.org/programs/agri/stateanimalprgms06.htm (last visited 26 Mar. 2007).

354. DRAFT USER GUIDE, *supra* note 317, at 18; APHIS, NAIS, Premises Registration, http://animalid.aphis.usda.gov/nais/premises_id/index.shtml (last visited 26 Mar. 2007). USDA notes that it "maintains limited premises information and will protect individuals' private information from disclosure." *Id.*

355. APHIS, NAIS: Take the First Step, Register to Protect Your Animals, Your Livelihood, Your Future (2006), *available at* http://animalid.aphis.usda.gov/nais/naislibrary/documents/factsheets_brochures/FirstStep-General.pdf.

356. Press Release, USDA, USDA to Award up to $14.3 Million to States and Tribes for National Animal ID System Premises Registration (No. 0223.05, 21 June 2005).

stock population, and $845,000 to tribes to facilitate implementation of premises registration systems.

All 50 states, as well as five tribes and two territories, now have standardized or compliant premises registration systems. As of 26 July 2007, 406,188 premises, about 28% of total premises, had been registered.[357] Thus, states have met the first stage of the current USDA goal, which is to have 25% of premises registered by 31 January 2007 and full participation ("a critical mass of producers") by 31 January 2009.[358] Some industry groups have more immediate goals. Pork producers, for example, expect to have all premises registered by the end of 2007.[359]

B. Animal Identification

Animal identification is the second component of NAIS. Like premises registration, animal ID under NAIS is voluntary, but NAIS does not waive any mandatory animal ID required under federal disease eradiation programs or under state requirements.[360]

APHIS defined the animal identification number (AIN) in an interim rule published in 2004.[361] The AIN is a "numbering system for the official identification of individual animals in the United States."[362] The AIN contains 15 digits. The first three are the country code (840 for the United States), and the last 12 are the unique lifetime number assigned to an animal. USDA has indicated that, in addition to the AIN, it will continue to use two existing numbering systems: the National Uniform Eartagging System (a nine-character number used for calf vaccines and other disease-related purposes)

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357. APHIS, NAIS, *supra* note 341. Livestock operations total 1,438,280. *Id.*

358. Knight, *supra* note 337. In April 2006, the USDA had stated the goal as 25 percent of premises by the end of 2006, 70 percent by the end of 2007, and 100 percent by the end of 2008. USDA, Strategies, *supra* note 322, at 3.

359. National Pork Producers Council, Issue Update: National Swine ID System 2, http://www.nppc.org/hot_topics/swineid/Nppc_3193.pdf. The NPPC and National Pork Board plan to hire regional coordinators who will encourage registration. About 40% of swine premises are registered, and USDA has provided $400,000 to help register the remaining premises. Press Release, NPPC, Pork Industry Announces Push On Premises Registration (11 Jan. 2007), http://www.nppc.org/wm/show.php?id=638&c=1.

360. DRAFT USER GUIDE, *supra* note 317, at 28. For example, disease programs for brucellosis, bovine tuberculosis, and scrapie in sheep and goats require identification. 9 C.F.R. parts 77-79 (2006).

361. APHIS, Livestock Identification; Use of Alternative Numbering Systems, *supra* note 345.

362. 9 C.F.R. § 71.1 (2006).

and the system used in the National Scrapie Eradication Program (a premises number with a herd management number).[363] Eventually, USDA hopes to use the AIN for animal disease programs, as well, and has already started to use AIN in programs to control tuberculosis and chronic wasting disease.[364] The AIN is appropriate for animals that "move through the production chain as individuals."[365] Animals raised and sold as groups (e.g., pigs and poultry) can be identified with Group/Lot Identification Numbers (GIN).[366]

Not all species will use the same means of identification. Some, like cattle and sheep, use visual devices (tags) for identification; others, like horses, may use implanted microchips or transponders. NAIS has set out requirements for visual identification devices, called AIN tags.[367] For some species, NAIS requires AIN ear tags, designed for one-time use. These are imprinted with the 15-digit animal identification number, a US shield, plus the words "unlawful to remove" and the manufacturer's logo or trademark. The visible ear tag is the "official identifier," but an RFID device can be incased in the tag.[368]

Producers can order AIN tags only after they have a PIN. USDA uses a web-based Animal Identification Numbering Management System (AINMS) to allocate AINs to authorized manufacturers. When tags are supplied to producers, AINs are recorded in the AINMS, so that AIN tags can be associated with individual producer premises.[369] After April 2007, AIN Device Distribution Databases will be authorized to record distribution of AIN numbers, and records will be available to government officials in case of an animal

363. APHIS, NAIS: Officially Recognized Numbering Systems, http://animalid.aphis.usda.gov/nais/animal_id/num_sys.shtml (last visited 26 Mar. 2007); DRAFT USER GUIDE, *supra* note 317, at 29. Registered brands, though not part of NAIS, will remain helpful. *Id.* at 32.

364. DRAFT USER GUIDE, *supra* note 317, at 34.

365. *Id.* at 29.

366. See 9 C.F.R. § 71.1 (2006), which defines the group/lot identification number (GIN) for a "unit of animals" managed together. The GIN consists of the PIN and a six-digit date of assembly of the group of animals. *Id.* The DRAFT USER GUIDE, *supra* note 317, at 30, appends another two digit number to identify the "count" of groups assembled on that day (03, for the third group), making the GIN fifteen characters. The GIN is generated by the producer.

367. APHIS, NAIS: Identification Devices with the Animal Identification Number (AIN), August 9, 2006, http://animalid.aphis.usda.gov/nais/naislibrary/documents/instructions_guidelines/NAISIDTagWebListingFactSheet8_9_06.pdf [hereinafter APHIS, NAIS: ID Devices].

368. *Id.*

369. *Id.*

disease outbreak.[370] As of August 2006, USDA had approved four styles of ID tags, sold by two companies.[371] Other ID manufacturers can apply for approval, and USDA hopes that competition for ID tags will minimize costs to livestock producers. Tag prices range from $1 to $3, depending on features.[372] Two ID manufacturers indicate that sale of some tag models will include the cost of enrollment into an animal tracing database. The US Animal Identification Organization entered agreements with the companies to help to spread the cost of animal tracking, but the per-tag cost to producers would be minimal.[373]

The animal owner or caretaker decides when to identify animals–at birth or later, perhaps at the time of a "reportable animal movements" under NAIS.[374] USDA recommends that animals be identified when they leave their premises of origin or when they are commingled with other animals at feedlots, auctions, or fairs.[375] These events are characterized as reportable animal movements.[376] USDA recognizes that some animals do not need identification, in part because they do not experience reportable movements. These include animals that do not leave their premises of origin (unless they escape temporarily) and those that leave the farm only for transport to slaughter for personal consumption.[377]

Identification devices are intended to remain on the animal for its lifetime. Though NAIS identification is voluntary, some disease eradication programs continue to require mandatory identification.[378] For those animals, APHIS regulations make it unlawful to remove permanent identification devices until slaughter.[379]

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370. DRAFT USER GUIDE, *supra* note 317, at 36.
371. APHIS, NAIS: ID Devices, *supra* note 367.
372. DRAFT USER GUIDE, *supra* note 317, at 35.
373. US eartags to include price of livestock tracking, Reuters, 22 Aug. 2006.
374. DRAFT USER GUIDE, *supra* note 317, at 29.
375. *Id.*
376. *Id.*
377. APHIS, NAIS: Animals NOT Needing Identification, http://animalid.aphis.usda.gov/nais/animal_id/not_need_id.shtml (last visited 26 Mar. 2007); DRAFT USER GUIDE, *supra* note 317, at 31.
378. E.g., scrapie in sheep and goats. *See* 9 C.F.R. § 79.2, which requires individual or premises identification for certain animals.
379. 9 C.F.R. § 71.22. A lost or damaged device may be replaced. *Id.*; DRAFT USER GUIDE, *supra* note 317, at 30.

C. Animal Tracking

Animal tracking, the third component of NAIS, will be developed by states and industry in cooperation with USDA. This component focuses on records of animal movements that are most likely to result in spread of animal disease, reportable animal movements.[380] In July 2006, USDA explained its plans for the animal tracking system concisely in the Federal Register:

> The [animal tracking] component will be developed through a government/ industry partnership, in which animal movement information will be maintained in private and/or State databases. USDA will operate a portal system that will enable animal health officials to submit requests for information to the animal tracking databases (ATDs) when investigating an animal disease event. The USDA's objective is to support the privatization of the animal tracking information component of the NAIS in the most practical, timely, and least burdensome manner possible.[381]

Animal tracking will depend on development of the Animal Trace Processing System (ATPS), which should be activated in 2007, with an interim phase available in 2006.[382] The ATPS is designed as a "technology solution to interact with multiple Animal Tracking Databases (ATDs)" that will allow "security, electronic data transfer, and auditing processes," as well as integration of animal health data.[383] Animal movement records from the various private and state databases will be submitted to USDA only when an animal tracing process becomes necessary–in an animal disease emergency, after a positive test for a foreign disease, or if officials must conduct a traceback or traceforward to find the source of infection from a disease for which USDA has a disease eradication program.[384] When tracing becomes necessary, the USDA will define appropriate search criteria, which will be processed automatically by both ATDs and by AIN Device Distribution Databases (linking ANIs with premises).[385] In this way, officials can identify cohorts of infected animals, as well as animals that contacted infected animals or their cohorts.

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380. NAIS does not affect other state or local rules for reporting movement of animals. DRAFT USER GUIDE, *supra* note 317, at 46.

381. Availability of a Revised Cooperative Agreement for Private Animal Tracking Databases, 71 Fed. Reg. 42,795, 42795-96 (28 July 2006).

382. APHIS, Integration, *supra* note 333, at 3.

383. *Id* at 2.; *see also* DRAFT USER GUIDE, *supra* note 317, at 42.

384. APHIS, Integration, *supra* note 333, at 2-3; DRAFT USER GUIDE, *supra* note 317, at 42.

385. DRAFT USER GUIDE, *supra* note 317, at 45 (providing a more detailed example of a NAIS response to animal disease).

Organizations with ATDs may enter cooperative agreements[386] with APHIS to participate in the development phase of ATPS, after their systems are reviewed to ensure that they meet data standards as well as technical requirements.[387] For the implementation phase, organizations that meet final specifications for the system and sign the cooperative agreement will be "NAIS Compliant Animal Tracking Databases."[388]

USDA is in the process of approving ATDs and, as of 31 October 2006, had approved ten interim ATDs. These databases had been evaluated, met the requirements in the document *Integration of Animal Tracing Databases with the NAIS*, and signed an agreement for cooperation with APHIS.[389] Of these databases, one is sponsored by The Wisconsin Department of Agriculture Trade and Consumer Protection and operated by the Wisconsin Livestock Identification Consortium. Another provider is the Holstein Association; others are various private organizations.[390] Some databases will hold basic information necessary for traceability; others may also hold data to aid in livestock record keeping and marketing. Cost is likely to depend on the services offered to the livestock producer.[391]

Producers who decide to participate in animal tracking will select an ATD available in their state.[392] Producers work directly with

386. See the Interim Cooperative Agreement form, at http://animalid.aphis.usda.gov/nais/downloads/print/CooperativeAgreementInterim_July06.pdf. The form cites statutory authority for cooperative agreements, 7 U.S.C. § 2279g, as well as provisions of the Animal Health Protection Act, 7 U.S.C. §§ 8308, 8310.

387. Those requirements are set out in APHIS, Integration, *supra* note 333, at 3. Applicants must file an Application for System Evaluation, which was available at www.usda.gov/nais. Press Release, USDA, Johanns Releases National Animal Identification System Implementation Plan (No. 0120/06, 6 Apr. 2006).

388. APHIS, Integration, *supra* note 333, at 3. The Interim Cooperative Agreement, *supra* note 386, art. 8, does not guarantee that the systems of participants in the interim phase will meet final implementation requirements.

389. NAIS, Interim Animal Tracing Databases, October 31, 2006, http://animalid.aphis.usda.gov/nais/naislibrary/documents/instructions_guidelines/NAIS_Interim_ATD_Listing_10_31_06.pdf.

390. *Id.* Early in 2006, a entity called the US Animal Identification Organization (USAIO) announced a database developed by ViaTrace and operated with Microsoft. Originally affiliated with National Cattlemen's Beef Association, but now an independent consortium, USAIO was intended to enroll beef cattle and bison, but also to provide a multi-species national database. Rod Smith, *How USAIO Will Work*, FEEDSTUFFS (20 Feb. 2006), at 16; *USAIO ready 'to go live,'* FEEDSTUFFS (24 July 2006), at 5. USAIO did not appear on the APHIS list dated 31 October 2006. See Steve Stecklow, *U.S. Falls Behind In Tracking Cattle To Control Disease*, WALL ST. J., 21 June 2006, at A1, A10.

391. DRAFT USER GUIDE, *supra* note 317, at 44.

392. *Id.* at 45.

that database, which will hold the data submitted and provide information to USDA only in case of an animal disease event. Producers who participate will notify their database, preferably within 24 hours, about reportable animal movements that pose a risk of disease transmission. NAIS has published a preliminary chart that assigns a relative reporting importance to various types of animal movements. Those with high reporting relevance include a private sale of animals, sale by auction or public market, and participation at regional or national exhibitions or events. Low reporting relevance is assigned to participation at local exhibitions and events and local trail rides. Movements from birth premises to a custom butcher or movement within the producer's premises need not be reported.[393]

Species working groups will provide more explicit guidelines on reportable animal movements. For example, the Cattle Industry Work Group Report, from September 2006, identified three types of events that should trigger reporting: change of ownership, interstate movement, and commingling of cattle from multiple owners. Commingling may occur in animal transport, joint grazing, livestock markets, rodeos, and other situations.[394] In contrast, the Equine Species Working Group, which recommended animal identification with implanted RFID microchips, stated that "Equine movements will not be reported. In the event traceback is needed, animal health officials will rely on the current system of maintaining brand inspection records." The Group recommended that states and USDA transfer equine records to electronic format.[395]

Participation in the animal tracing component of NAIS requires only minimal information: PIN, AIN, date of the reportable animal movement, and nature of that event. APHIS noted that "[o]ther animal-specific data (age, species, sex, etc.) that supports NAIS in traceback situations is also standardized, but are [sic] not necessary for participation."[396] The importance of an animal's age in connection with BSE, however, suggests that, at least for cattle, age or date of birth should be part of the animal tracing data. Response to USDA's decision to omit age or date of birth from tracing was in

393. *Id.* at 48. Producers may choose to report any movement. *Id.*

394. Cattle Industry Work Group, *supra* note 313, at 3.

395. Equine Species Working Group, NAIS Recommendations to USDA, August 1, 2006, at 2, linked from http://animalid.aphis.usda.gov/nais/naislibrary/plans.shtml (last visited 26 Mar. 2007). Horses, though livestock, are different from other livestock with longer life expectancy, more value, and more frequent transport. *Id.*

396. DRAFT USER GUIDE, *supra* note 317, at 43.

part critical, because the age of livestock is important for some, though not all, diseases.[397]

VII. NAIS ISSUES

A number of issues have made NAIS and its implementation controversial. Cost is important, of course, both for producers and producer groups and for government agencies. The federal government has assumed much of the cost of developing NAIS, and premises registration is free to producers. Animal identification costs will vary, depending on the species and the type of identification device. The cost of ATDs will depend on the services offered by each database.[398] NAIS is expected to deliver economic benefits if an animal disease outbreak occurs, by ensuring rapid response to disease, thereby reducing possible losses to producers, and by maintaining "valuable domestic and foreign markets" and protecting prices.[399] In a broader sense, NAIS is expected to help the US economy by reducing the cost to taxpayers of animal disease eradication.[400]

Other important issues include whether a mandatory system should be required, possible liability for producers, and the privacy of animal records. The following sections discuss those issues briefly.

A. Does the US Need Mandatory NAIS?

Livestock identification in a number of countries is mandatory, and substantial controversy has surrounded the mandatory or voluntary nature of NAIS. As the discussion above indicated, USDA officials have now established NAIS as a voluntary system, at least at on the federal level. Indeed, in late November 2006, Secretary of Agriculture Johanns indicated that "Producers want a voluntary system, . . . They just recoil against this notion that it's going to be the Wash-

397. Libby Quaid, *Animal ID system won't require birth date*, Assoc. Press, 17 April 2006, *available at* http://foodsafetynetwork.ca/animalnet/2006/4-2006/animalnet_april_18.htm.

398. DRAFT USER GUIDE, *supra* note 317, at 10. Some issues with animal identification, including cost, are discussed briefly in Doug O'Brien, Animal Identification and the Next Farm Bill (Oct. 2006), www.NationalAgLawCenter.org.

399. DRAFT USER GUIDE, supra note 317, at 11.

400. *Id.* at 11-12.

ington way or the highway."[401] Johanns believes that market forces will ensure that USDA meets its goals for participation.[402]

Earlier USDA statements, however, were less definitive. For example, in a Federal Register statement, published in July 2004, APHIS noted

> The ability to achieve the 48-hour goal [for traceability] is directly related to the completeness of animal movement data that is reported to the national system. . . . APHIS recognizes the need to be able to ensure that data provided by producers is protected, and that all components of the system are in place and have been tested, before making the system mandatory.[403]

APHIS asked for comments on "[w]hen and under what circumstances . . . the program [should] transition from voluntary to mandatory?"[404]

USDA's April 2006 *Strategies* document set benchmarks for participation needed to achieve the objectives of NAIS. If market incentives and industry "buy-in" did not lead to sufficient participation, USDA indicated that it might require producers to comply, at least with some parts of NAIS, through regulation.[405] In this document, USDA seemed to suggest that the goals and objectives of NAIS could not be met without full participation in premises registration and animal identification. The November 2006 *User Guide* makes it clear that the program is now voluntary, with no plans for making the system mandatory. But in light of earlier USDA observations, one could reasonably ask whether the decision to make

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401. Philip Brasher, *Johanns rules out mandatory Livestock ID*, DES MOINES REGISTER, 29 Nov. 2006.

402. *Id.*

403. APHIS, FSIS, FDA, Federal Measures to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 42,288, 42,298 (14 July 2004). APHIS recognized that market forces might compel producer participation. *Id.*

404. *Id.* Similarly, a Question and Answer document for producers also suggested the possibility of a mandatory system:

> The [NAIS] system needs to be tested to be sure it is effective and workable. While the NAIS is being developed and refined, producer participation will be voluntary. As the system continues to take shape and is tested for all livestock and food animals, USDA will reassess the need for making some or all aspects of the program mandatory. . . .
>
> Eventually, USDA may move toward a requirement for mandatory premises and animal identification for all species included in the system.

APHIS, National Animal Identification System: Questions and Answers (Sept. 2004), http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahaids.html.

405. USDA, Strategies, *supra* note 322, at 3.

NAIS voluntary will prevent (or at least hamper) development of an effective system.

A mandatory system has support of some in the animal industries. For example, the American Veterinary Medical Association supports an effective NAIS and recommends a number of key elements. Among these is "[r]apid implementation of a mandatory NAIS" with databases accessible at all times by animal health officials.[406] Industry leaders, too, are willing to accept a system with at least some mandatory elements.[407] Pork producers, for example, support a swine identification system to include mandatory premises registration by the end of 2007 and mandatory animal ID by the end of 2008.[408] A consultant for the pork industry, who ran APHIS until April 2004, has been quoted as saying, "If it isn't mandatory, it simply will not work," . . . There are not enough market forces to make it happen."[409] Others believe that a mandatory system is required because some producers "who fear legal liability if their animals are found to be diseased," will not participate in a voluntary system.[410]

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406. American Veterinary Medical Association, Position Statements, National Animal Identification System (Mar. 2006), http://www.avma.org/issues/policy/national_identification.asp. The Position Statement reads

> The American Veterinary Medical Association (AVMA) supports an effective National Animal Identification System (NAIS) that contains the following key elements:
>
> 1. USDA implementation of all species working group reports that were submitted to the NAIS Subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases.
> 2. USDA development of minimum standards for a NAIS.
> 3. Rapid implementation of a mandatory NAIS.
> 4. Implementation benchmarks and timelines established in federal regulation to achieve the NAIS goals identified in the strategic plan.
> 5. Implementation that continues to engage all stakeholders in providing input through the NAIS Subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases and other designated forums.
> 6. Database(s) that are accessible 24 hours a day and 7 days a week by animal health officials.
> 7. System cost does not detract from effective implementation.
> 8. A system that is workable for producers of all sizes.
> 9. Exception from freedom of information disclosure laws for data collected in support of the NAIS.

Id.

407. Becker & Lister, RL32199, *supra* note 227, at 43.

408. NPPC, Issue Update, *supra* note 359.

409. Stecklow, *supra* note 390, at A10.

410. *Id.*

Many producers, however, would prefer to minimize government involvement–or worse, intrusion–in their livestock operations. Cattlemen, for example, believe that animal identification is important, but believe any system should be voluntary and led by industry.[411] And small livestock producers, in particular, are opposed to mandatory animal identification.[412]

With a voluntary federal system as a model, states may be unlikely to require participation. All states now participate in the first component of NAIS, premises registration. Though they encourage livestock premises to register and make the process free and simple, few states require registration. Wisconsin[413] and Indiana,[414] have enacted programs with mandatory elements; both require premises registration–Wisconsin by 1 January 2006 and Indiana by 1 September 2006.[415] A few other states have planned to make registration mandatory, but have not done so. For example, the Texas Animal Health Commission delayed its proposed mandatory premises registration, influenced by protests, including some small producers.[416] Vermont decided against enacting proposed rules that would require registration for livestock premises.[417] Most other states have authorized a voluntary premises registration, animal identification, and tracking system, consistent with NAIS.[418] A

411. NCBA on Animal ID, LEAN TRIMMINGS, 6 Nov. 2006, www.nmaonline.org/files/pdf/LT11.06.06.pdf. NCBA supports the US Animal Identification Organization (USAIO).

412. E.g., Caroline Dohack, *Animal ID system proves worrisome*, MISSOURIAN, 26 Oct. 2006; Leah Beth Ward, *Small-scale livestock owners wary of animal ID program*, YAKIMA HER.-REP., 14 Aug. 2006.

413. The Wisconsin Premises Registration Act, enacted in April 2004 and effective 1 Nov. 2005, makes it unlawful to keep livestock at a location not registered under the act. 2003 Wis. Act. 229, codified at WIS. STAT. § 95.51 (2006 Supp.). The Wisconsin Livestock Identification Consortium is the agent for registration. *See* WLIC, Premises Registration, Frequently Asked Questions (Nov. 2005), http://www.wiid.org/resource/1145366259_FAQ%20Prem%20Reg%20%20NOV%20FINAL.pdf

414. Indiana State Board of Animal Health, A Hoosier's Guide to Premise & Animal Identification, http://www.in.gov/boah/premiseid/idguide.htm (last visited 26 Mar. 2007).

415. *See* National Conference of State Legislatures, State Livestock Identification Programs (13 July 2006), http://www.ncsl.org/programs/agri/stateanimalprgms06.htm (listing state premises registration programs). A few states have pending legislation.

416. Stecklow, *supra* note 390, at A10.

417. Louis Porter, *State Derails Farm Registration Program*, THE BARRE MONTPELIER TIMES ARGUS, 18 Aug. 2006,

418. *See, e.g.*, KAN. STAT. ANN. § 47-674 (2004, amended 2005). "The livestock commissioner is authorized . . . to develop and implement a voluntary premises

few have made it clear that their state programs will not be mandatory unless federal law requires mandatory livestock identification.[419]

At least one influential NGO has emphasized the importance of a mandatory system of livestock identification. The Center for Science in the Public Interest (CSPI) noted that the Canadian traceability system allowed that country to identify the farm of origin of infected cattle and test other animals that might have been exposed to BSE, while the US, without a system of traceability, was far less successful in tracing its first infected cows to its farm of origin.[420] CSPI recommended strongly that the US implement a "mandatory system of livestock identification and tracking."[421] A voluntary system will not achieve the goal of NAIS, to identify within 48 hours the animals and premises that have been in contact with an infected animal. Moreover, the threat of bioterrorism, which could involve highly infectious diseases like foot and mouth disease, also points toward a mandatory system.[422]

USDA has assured producers that NAIS will be voluntary, and Congress could ensure that the program remains strictly voluntary. Senate Bill 3862 and H.R. Bill 6042, introduced in September 2006,[423] would amend the Animal Health Protection Act to prohibit USDA from implementing a mandatory animal identification system. As introduced, section 1 of the bill would add a new subsection to the Act:

> (c) Prohibition on Mandatory Animal Identification Program—Notwithstanding any other provision of law, the Secretary shall not implement or carry out, and no Federal funds shall be used to implement

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registration and animal identification and tracking system for Kansas." *Id.* § 47-674(a).

419. *E.g.*, Alabama enacted a law (HB 254) in April 2006, with language to ensure confidentiality and to ensure that animal ID would not be mandatory unless required by federal law. Press Release, Alabama Dept. of Agriculture & Industries, 17 April 2006, http://www.agi.state.al.us/press_releases/april-17-2006--hb-254-signed-into-law?pn=2.

420. NAME THAT COW, *supra* note 224, at 6.

421. *Id* at 10.

422. *Id.* at 10-11. CSPI suggests that the beef industry will benefit from a mandatory system, because beef-importing countries will have more confidence in the age of cattle. *See also* Odeshoo, *supra* note 75, at 314: "[G]iven the difficulty in ensuring compliance with the government's BSE policies so far, making the system mandatory is essential."

423. S. Bill 3862 & H.R. Bill 6042, 109th Cong., 2d Sess. (2006). The bills were introduced by US Senator Jim Talent and Representative Jo Ann Emerson.

or carry out, a National Animal Identification System, or similar requirement, that mandates the participation of livestock owners.[424]

B. Liability Issues

NAIS, of course, enhances the ability to identify animals and trace their progress through the food chain. Therefore opponents of an animal identification fear that traceability may trigger liability for food safety problems.[425] As a government report indicated, "[t]he possibility that traceability could be used to place liability for unhealthy or low-quality animals on farmers makes many in the livestock sector uncomfortable."[426] Beef growers, for example, fear liability for outbreaks of *E. coli* that could be traced to their premises.[427] Some producers fear liability for problems (e.g., contamination) that occur in the marketing chain, even after the animal has left the farm.[428] Drug residues in food animals, from use of inappropriate drugs or failure to allow sufficient withdrawal times, are another exposure to liability. In light of concerns about liability, the Kansas Livestock Association has supported state and federal legislation to limit producer liability under a government or private animal ID program.[429]

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424. S.B. 3862, section 1, Prohibition on Mandatory Animal Identification Program, amending 7 U.S.C. § 8308. In addition, the bill would protect confidential producers records from FOIA requests and limit their access by other government agencies.

425. An article published in 2004 quoted a former USDA official who worked toward mandatory cattle ID. "It never moves an inch – the cattlemen always oppose it," the official said. Leuck, *supra* note 163.

426. GOLAN ET AL., AER 830, *supra* note 217, at 30.

427. Odeshoo, *supra* note 75, at 313.

428. Becker, Animal ID, *supra* note 211, at 12.

429. Kansas Livestock Association, Key KLA Policy, http://www.kla/org/policy.htm; also printed in GOLAN ET AL., AER 830, *supra* note 217, at 33. The text of the policy statement follows:

Animal Identification Liability

WHEREAS, livestock producers and government officials are researching the feasibility of a national individual animal identification program, and

WHEREAS, such a program, on a voluntary or mandatory basis, could provide the livestock industry a tool to quickly trace animal disease sources and enhance a breeder's ability to identify genetics that meet consumer demands, and

WHEREAS, animal trace-back technology can increase the liability exposure for owners of animals whose food and by-products threaten or cause damages to consumers, and

The USDA itself indicated that NAIS is not designed to affect liability.

> USDA's goal for the NAIS is to enhance animal health officials' ability to trace and respond to animal diseases. The key objective is to achieve a timely traceback to minimize the detrimental effect of livestock diseases. Accordingly, USDA and the States will only collect and retain necessary identification data in the preharvest production chain and through final inspection at slaughter establishments. USDA would emphasize that the NAIS, in serving as a repository of verifiable data, will increase the accuracy of animal health information and will not expose producers to unwarranted or additional liability.[430]

Responding to producer fear of liability, others suggest that NAIS will not significantly increase the liability of livestock producers and, in some instances, accurate traceability may protect producers who use proper management practices. On that issue, the National Identification Development Team indicated that

> Animal owners are, and have always been[,] responsible for the animals they produce. If practices are employed that would endanger consumers at any level, the animal owner responsible for creating that threat could have increased liability. Effective traceability can help protect animal owners who apply best management practices. The system can help limit liability and narrow the scope of eradication efforts in the case of a disease emergency by being able to document that appropriate and responsible measures were followed.[431]

Researchers have made similar observations:

> Like so many of the issues associated with traceability, there are two sides to the liability issue. There is concern among some producers that they will be held liable for contamination or other problems over which they have no control once an animal leaves the farm. The flip side of this perception is that documentation of management practices, animal health programs, inputs, and animal movements can serve as protection

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> WHEREAS, liability in these circumstances can often be classified as "strict liability", even though an animal owner may not be at fault for such damages.
>
> THEREFORE, BE IT RESOLVED, the Kansas Livestock Association supports state and federal legislation to limit animal owners' liability exposure that may arise under a private or public animal identification program.

430. APHIS, Question and Answers, *supra* note 404.

431. US Animal Identification Plan, Frequently Asked Questions (FAQs) on the U.S. Animal Identification Plan, # 30, http://usaip.info/faq.htm (last visited 26 Mar. 2007).

> against liability because they can prove where animals came from and how they were raised.[432]

NAIS, which is an information system, does not affect basic principles of tort or contract liability. Insofar as tort is concerned, NAIS has no effect on the legal principles of tort liability, but the system does increase the amount of information available. That is, without traceability, a meat packing plant will know the identity of the immediate seller (e.g., the feeder) of an individual animal, but is far less likely to know the identity of earlier owners, including producers.[433] NAIS would allow an individual animal to be traced from birth to slaughter. Thus, by making it easier to identify the source of disease or residue in animals or their products, traceability may make proof of causation possible, exposing livestock producers to potential lawsuits.[434]

As the general discussion of traceability indicated, however, the chain of traceability is normally broken once animals have been slaughtered and the meat has been processed for sale. Though meat can be traced to the processing plant, further traceback to the producer may be impossible, unless the plant traces meat from individual animals.[435] NAIS is not designed to bridge this gap in the chain of traceability, so it is not likely to lead directly to consumer claims against livestock producers.[436]

Liability under contract may also be an issue, particularly when an animal carries disease. Many states, especially those with major livestock industries, have protected farmers by excluding implied warranties from the sale of livestock when the owner has made a good faith effort to comply with animal health requirements. The Illinois law is fairly typical:

> the implied warranties of merchantability and fitness for a particular purpose do not apply to the sale of cattle, swine, sheep, horses, poultry and turkeys, or the unborn young of any of the foregoing, provided the seller has made reasonable efforts to comply with State and federal regu-

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432. Roxanne Clemens & Bruce A. Babcock, *Meat Traceability: Its Effect on Trade*, 8(1) IOWA AG REVIEW 8, 9 (Winter 2002), available at http://www.card.iastate.edu/iowa_ag_review/.

433. Michael Roberts & Doug O'Brien, Animal Identification: Liability Exposure and Risk Management 2 (WEMC FS #6-04, Fall 2004) [hereinafter Roberts & O'Brien, Animal ID].

434. *See* Michael T. Roberts & Harrison M. Pittman, *Legal issues in developing a national plan for animal identification*, 21 AGRIC. L. UPDATE 1, 6 (Jan. 2004).

435. *See supra* text accompanying notes 239-43.

436. *See* Roberts & O'Brien, Animal ID, *supra* note 433, at 2-4 (noting also that consumers seldom sue livestock producers).

> lations pertaining to animal health. This exemption does not apply if the seller had knowledge that the animal was diseased at the time of the sale.[437]

Not every state excludes implied warranties so broadly. For example, the analogous Kansas provision does not exclude implied warranties for sellers of livestock for immediate slaughter: "with respect to the sale of livestock, other than the sale of livestock for immediate slaughter, there shall be no implied warranties, except that the provisions of this paragraph shall not apply in any case where the seller knowingly sells livestock which is diseased."[438]

As a USDA report noted, "[m]any in the livestock sector worry that traceability systems linking meat to animals will break this tradition [of exemption from implied warranties] and shift at least some of the liability for foodborne illnesses back to cow-calf operators and feedlots."[439] But, in addition, USDA researchers indicate that the traditional exemption of livestock sellers from implied warranties of the health of their animals may impede animal-to-meat traceability, which could bridge the gap in the chain of traceability.[440] "Limiting the liability of the cow-calf operator or feedlot will dampen incentives to establish traceability from meat to animal. Traceability to the animal supplier is less valuable if the supplier cannot be held legally accountable for animal disease."[441] Nonetheless, traceability can be valuable in preventing the spread of disease or locating other diseased animals.

In Canada, too, animal identification has raised issues of liability, and Canadian officials addressed the question of liability, stating that participation in the national tracking and tracing system does not affect liability. Instead, tracing a problem will be more efficient, with fewer tests and quarantines and less disruption of livestock markets.[442] Further, the Canadian Cattle Identification Agency indicated that the system traced animals "to the point of carcass inspection. Most contamination food safety problems are discovered after that point and are recognized to be beyond the control of primary

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437. 810 ILL. COMP. STAT. 5/2-316(3)(d).

438. KAN. STAT. ANN. § 84-2-316(3)(d).

439. GOLAN ET AL., AER 830, *supra* note 217, at 32.

440. *Id.* at 34.

441. *Id.* at 34. Another barrier is the lack of incentives for meat processors to maintain identity of meat, when USDA, rather than the processor, is responsible for animal inspection and certification. *Id.*

442. CCIA, Frequently Asked Questions, Q 7, http://www.canadianlive-stock id.ca/eng/faqs_e.htm (last visited 26 Mar. 2007)

producers."[443] Canada's longer experience with traceability may help to reassure US producers.

C. NAIS and Producer Privacy

1. Privacy Concerns with Animal ID

Livestock producers have expressed concern about protecting confidential business information from competitors, government agencies, and even bioterrorists or animal rights extremists.[444] The goal of NAIS is to provide information to control animal disease. But "many in the industry worry about government intrusion into their business practices generally."[445] Fear of "government interference in private enterprise and its access to private business data" have triggered industry resistance to NAIS.[446] Numerous news reports reflect this concern; for example, representatives of the New Mexico Cattle Growers Association report producer worries about abuse of a livestock registry, citing vulnerability to criminals, terrorists, or even buyers who might gain a price advantage.[447]

Industry groups, too, have focused on the need to protect producer records. For example, the National Cattlemen's Beef Association published a *White Paper* on NAIS in 2005. Prominent among their requirements for the animal ID system is "[m]aintaining the confidentiality of information on animal movements and ownership in private hands–free from freedom of information act requirements of state and federal governments."[448] The American Veterinary Medical Association (AVMA) issued a position statement on NAIS. The AVMA supports an effective NAIS and insists on critical

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443. CCIA, About CCIA, http://www.canadaid.com/About/#Description_and_Purpose (last visited 26 Mar. 2007). The CCIA also noted that Canadian Food Inspection Agency "traces from the first location of the animal (herd of origin) and last location of the animal (usually the packing plant) to find the true source of the problem. The CFIA will rely on scientific information and tests to confirm infection and toxin sources." *Id.*

444. Michael Roberts & Doug O'Brien, Animal Identification: Confidentiality of Information 1 (WEMC FS #5-04, Fall 2004) [hereinafter Roberts & O'Brien, Confidentiality]; Becker, Animal ID, *supra* note 211, at 12.

445. Becker, Animal ID, *supra* note 211, at 12.

446. Pressler, *supra* note 342.

447. Sandy Nelson, *National Animal ID System: Tracking the livestock*, NEW MEXICAN, 13 Aug. 2006.

448. National Cattlemen's Beef Association, National Animal Identification System (NAIS), Industry Proposal White Paper for Consideration 1-2 (2005), www.beefusa.org/animAnimalIDWhitePaper.aspx (last visited 26 Mar. 2007).

key elements, including an "[e]xception from freedom of information disclosure laws for data collected in support of the NAIS."[449]

Species working groups, appointed to advise APHIS in development of NAIS, agree. For example, the Cattle Work Group devoted four of its nine guiding principles to confidentiality.[450] Providing input to USDA, this species group insisted that producers' data be kept confidential, both exempt from FOIA and protected from "passing among varied governmental agencies."[451] Approved federal and state animal health authorities should have access to NAIS data, but only information "essential to the enhancement of animal disease surveillance and monitoring" should be stored in state or federal databases.[452] Moreover, access to the data system should occur only through a "regulatory need" for tracing of a foreign animal disease or a program disease, or after declaration of an animal disease emergency.[453] Similarly, the NAIS equine working group also recommended exemption from FOIA requirements and access to other agencies, as well as government access to data only for animal disease surveillance and monitoring.[454]

Though the existence of any type of traceability system raises concerns about privacy, those concerns may escalate when RFID tags are used. RFID technology is already familiar to consumers who use transponders to pay highway tolls[455] and those who have had micro-chips implanted to identify family pets. Passive RFID chips are now used in US passports, under regulations promulgated in October 2005.[456] The technology has significant potential for supply chain management and inventory in the retail sector.[457] The use of RFID tags in consumer goods, it has been argued, can lead to intru-

449. AVMA, Position Statement, *supra* note 406.
450. Cattle Work Group, *supra* note 313.
451. *Id.* at 1.
452. *Id.*
453. *Id.*
454. Equine Species Working Group, *supra* note 395.
455. The I-Pass system used on Open Road Tolling in Illinois is an example. *See* http://www.illinoistollway.com.
456. Electronic Passport, 70 Fed. Reg. 61,553 (25 Oct. 2005), codified at 2 C.F.R. part 51. The RFID chip used for passports will be a proximity chip readable at about 10 centimeters, rather than a vicinity chip, used for inventory tracking. 70 Fed. Reg. at 61,553.
457. *See generally* Hildner, *supra* note 298. Hildner refers to the Broken Arrow Affair, in which Wal-Mart used RFID tags on lipsticks in an Oklahoma store; movement of the lipsticks turned on a video monitor and alerted researchers hundreds of miles away, who could watch consumers. The experiment triggered consumer objections. *Id.* at 133, 136-37.

sions in privacy through "profiling, surveillance, and targeted action," especially when RFID tags can be related "to personally identifying information through a database."[458] Few state or federal laws, however, regulate RFID use.[459]

In a conference speech printed in the Congressional Record, Senator Leahy (Vt.) acknowledged RDIF's "potential for many constructive uses."[460] He supported its use in "a Vermont pilot program for tracking cattle to curtail outbreaks, like mad cow disease," noting that the national tracking system was modeled after the Vermont program.[461] Nonetheless, Leahy expressed concern about the important privacy issues raised by RFID technology[462] and insisted on "a general presumption that Americans can know when their personal information is collected, and to see, check and correct any errors."[463]

Mike Johanns, US Secretary of Agriculture, addressed the issue of confidentiality in a 24 August 2006 speech at the Animal Identification/Information Exposition. He emphasized the importance of protecting confidential business information in a competitive business world. USDA should not hold or be able to release animal tracking records; instead, private and state databases will be used. If an animal disease breaks out, USDA will request specific information from private and state databases for the required investigation.[464]

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458. *Id.* at 141.

459. *Id.* at 138. The federal government recognized privacy issues related to commercial and federal use of RFIDs. These include "notifying individuals of the existence or use of the technology; tracking an individual's movements; profiling an individual's habits, tastes, or predilections; and allowing for secondary uses of information." U.S. GOV'T ACCOUNTABILITY OFFICE, PRIVACY: KEY CHALLENGES FACING FEDERAL AGENCIES, TESTIMONY OF LINDA D. KOONTZ, GAO-06-777T (2006) [hereinafter GAO, PRIVACY].

460. Leahy, *supra* note 295, at S2989-90.

461. *Id.*

462. *Id.* at S2990. For example,

> What information will it gather, and how long will that data be kept? Who will have access to those data banks, and under what checks-and-balances? Will the public have appropriate notice, opportunity to consent and due process in the case mistakes are made? How will the data be secured from theft, negligence and abuse, and how will accuracy be ensured? In what cases should law enforcement agencies be able to use this information, and what safeguards should apply?

Id.

463. *Id.*

464. Press Release, USDA, Mike Johanns, Transcript of Remarks to the Animal Identification/Information Exposition 2006, Kansas City, MO (No. 0318.06, 24 Aug. 2006) [hereinafter Johanns, Release 0318.06].

Recent documents from USDA have responded clearly to the privacy concerns of livestock producers. The draft *User Guide*, released in November 2006, mentions confidentiality repeatedly. For example, in a discussion of animal tracking databases, the *User Guide* states

> The information held in ATDs is within the control of [the] private entity or State. USDA will not hold and, therefore, cannot distribute this information. If USDA needs animal movement and location information to respond to an animal disease issue, we will request the data from the private and State databases only for animals involved in the disease of concern. Federal law protects individuals' private information and confidential business information from public disclosure.[465]

By cooperating with state and private databases, USDA has structured NAIS to avoid having data about livestock premises and animal identification data under federal control, unless information is needed for tracing an animal disease. Even then, the data provided to USDA will be minimal, perhaps further reducing privacy concerns.[466] Data held in state databases, however, may continue to raise concerns for livestock farmers.

> First I will tell you that I agree wholeheartedly with the livestock producers who believe that information about your livestock is your business, period. The business of agriculture has undergone significant change in the past few decades. The image of a producer taking his crops and livestock to market is changing. In today's very highly competitive marketplace, a farm or a ranch's operations should remain confidential, they should be protected.
>
> . . . [A]s your Secretary of Agriculture, I do not believe I should be in the business of possessing your information, your personal business information.
>
> That's why I have directed APHIS to create an Animal ID System that will hold information about animal movements in the private sector and in the state databases that chose to go in a state direction. Animal movement information registered in the private animal tracking database is private. It should not be a USDA record. That information cannot be released by USDA because we don't own it, and we don't control it, nor should we.
>
> Only in the event of an animal disease outbreak will USDA go to the holder of that information and explain to them what they need, and the holder of that information will supply it to us. Even then and only then, only that information relative to the disease outbreak will be collected and retained as a part of that investigation.

Id.

465. DRAFT USER GUIDE, *supra* note 317, at 43.

466. Daniel Grant, *Cost, confidentiality among key NAIS concerns*, FARMWEEK, 30 Aug. 2006. Dr John Wiemers, a veterinarian on the NAIS staff, noted that the data recorded is similar to a phone book, rather than commercial information. The

Despite USDA assurances of confidentiality, some further analysis may be useful. Discussions of confidentiality of livestock data invoke both the federal Freedom of Information Act, with its disclosure mandates and exceptions to disclosure, and the federal Privacy Act, which protects some government records from disclosure.

It must be noted that FOIA and the Privacy Act may protect some livestock information in the hands of the federal government, and state FOIA and privacy laws may protect information in state databases. But those laws apply to federal and state governments, not to private organizations that are not controlled by governments. Thus, though discussions of confidentiality have focused on USDA, privacy concerns may still apply to information about animal identification and tracking held by private organizations, breed groups, or other organizations. Producers might demand that contracts with these organizations be drafted to require protection of confidential information.[467] Moreover, even information protected by statute from routine disclosure may be vulnerable in litigation related to animal health or food safety, e.g., under subpoena by a party to the litigation.[468]

2. Freedom of Information Act

One fear of livestock producers is that others will be able to request information collected pursuant to NAIS under the federal Freedom of Information Act (FOIA) or analogous state laws. FOIA authorizes public access to records held by federal executive agencies,[469] but several specific exemptions protect some records. For example, FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[470] Some commentators seem to suggest that this exemption would protect confidential commercial information from livestock owners.[471]

Under another FOIA exemption, the duty to disclose agency records does not apply to matters exempted from disclosure by stat-

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"nature of the data is not that economically sensitive. We may even be overstating the risk." *Id.*

467. Roberts & O'Brien, Confidentiality, *supra* note 444, at 3.

468. *Id.* at 3-4.

469. 5 U.S.C. § 552. State FOIAs exist, as well.

470. 5 U.S.C. § 552(b)(4).

471. E.g., Becker, Animal ID, *supra* note 211, at 12.

ute.[472] Recent statutory exemptions from FOIA include the Livestock Mandatory Price Reporting Act, as to cattle and beef pricing information, the Bioterrorism Act as to location of food supplies, and the Homeland Security Act, as to certain information.[473] These exemptions do not apply to NAIS, of course, but illustrate possible approaches to protect confidentiality of information from livestock producers.

The Livestock Mandatory Reporting Act imposed mandatory reporting for transactions in livestock. That law, which had expired 30 September 2005, has been extended until 30 September 2010.[474] Confidentiality provisions protect the identity of persons and proprietary business information. In addition, no facts or information obtained under the Act can be disclosed under FOIA.[475]

The Bioterrorism Act of 2002 now requires registration of facilities (but not farms) that manufacture, process, pack or hold food for consumption in the US.[476] Though a list of registered facilities must be compiled, the list and registration documents are exempt from disclosure under FOIA. Information from the list or documents is also exempt "to the extent that it discloses the identity or location of a specific registered person."[477] Similarly, the Bioterrorism Act authorizes enactment of regulations that require food re-

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472. 5 U.S.C. § 552(b)(3):

> (b) This section does not apply to matters that are –
>
> (3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld.

473. *See generally* Roberts & O'Brien, Confidentiality, *supra* note 444, at 2-3; Amy K. Guerra, Comment, *Agricultural Accountability: The National Animal Identification Plan, Confidentiality and the Freedom of Information Act*, 15 SAN JOAQUIN AGRIC. L. REV. 213, 227-28 (2006).

474. 7 U.S.C. § 1636 (terminated 30 Sept. 2005, as per note under 7 U.S.C. § 1635); Livestock Mandatory Reporting Act-Extension, Pub. Law No. 109-296, 120 Stat. 1464 (2006) (extending the law and amending its swine reporting provisions).

475. *See generally* JANET PERRY ET AL., DID THE MANDATORY REQUIREMENT AID THE MARKET? IMPACT OF THE LIVESTOCK MANDATORY REPORTING ACT (Outlook Rep. LDP-M-135-01, 2005),

476. 21 U.S.C. § 350d(a)(1)-(2). A farm is not considered a facility. *Id.* § 350d(b)(1). The Bioterrorism Act of 2002 is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, tit. IIIA, §§ 301-315, Pub L. 107-88, 116 Stat. 594, 662-75 (2002).

477. 21 U.S.C. § 350d(a)(4). A facility itself may disclose information and may need to provide information, e.g., its registration number, to customers. *See* FDA, Questions and Answers Regarding Registration of Food Facilities (Edition 4) (Aug. 2004), http://www.cfsan.fda.gov/~dms/ffregui4.html.

cord keeping (for a maximum of two years) that will identify the "immediate previous sources and the immediate subsequent recipients of food."[478] The FDA must implement effective procedures to prevent unauthorized disclosure of trade secrets or confidential information.[479]

The Homeland Security Act also includes a FOIA exemption for "critical infrastructure information (including the identity of the submitting person or entity) that is voluntarily submitted to a covered federal agency [defined as the Department of Homeland Security] . . . regarding the security of the critical infrastructure." Such information is exempt from federal and state FOIA disclosure and enjoys other protections of confidentiality.[480] Either the President or the Secretary of Homeland Security may designate a critical infrastructure program,[481] and the President has identified the agriculture and food system as a critical infrastructure and established a national policy to protect that system.[482]

3. Privacy Act

Though much concern about disclosure of livestock information has focused on FOIA, the Privacy Act[483] may also be relevant. In his August 2006 speech, Secretary of Agriculture Johanns addressed worries about access of other federal agencies or activist groups to confidential data about individuals or their premises. He assured livestock owners that the Privacy Act protects USDA records systems, including names and addresses, from disclosure to other persons or other federal agencies.[484]

In enacting the Privacy Act, Congress found that "the privacy of an individual is directly affected by the collection, maintenance, use and dissemination of personal information by Federal agencies,"

478. 21 U.S.C. § 350c(b).
479. *Id.* § 350c(c).
480. 6 U.S.C. § 133(a). "Covered federal agency" is defined at *id.* § 131(2).
481. *Id.* § 132.
482. Directive on Defense of United States Agriculture and Food, 30 Jan. 2004, 40 WEEKLY COMP. PRES. DOC. (BBR 14.7 p128) 183 (3 Feb. 2004).
483. 5 U.S.C. § 552a, which protects agency records containing information about individuals from disclosure to other persons or to another agency. *See* U.S. Congress, Senate Committee on Government Operations, 94th Cong. 2d Sess., Legislative History of the Privacy Act of 1974: S. 3418 (Public Law 93-579), Source Book on Privacy http://www.loc.gov/rr/frd/Military_Law/pdf/LH_privacy_act-1974.pdf. Other federal laws and regulations protect privacy.
484. Johanns, Release 0318.06, *supra* note 464.

and that "the increasing use of computers and sophisticated information technology . . . has greatly magnified the harm to individual privacy that can occur . . .."[485] The Privacy Act is intended to protect the privacy of individual information, while recognizing that governments often need information to function effectively.

Under the Privacy Act, federal agencies that maintain a "system of records"[486] must allow any individual to review and copy information pertaining to him or her and to request amendment of a record found to be inaccurate.[487] Moreover, agencies may not disclose any record contained in a system of records without written consent of the individual to whom the record pertains. A number of exceptions ensure that the information can be disclosed if used for the purpose for which it was collected ("routine use") and for other limited governmental purposes. Information can also be disclosed if "required" under the FOIA,[488] but FOIA exemptions protect certain personal information and information exempted by statute from required disclosure.[489]

The Privacy Act applies only to records included in a "system of records," defined as "a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual."[490] Indeed, "the determination that a system of records exists triggers virtually all of the other substantive provisions of the Privacy Act"[491]—that is, whether the records are available for review by the individual involved and protected from disclosure to others. According to a leading Privacy Act

485. Pub. L. No. 93-579, § 2(a)(1), (2), 88 Stat. 1896 (1974), codified at 5 U.S.C. § 552a note.

486. On the difficulty of determining what constitutes a system of records (defined in 5 U.S.C. § 552a(a)(5)), especially in light of technology used since 1974, see Julianne M. Sullivan, Comment, *Will the Privacy Act of 1974 Still Hold Up in 2004? How Advancing Technology Has Created a Need for Change in the "System of Records" Analysis*, 39 CAL. W. L. REV. 395 (2002-03).

487. This right to access is intended to improve the quality of information. Smiertka v. Dep't of Treasury, 447 F. Supp. 221, 226 (D.D.C. 1987), *remanded on other grounds*, 604 F.2d 698 (D.C. Cir. 1979), quoted in Henke v. US Dep't. of Commerce, 83 F.3d 1453, 1457 n.2 (D.C. Cir. 1996).

488. 5 U.S.C. § 552a(b). The Privacy Act authorizes civil action, with injunctions and monetary damages for successful plaintiffs. On damages, see Haeji Hong, *Dismantling the Private Enforcement of the Privacy Act*: Doe v. Chao, 38 AKRON L. REV. 71 (2005) (analyzing 2004 Supreme Court decision that requires plaintiffs claiming even the minimum statutory damages to have suffered actual damages).

489. *See supra* text accompanying note 472.

490. 5 U.S.C. § 552a(a)(5).

491. Henke, 83 F.3d at 1459.

decision, whether an agency maintains a system of records keyed to individuals depends on the "entirety of the situation, including the agency's function, the purpose for which the information was gathered, and the agency's actual retrieval practice and policies."[492] The Privacy Act applies to government agencies, as well as to government contractors who maintain a system of records to carry out an agency function.[493]

Thus, whether the Privacy Act applies to data held by the federal government under a program like NAIS will depend in part on whether that information is considered a "system of records." If the agency's purpose in gathering information is linked to individual livestock producers (instead of animals, perhaps), the information is more likely to be a system of records.[494] Records actually about the individual (instead of records that only mention the individual) should be covered under the Act.[495]

In addition, the actual method of retrieval practiced by the agency (e.g., retrieval by name or code linked to an individual), rather than the agency's retrieval capability, helps to determine whether the records are part of a system of records governed by the Act.[496] If the agency practice is to retrieve that data by the name of the individual or by a code linked to that individual—e.g., the premises identification number—a system of records may exist.[497] If the practice is to retrieve data based on the unique identification num-

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492. Henke, 83 F.3d at 1461. See Sullivan, *supra* note 486, for the argument that the Privacy Act definition of system of records did not anticipate methods of retrieval of computerized databases.

493. 5 U.S.C. § 552a(m). Employees of such contractors are considered employees of the agency. See John M. Eden, *When Big Brother Privatizes: Commercial Surveillance, the Privacy Act of 1974, and the Future of RFID*, 2005 DUKE L. & TECH. REV. 20, 29-30 (recommending that the Privacy Act be amended to obligate corporations to minimize data collection and preserve anonymity, obtain permission for use of personally identifying information, and not discriminate against consumers who opt out of RFID data collection).

494. Henke, 83 F.3d at 1461.

495. Henke, 83 F.3d at 1462; Sullivan, *supra* note 486, at 401.

496. See Henke, 83 F.3d at 1459-60 (holding that an agency does not hold a system of records where information about individuals was kept only as an adjunct to a grant program that focused on businesses and the agency did not retrieve information keyed to individual names). For discussion of *Henke*, see Sullivan, *supra* note 486, at 339-401.

497. Henke, 83 F.3d at 1461. The PIN, however, is associated with a geographic location, rather than only the land owner or livestock producer. Because of the nature of land and an established livestock operation, the PIN is more likely to be associated with an individual than the AIN, which is connected to an animal that may move frequently in commerce.

ber of an animal (which may change ownership and therefore not maintain a link to an individual), one could argue that the data may be only a group of records instead of a system of records, as defined by the Privacy Act. Records not part of a system of records are not available for individual review, nor are they protected from disclosure. Thus, to ensure protection under the Privacy Act for the few records USDA does keep, USDA may want to consider the system of records requirement.

The Privacy Act "covers federal agency use of personal information, regardless of the technology used to gather it. As a practical matter, however, the Privacy Act is likely to have a limited application to the implementation of RFID technology because the act only applies to the information once it is collected, not to whether or how to collect it."[498] The Federal Trade Commission decided in 2005 that companies that make and use RFID technology would be responsible for protecting consumer privacy and that database security is an important component of that protection.[499] Thus, privacy concerns raised by RFID technology in particular might be addressed by allowing livestock producers to choose whether to use RFID tags or standard identification tags without RFID.[500] Indeed, under NAIS, the AIN device without RFID is the standard for animal identification, though some industry groups prefer RFID.

4. State and Other Responses

State reactions to confidentiality concerns have taken several forms. Some states have refused to send information to national

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498. U.S. GOV'T ACCOUNTABILITY OFFICE, INFORMATION SECURITY: RADIO FREQUENCY IDENTIFICATION TECHNOLOGY IN THE FEDERAL GOVERNMENT 23, GAO-05-551 (2005) [hereinafter GAO, RFID]. Privacy impact assessments are required by the E-Government Act in connection with the decision to collect information. *Id.* Technological measures to address privacy concerns are being developed. *Id.* at 22-24.

The E-Government Act of 2002, Pub. L. No. 107-347, protects personal information in part by requiring privacy impact assessments that analyze how information is handled. The Federal Information Security Management Act of 2002 (earlier the Government Information Security Reform Act), title II of Pub. L. No. 107-347, requires information security programs. *See generally* GAO, PRIVACY, *supra* note 459.

499. FTC, Radio Frequency Identification: Applications and Implications for Consumers (March 2005), cited in GAO, RFID, *supra* note 498, at 24.

500. *See* GAO, RFID, *supra* note 498, at 24, which mentions an opt-in/opt-out system that would allow voluntary participation, but risk penalizing consumers who opt out.

databases. Other states have enacted specific legislation to promote privacy, while still others have relied on existing FOIA-like exemptions or have not focused on confidentially, perhaps with the rationale that premises registration conveys information already available to the public in telephone books and public records.[501]

Vermont and Massachusetts are examples of the states that have withheld information. An August 2006 news report indicated that Vermont would "put on hold" proposed new rules for mandatory registration of livestock farms. Those rules would have required registration of livestock premises, but ensured that the premises information provided would be confidential under Vermont Law.[502] Citing concerns about confidentiality in USDA, the Vermont Agency of Agriculture Food and Markets indicated that no information would be sent to the USDA database. Instead, Vermont plans to keep registration voluntary and restrict information to Vermont.[503] Similarly, a September 2006 news report indicated that privacy concerns have led agricultural officials in Massachusetts to withhold information about livestock premises registration from USDA.[504]

Kansas has enacted a state requirement of confidentiality. In a law enacted in 2004 and amended in 2005, Kansas authorized its livestock commissioner to cooperate with federal and other officials in developing systems for voluntary premises registration, animal identification, and tracking. The statute gives the commissioner authority to enter agreements with federal agencies and others to "coordinate efforts and share records and data systems pursuant to law to maximize the efficiency and effectiveness [of the system]."[505] But the law also states explicitly that "Any data or records provided

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501. A brief article categorizes three state approaches to confidentiality: no particular action to protect confidentiality, reliance on existing statutory protections, and specific state confidentiality laws. Eric Pendergrass, *Varying state approaches to confidentiality with premises and animal identification systems*, 23(11) AGRIC. L. UPDATE 4 (Nov. 2006).

502. *See* http://www.vermontagriculture.com/prs/premisesRules.html, visited 17 August 2006; 6 VSA § 61. The proposed rules are at http://www.vermontagriculture.com/prs/premisesrulev3%202.pdf. Part III. Confidential Information would have allowed limited disclosure, including to APHIS, under a memorandum of understanding.

503. Lisa Rathke, *Vt. negs farm ID program*, BENNINGTON BANNER, 16 Aug. 2006. No central USDA database actually exists.

504. Stan Freemen, *State muzzles disclosure of livestock data to U.S.*, REPUBLICAN (Springfield MA), 15 Sept. 2006, B6, also reported in Ann Bagel, Confidentiality concerns prompt state officials to withhold livestock reports, http://meatingplace.com (18 Sept. 2006).

505. KAN. STAT. ANN. § 47-674(f).

or obtained pursuant to this section to an official of the animal health department shall be considered confidential by the animal health department and shall not be disclosed to the public."[506] The Kansas Attorney General concluded that contracts between the Department of Animal Health and federal or other agencies should contain a confidentiality provision, but that federal agencies, not acting on behalf of the Department, may handle the records as required by federal law.[507] According to the livestock commissioner, because of the law requiring that participation be voluntary, existing Kansas records cannot be added to the premises registration system.[508]

Since 2004, several bills have been introduced in Congress to protect information collected through NAIS from disclosure.[509] Most recently, Senate Bill 3862, introduced in September 2006, would seem to resolve some, if not all, of the privacy issues raised by NAIS. It would add a subsection called "Protection of Information in a Voluntary Animal Identification System" to the Animal Health Protection Act.[510] The bill would protect information submitted to the system from disclosure, except in limited situations when livestock is threatened by a disease or pest. Mandatory disclosure about particular animals would be permissible for specific purposes, including law enforcement and homeland security. Moreover, the bill would prevent state or local governments from disclosing information relating to animal identification under their FOIA or other disclosure laws.[511]

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506. KAN. STAT. ANN. § 47-674(g). Moreover, the statute refers to the Kansas Open Records Act, KAN STAT. ANN. 45-229(b), and indicates that the protection from disclosure is exempt from the 5-year time limit ordinarily applied to exceptions to disclosure.

507. Kansas Attorney General Opinion No. 2005-21 (20 Sept. 2005), http://www.kscourts.org/ksag/opinions/2005/2005-021.htm.

508. George Teagarden, Livestock Commissioner, Kansas Animal Health Department, Legal Authority-Open Records Act, Id Info Expo, 22-24 Aug. 2006, Kansas City, MO, http://www.animalagriculture.org/proceedings/IDINFOEXPO 2006/Wednesday/3GeneralSessionIII/2%20Legal%20Authority,%20FOIA%20Teagarden.pdf.

509. For a brief discussion of some of these, see Guerra, *supra* note 473, at 228-30.

510. S. Bill 3862, 109th Cong., 2d Sess. (2006) to amend 7 U.S.C. § 8308, adding subsection (d).

511. Section 2 of S. Bill 3862 would have added subsection (d) to 7 U.S.C. §8308:

> (d) Protection of Information in a Voluntary Animal Identification System-
>
> (1) Definition Of Animal Identification System- In this subsection, the term 'animal identification system' means a voluntary system for identifying or tracing animals that is established by the Secretary.

VIII. CONCLUSION

USDA, with the cooperation of states, livestock producer groups, and private organizations, is continuing to develop and implement NAIS. Despite the reluctance of some livestock producers, registration of premises is well under way, with all states, five tribes, and two territories participating. More than 406,000 premises had

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(2) Protection From Disclosure-

(A) In General- Information obtained through the animal identification system shall not be disclosed except as provided in this subsection.

(B) Waiver Of Privilege Or Protection- The provision of information to the animal identification system and the disclosure of information in accordance with this subsection shall not constitute a waiver of any applicable privilege or protection under Federal law, including trade secret protection.

(3) Limited Release Of Information- The Secretary may disclose information obtained through the animal identification system if-

(A) the Secretary determines that livestock may be threatened by a disease or pest;

(B) the release of the information is related to actions the Secretary is authorized to take under this subtitle; and

(C) the Secretary determines that the disclosure of the information to a government entity or person is necessary to assist the Secretary in carrying out the purposes of-

(i) this subtitle; and

(ii) the animal identification system.

(4) Mandatory Disclosure Of Information- The Secretary shall disclose information obtained through the animal identification system regarding particular animals to-

(A) the person who owns or controls the animals, if the person requests the information in writing;

(B) the Attorney General for the purpose of law enforcement;

(C) the Secretary of Homeland Security for the purpose of homeland security;

(D) the Secretary of Health and Human Services for the purpose of protecting the public health;

(E) an entity pursuant to an order of a court of competent jurisdiction; and

(F) the government of a foreign country if disclosure of the information is necessary to trace animals that pose a disease or pest threat to livestock or a danger to human health, as determined by the Secretary.

(5) Prohibition On Disclosure Under State Or Local Law- Any information relating to animal identification that a State or local government obtains from the Secretary shall not be made available by the State or local government pursuant to State or local law requiring disclosure of information or records to the public.

been registered by mid-July 2007.[512] The USDA is actively evaluating applications for animal tracking databases and has approved several identification tags, designed to bear an animal's lifetime number. Moreover, in light of stakeholder comments and concerns, USDA has published a comprehensive draft document, the *User Guide*, to explain the animal identification system.[513] In recent months, USDA has indicated that NAIS will remain voluntary, an action that has helped to resolve some of the concerns of livestock owners.

NAIS is not free from controversy, and lingering issues remain contentious. Producers remain concerned about their cost, their possible exposure to liability in tort or contract, and the protection of their privacy from government, competitors, and others. Non-government organizations and others question the wisdom of a voluntary system and wonder whether the ambitious goals of NAIS can be met without requiring producers to participate.

Despite disagreements about the implementation of NAIS, numerous contagious animal diseases, as well as transmissible diseases like BSE, continue to threaten livestock and human health. Moreover, the importance of traceability to many US trading partners indicates that an effective system is necessary. As one analyst noted, "[a] rigorous traceback and animal ID system would not prevent safety problems (process controls, testing, and other science-based food safety regimes are intended to do that), but it could facilitate recalls, possibly contain the spread of an illness, and help authorities stem future incidents . . . . Besides building public confidence in the U.S. food safety system, improved traceability may enable firms to limit their legal and financial liabilities."[514] As the Secretary of Agriculture insisted, "the system is a critical tool in safeguarding the health of agricultural animals from disease" and an important way to "assure consumers and trading partners of the health of our herd" in case of an outbreak of disease.[515]

512. APHIS, NAIS, *supra* note 341. Indeed, NAIS allowed delivery of help to farmers and their livestock in Colorado after a January blizzard. APHIS, National Animal Identification System Proves to be a Valuable Tool During Blizzard Recovery Operations (4 Jan. 2007), http://animalid.aphis.usda.gov/nais/newsroom/spotlight_blizzard.sthml.

513. DRAFT USER GUIDE, *supra* note 317.

514. Becker, Animal ID, *supra* note 211, at 3.

515. Johanns, Release 0318.06, *supra* note 464.