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Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards

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Summary

Shortly after the first case of bovine spongiform encephalopathy (BSE or “mad cow disease”) in the United States was announced in December 2003, U.S. Department of Agriculture (USDA) and other officials announced measures to improve existing safeguards against the introduction and spread of BSE. Previously, these safeguards, often called the “three firewalls,” were: (1) USDA restrictions on imports of ruminants and their products from countries with BSE; (2) a ban on feeding most mammalian proteins to cattle and other ruminants, issued by the Food and Drug Administration (FDA); and (3) a targeted domestic surveillance program by USDA’s Animal and Plant Health Inspection Service (APHIS), the agency responsible for animal health monitoring and disease control.

Some argued that these safeguards were inadequate, as evidenced by the finding of the BSE case and subsequent federal efforts to bolster protections. Most new actions announced by USDA on December 30, 2003 are under the purview of the Food Safety and Inspection Service (FSIS), responsible for the safety of most U.S. meat and poultry. These actions, which some call the “fourth firewall,” took effect in January 2004 and include: (1) holding tested carcasses until BSE-negative results are obtained; (2) banning nonambulatory (“downer”) cattle from human food; and (3) banning certain additional animal parts from human food. USDA announced accelerated work on a national animal identification and tracking system, and sought increased funding for that system, for expanded BSE surveillance, and other activities. On January 26, 2004, FDA also announced planned changes to its safeguards, including additional bovine materials banned from the human foods and cosmetics it regulates; a ban on poultry litter, restaurant waste, and ruminant blood products from ruminant feed; and stricter oversight of feed manufacturing.

On February 4, 2004, international BSE experts on a USDA-named subcommittee recommended additional steps, including more stringent animal feed restrictions and increased testing of cattle, in part because the panel concluded that BSE might now be resident in North America. Some in industry responded that the panel had exaggerated the risks based on flawed assumptions, and had contradicted other findings, such as a study of the U.S. BSE situation by the Harvard Center for Risk Analysis. Others, including some BSE experts, embraced some or all of the panel’s recommendations. On February 23, 2004, a full committee of USDA advisors questioned some of the subcommittee recommendations, and recommended that the Harvard Center review the subcommittee report in light of its prior work.

As Members of Congress conduct oversight of the BSE issue and consider possible legislative options, some have asked whether the expanded agency actions will protect further against BSE, whether they are scientifically sound, and what cost they will impose on taxpayers and industry. Also at issue is whether they will restore foreign markets’ confidence in the safety of U.S. beef, and whether other types of actions should be considered, among other questions. This report will be updated if events warrant.

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Bovine Spongiform Encephalopathy (BSE, or “Mad Cow Disease”): Current and Proposed Safeguards

Introduction

Overview. Bovine spongiform encephalopathy (BSE or “mad cow disease”) is a fatal degenerative neurological disease of cattle. It is believed to be caused by an abnormal protein, called a *prion*. It is in the family of related diseases referred to as *transmissible spongiform encephalopathies*, or TSEs. TSEs include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease, or CJD, in humans. BSE is believed to be spread to cattle in feed, but not transmitted directly from one animal to another in a herd. BSE is also thought to be transmissible to humans who eat contaminated beef, causing a variant form of CJD (variant or vCJD) that was first recognized in 1996 during the BSE outbreak in the United Kingdom.

On December 23, 2003, USDA announced the finding of a single case of BSE in a cow in a Washington state dairy herd — the first U.S. case, and the third in North America.¹ USDA stated that the case posed virtually no risk to public health but immediately launched an intensive investigation, which, officials announced on February 9, 2004, is now officially concluded. During the investigation, more than 700 cattle at 11 facilities were destroyed and 255 of those were tested for BSE, all with negative results. The 255 were deemed “of interest” because they could have been from the source herd in Alberta, Canada.²

The first finding of BSE in the United States has prompted intense debate on the effectiveness of existing U.S. safeguards against BSE.

Safeguards in Place Prior to December 2003. In the wake of the far more extensive BSE outbreaks in the United Kingdom starting in 1986, U.S. officials had, by the late 1980s, begun erecting what they and beef industry leaders have

¹ Canada announced a single case in May 2003, and following intensive investigation, has not reported any additional cases. A 1993 case in Canada was found to have been imported from the United Kingdom during the height of the outbreak there.

² USDA, *Final BSE Update — Monday, February 9, 2004*. Included in the 255 were 28 of the 80 cattle that had entered the United States with the cow that tested positive for BSE. Because of a lack of records, only 28 of these 80 other imports were positively identified, contributing to the need for the wider investigation and destruction of more animals. For an overview of the current BSE situation, see CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*, by Geoffrey S. Becker.

termed the “three firewalls” to keep the disease out of the United States and to contain it immediately if it should occur here. These firewalls are: (1) restrictions on imports of ruminants and their products from countries with BSE; (2) a ban on feeding most mammalian proteins to cattle and other ruminants; and (3) a targeted domestic surveillance program. A number of critics have argued that this system has been inadequate.

Government officials have acknowledged that the system is not fail-safe, but have asserted that it is scientifically defensible and has kept the risks of BSE — to both U.S. agriculture and human health — at extremely minimal levels. Among other evidence, they cite reviews they commissioned by the Harvard School of Public Health’s Center for Risk Analysis (the “Harvard study”) concluding that the safeguards are sound and would reinforce each other in preventing the spread of isolated BSE cases, should they arise.³ It should be noted that the Harvard study was a mathematical model that used assumptions based on existing evidence whenever possible. The study does, however, consider protections provided by each of the firewalls and a variety of scenarios in which they could be challenged.

The Organization of International Epizootics (OIE), the international animal disease control organization, recommends that disease risk assessments be carried out to promote consistent, science-based practices and transparency in international trade. OIE provides guidance and standards for countries managing BSE within their borders, and BSE-free countries wanting to maintain their status.⁴

Additional Safeguards Since December 2003. Despite assurances, the appearance of BSE in the United States ignited a more vigorous debate on the U.S. safeguards. It also spurred USDA officials to announce, on December 30, 2003, a number of major new actions aimed at strengthening BSE protections. These additional actions, the Secretary of Agriculture stated, had been under consideration for some time prior to confirmation of the U.S. BSE case.

The new USDA actions include: (1) holding carcasses of tested animals until BSE-negative results are obtained; (2) banning nonambulatory (“downer”) cattle from entering facilities that slaughter them for human food; (3) keeping additional animal parts considered to be at higher risk — such as central nervous system and several other tissues of older animals — from the human food supply; (4) moving more quickly to implement a national system to identify and track individual animals from their place of birth to slaughter; and (5) naming an international scientific panel to review the government’s BSE response and recommend any needed improvements.

The Administration’s FY2005 budget proposal includes a request for a total of \$60 million for USDA’s BSE-related activities, or \$47 million more than in FY2004.

³ Joshua Cohen et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Nov. 2001, revised Oct., 2003, Harvard Center for Risk Analysis, School of Public Health, at [http://www.aphis.usda.gov/lpa/issues/bse/bse_initiatives.html]. (Hereafter cited as Cohen, Harvard study.)

⁴ For more information about OIE activities, see [http://www.oie.int/eng/oie/en_oie.htm].

Of the total, \$33 million would be used to accelerate development of an animal ID system; \$17 million would go to APHIS to collect and test more BSE samples at rendering plants and on farms; \$5 million would go for the research and development of BSE testing technologies; \$4 million would fund FSIS monitoring of compliance with its BSE-related rules; and \$1 million would be used by the Grain Inspection, Packers and Stockyards Administration to ensure that markets are operating fairly in the wake of the BSE case. The Secretary of Agriculture earlier had announced that the Department intended to commit \$178 million to complete renovations at the Ames, Iowa, lab that conducts tests for BSE and other animal diseases.

On January 26, 2004, FDA announced it will publish changes to its own BSE safeguards, such as banning a number of bovine materials from the human foods and cosmetics it regulates; banning poultry litter, restaurant plate waste, and ruminant blood products from ruminant feed; and tightening feed manufacturing procedures and oversight. As of late February, these changes had not yet been published.

The international panel of BSE experts released its findings on February 4, 2004.⁵ The panel (a subcommittee of a USDA advisory committee) concluded that it is probable that material from other infected animals imported earlier from Canada and possibly Europe has been rendered and fed to U.S. cattle, likely causing indigenous infection here. Although the panel observed that many of the government actions taken so far had been effective and conformed to international standards, it nonetheless recommended additional steps. These include further tightening animal feeding rules by FDA, and increasing cattle testing, at least until USDA has a better understanding of the extent of the prevalence of BSE here.

Some BSE experts and consumer groups welcomed findings from the report. Others in the beef, feed, and related industries responded that the panel had exaggerated the risks based on faulty assumptions, and had not properly distinguished between the BSE situation in North America and the far more extensive problems experienced in Europe. The panel's findings contradicted other scientific findings, such as a three-year examination of the U.S. BSE situation by the Harvard Center for Risk Analysis, these critics asserted. An FDA official commented that, as a regulator, he was now "confronted with two very different scientific opinions."⁶

On February 23, 2004, a full committee of USDA advisors concurred with some of the subcommittee recommendations, and questioned others. The full committee recommended that the Harvard Center review the subcommittee's report in light of its prior risk analysis, and report back to the Secretary.⁷

⁵ USDA, *The Secretary's Foreign Animal and Poultry Disease Advisory Committee's Subcommittee Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, Feb. 4, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

⁶ Denise Grady, "Mad Cow Quandary: Making Animal Feed," *The New York Times*, Feb. 6, 2004, p. 22.

⁷ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, Feb. 23, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

The regulatory and other actions being taken by USDA and FDA are intended not only to reassure consumers and protect livestock health, but also to calm foreign markets, most of which have banned the entry of U.S. cattle and beef products. At issue is whether these steps are needed to protect further against BSE, whether their cost to taxpayers and industry is justified; whether such steps are defensible scientifically and will restore foreign markets' confidence in the safety of U.S. cattle and beef; and whether other types of regulatory and/or legislative actions should be considered, among other questions.

Trade Restrictions

With few exceptions, countries with BSE can trace the first case(s) to importation of affected animals or infected by-products. In this section, import controls to prevent BSE are examined. For a discussion of economic issues and impacts on the U.S. beef trade following the discovery of BSE, see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*.

Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS), the lead agency for controlling animal diseases, has banned the importation of live ruminants (i.e., cattle, sheep, goats, deer, elk, buffalo) and most ruminant products from the United Kingdom and other countries where BSE has been diagnosed.⁸ In 1991, APHIS published formal rules banning the import of ruminant meat and meat products from BSE countries. In 1997, USDA instituted a ban on importing ruminants and most ruminant products from all of Europe. In December 2000, USDA prohibited imports of all rendered animal protein products, regardless of species, from Europe out of concern that feed of nonruminant origin was potentially cross-contaminated with the BSE agent.⁹ (These prohibitions on imports, while similar to the domestic feed controls imposed by FDA, are nonetheless a distinct federal program.)

The exception to the import ban is Canada, which announced its first indigenous case of BSE in May, 2003. (Prior to the findings of BSE in the United States and Canada, the two countries had similar systems of import and feed controls in place.) The United States immediately banned imports of live cattle and most meat and cattle products from Canada. On August 8, 2003, USDA announced that it would accept applications for permits to import selected ruminant products from Canada, including boneless beef from cattle under 30 months old, boneless veal from calves no older than 36 weeks at slaughter; and boneless sheep and goat meat from animals under 12 months old. USDA's decision was based on what it said was a "thorough scientific analysis" that found minimal risk from these imports. These Canadian imports are again entering the United States.

⁸ As of February 23, 2004, 23 countries had reported indigenous cases of BSE, and another three, including the United States., reported only imported cases. OIE provides updated information on countries with BSE at [http://www.oie.int/eng/info/en_esb.htm].

⁹ Source for this section: various APHIS backgrounders and briefing materials, available at: [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>]. Under FSIS's foreign inspection program, no establishments in countries with BSE have been permitted to ship beef to the United States.

On October 31, 2003, USDA announced proposed changes to its standing BSE rules that would allow the importation of certain live ruminants and ruminant products from proposed “minimal risk” regions, including Canada.¹⁰ The proposed rules would permit imports of cattle for slaughter before 30 months of age; sheep and goats for slaughter before 12 months of age; cervids (e.g., deer and elk) for immediate slaughter; and various products from these animals. The future of these proposals, for which the comment period ended January 5, 2004, is unclear at this time. USDA officials recently said they are again reviewing them in light of the U.S. BSE case, and are expected to reopen the rule for additional public comment.¹¹

Assessment of Import Safeguards. The adequacy of current import protections against BSE has been under added scrutiny since the Washington state case was announced. After discovery of the Canadian BSE case but before the U.S. case, USDA officials had asked the Harvard Center for Risk Analysis to reassess its earlier analysis (completed in 2001) of the potential for an outbreak and spread of BSE in the United States. The reassessment concluded in part that “the possible introduction of BSE into the United States from Canada cannot be dismissed,” but that the likelihood is very low, and U.S. protective measures by now would have contained any possible spread.¹² However, the reassessment also noted that a group of cattle imported into Canada from the United Kingdom in 1993 included one that was found to have BSE:

If additional animals in this group harbored the disease and were slaughtered and rendered, infectivity may have been introduced into the Canadian and U.S. cattle feed supplies before the 1997 feed ban was implemented in both countries.... If additional animals were infected, they may have been exported to the U.S. as well.... [It] appears that any related introduction of BSE into the U.S. from Canada would have been due to the import of either infected animals or contaminated feed. Imports are a plausible source of introduction of BSE into the U.S. from Canada because the American and Canadian beef industries are closely linked. During the last five years, the U.S. has on average imported over 1.2 million cattle and 185,000 tons of feed annually from Canada.¹³

In its February 4 report, the international panel of BSE experts observed that it believes:

... the number of cattle actually infected on the farm of origin in Canada was probably small. Indeed the index case identified in the USA may be the only infected animal from the Canadian herd of origin that survived to adulthood.

¹⁰ U.S. Dept. of Agriculture, “Exportation and importation of animals and animal products: Bovine spongiform encephalopathy; minimal risk regions and importation of commodities,” 68 *Federal Register* 62386, Nov. 4, 2003.

¹¹ Testimony of Dr. Ron DeHaven, USDA chief veterinarian, before the Senate Committee on Appropriations hearing on Bovine Spongiform Encephalopathy, Feb. 24, 2004.

¹² Joshua Cohen and George M. Gray, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, pp. 1-2 (undated 2003 report). Harvard Center for Risk Analysis, School of Public Health. [http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf].

¹³ *Ibid.*

However, it is probable that other infected animals have been imported from Canada and possibly also from Europe. These animals have not been detected and therefore infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the USA have also been indigenously infected. Therefore, animals that have not been identified from the birth cohort of the index case do not represent significant additional risk for further propagation of BSE within the USA.¹⁴

A report by the General Accounting Office (GAO), published more than one year before the May 2003 Canadian BSE case, stated that federal actions did not ensure that all BSE-infected animals or products are excluded from the United States. GAO observed that:

[T]he United States had imported about 125 million pounds of beef (0.35% of total imported) and about 1,000 cattle (0.003% of total imported) from countries that later discovered BSE — during the period when BSE would have been incubating. In addition, weaknesses in USDA's and FDA's import controls, such as inspection capacity that has not kept pace with the growth in imports, may allow BSE-infected products to enter the country.¹⁵

GAO recommended that the Secretaries of Health and Human Services (HHS) and of Agriculture develop a coordinated strategy to strengthen import inspections, in consultation with the Commissioner of Customs.

A January 2003 federal interagency report on animal disease prevention also recommended that USDA and HHS should update risk assessments, import regulations, and guidance on enforcing regulations at ports of entry.¹⁶ More specifically, it was noted that agencies need to develop guidance and plans at ports of entry to fully implement the recently enacted Animal Health Protection Act (7 U.S.C. 8301 *et seq.*). Further, the report recommended revisions to the Virus-Serum-Toxin Act to help APHIS enforce import rules on animal biologics products. The interagency report also concluded that the FDA needs additional authority to strengthen its BSE capabilities at ports of entry. The report said FDA has been considering a number of additional protective measures for FDA-regulated products, including: directing importers to use only designated ports for entry of products that might contain bovine materials; requiring certain importers to be certified in order

¹⁴ *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, p. 3. The expert panel, formally a subcommittee of the Secretary of Agriculture's Foreign Animal and Poultry Disease Advisory Committee, included two Swiss experts and one each from the United Kingdom, New Zealand, and the United States, the latter Dr. Will Hueston, a veterinarian who is Director of the Center for Animal Health & Food Safety at the University of Minnesota and a former FSIS official. The report can be viewed at [http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf].

¹⁵ General Accounting Office, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts* (GAO-02-183), p. 3, Jan. 2002. (Hereafter cited as GAO Mad Cow Disease report.)

¹⁶ *Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9) Final Report*, pp. 44-45, prepared by the P.L. 107-9 Federal Interagency Working Group, Jan. 2003.

to import such products into the United States; destroying detained products so that they cannot be re-imported at another time or port; requiring country-of-origin documentation of all imports containing mammalian or mammalian sourced ingredients; and prohibiting imports containing bovine materials from any BSE country.¹⁷

International BSE Standards. In August 2003, U.S. officials said that they, Canadian and Mexican authorities had entered into discussions with the OIE to develop new guidance for resuming trade with countries that have reported BSE, under certain conditions. U.S. officials believe that even under present OIE standards, certain U.S. beef products could be exported to other countries.¹⁸

In a section of its report entitled “Lessons Learned,” the international panel commended the United States for following a science-based approach to policy formulation. It further noted that the North American BSE cases “demonstrate again that exporting countries feel significant national social and financial impacts when importing countries fail to comply with international rules regarding trade.” Therefore, the United States “should demonstrate leadership” by following international standards and by encouraging “the discontinuation of irrational trade barriers when countries identify their first case of BSE.” At the same time, the panel concluded, the United States should “continue to act responsibly when considering export of potentially contaminated materials such as live cattle, MBM [meat and bone meal] and feed. Risk materials must be destroyed or safely utilized to protect human health, animal health, and the environment in the USA and worldwide.”¹⁹

Congressional Role. USDA and FDA so far have not recommended any changes in import safeguards since the December 2003 BSE case.²⁰ If Congress decides to consider ways to strengthen import controls, among the recommendations that they might examine are those from the Harvard report, the GAO report, the international panel’s report, and the response of the full USDA advisory committee.

¹⁷ Ibid.

¹⁸ OIE standards are at: [http://www.oie.int/eng/normes/mcode/A_00068.htm]. See also, OIE, *The OIE standards on BSE: a guide for understanding and proper implementation*, press release, Jan. 9, 2004, at [http://www.oie.int/eng/en_index.htm].

¹⁹ *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, p. 11. For more information on beef trade issues resulting from finding of BSE in the United States, see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*, by Charles E. Hanrahan and Geoffrey S. Becker..

²⁰ However, because foreign countries that import animals and meat products to the United States must have equivalent safety and inspection measures in place, they will have to comply with many of the new U.S. rules like the downer ban, for example (see later sections of this report).

The Livestock “Feed Ban”

Overview. It is believed that feed is the most common, and perhaps the only, route of infection for BSE in cattle, and that the emergence of BSE in the U.K. resulted from the practice of feeding rendered by-products of infected animals, including highly infectious brain tissue, to other cattle as a protein supplement. The cause of the first case or cases is unknown; theories include spontaneous emergence of a single case, or the anomalous transmission of the sheep scrapie agent to cattle. It is thought that the long incubation period and possibly changes in rendering and feeding practices led to amplification of the agent in the feed supply and spread of the disease for years before it was recognized in 1986.

In 1988, the U.K. banned the practice of feeding ruminant by-products back to ruminants. When the purported causal link between BSE and the human disease, variant Creutzfeld-Jakob disease (vCJD), was announced by the U.K. in 1996, the United States added similar controls over cattle feed, to prevent spread of the disease should it emerge. The FDA Center for Veterinary Medicine (CVM), responsible for the safety of animal feeds, began prohibiting the use of most mammalian protein in feeds for ruminants in August, 1997, a restriction commonly called the “feed ban.”²¹ FDA registers and inspects renderers, feed mills, pet food manufacturers, animal feed distributors and others to ensure compliance.

The Harvard study concluded that the feed ban was the dominant protective firewall, and would protect against spread of the disease even if the other firewalls failed. On January 26, 2004, FDA announced that it would publish a new interim final rule to strengthen further the feed ban. One week later, international BSE experts on a USDA-named panel recommended additional steps, including more stringent animal feed restrictions than those just announced by FDA. These rules and recommendations are discussed below.

The Feed Ban Prior to the Finding of BSE in the United States. The feed ban imposed in 1997 did not prohibit the inclusion of potential bovine risk materials such as brain and spinal cord in all animal feeds, but only those feeds intended for ruminants. FDA required that feeds containing ruminant material be labeled with a prohibition against feeding to ruminants, and that firms and farms effectively separate prohibited and non-prohibited feeds in production, shipping and feeding. The ban exempted certain bovine by-products, such as blood, milk, gelatin and restaurant plate waste, on the premise that the exempted materials pose a minimal risk of transmission. Following the discovery of the U.S. BSE case in December 2003, FDA reported that prior inspections of renderers and feed mills found 99% to be in compliance with the ban.²²

The GAO noted in 2002 that, relative to other countries, U.S. surveillance and import controls were stronger, but the feed ban was more permissive. The Harvard

²¹ 21 CFR Part 589.2000, published in the *Federal Register* on June 5, 1997.

²² Food and Drug Administration, *FDA Statement on Rendered Products Derived From BSE Cow in Washington State*, Dec. 27, 2003, at [<http://www.fda.gov/bbs/topics/NEWS/2003/NEW01000.html>].

study, while finding that the feed ban was the dominant protective firewall, also showed in its hypothetical model that failure of the feed ban led to the greatest increase in number of BSE cases. Many also noted that certain permissible practices may nonetheless result in the feeding of rendered ruminant materials to cattle; one such potential breach is the feeding of rendered cattle to poultry and the subsequent incorporation of poultry waste, which may contain uneaten feed, into livestock feeds.

Though GAO limited its recommendations for the feed ban to improved enforcement of the existing regulation, others suggested that the regulation itself be changed to enhance protection. The Harvard study found that if BSE were present in the United States, the greatest source of resulting feed contamination would come from cattle that died on the farm and were rendered. By-products from these animals could legally be fed to non-ruminants, and the Harvard study found that if one rendered cow were BSE-positive, the resulting infusion of infectivity into the feed supply could lead to new bovine cases from a single subsequent breach in the feed ban.²³ Some experts argued that if high-risk materials were absolutely prohibited in all animal feeds, that cross-contamination, breaches at feeding, and the concurrent regulatory oversight of these activities, would become irrelevant.

Some also questioned the feed ban exemptions, including the practice of using rendered bovine blood in milk substitutes for calves. Based on concerns that the agent linked to the human form of BSE, vCJD, could be present in blood, another center at FDA had recommended that persons having resided in the U.K. be barred from blood donation in the United States, to eliminate the potential for transmission from blood donors infected in the U.K. and not yet showing symptoms.²⁴

In 2002, FDA published an advance notice of proposed rule-making, stating that it was considering revising its feed regulation and seeking comments on five relevant topics: excluding from feed the brain and spinal cord from rendered animal products; use of poultry litter in cattle feed; use of pet food in ruminant feed; preventing cross-contamination; and elimination of the plate waste exemption.²⁵

Measures to Strengthen the Feed Ban After Finding BSE in the United States. On January 26, 2004, FDA announced the imminent publication of a new interim final rule with four provisions to further strengthen the feed ban, saying:

First, the rule will eliminate the ... exemption ... that allows mammalian blood and blood products to be fed to other ruminants as a protein source. Recent scientific evidence suggests that blood can carry some infectivity for BSE.

²³ Cohen, Harvard study, p. 111.

²⁴ FDA, *Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products*, Jan. 2002, at [<http://www.fda.gov/cber/gdlns/cjdvcjd.htm>].

²⁵ Food and Drug Administration, "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed," *67 Federal Register* 67572, Nov. 6, 2002.

Second, the rule will also ban the use of “poultry litter” (in feed) for ruminant animals. Poultry litter consists of bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised. ... Poultry feed may legally contain protein that is prohibited in ruminant feed, such as bovine meat and bone meal. The concern is that spillage of poultry feed in the chicken house occurs and that poultry feed (which may contain protein prohibited in ruminant feed) is then collected as part of the “poultry litter” and added to ruminant feed.

Third, the rule will ban the use of “plate waste” (in feed) for ruminants. Plate waste consists of uneaten meat and other meat scraps that are currently collected from ... restaurant operations and rendered into meat and bone meal The use of “plate waste” confounds FDA’s ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the Agency’s ability to fully enforce the animal feed rule.

Fourth, the rule will further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed. Currently, some equipment, facilities and production lines process or handle prohibited and non-prohibited materials and make both ruminant and non-ruminant feed — a practice which could lead to cross-contamination.²⁶

On February 3, 2004, international BSE experts on a USDA-named panel (a subcommittee of an existing advisory committee) recommended additional steps, including more stringent animal feed restrictions than those just announced by FDA. The panel expanded both the proposed list of products that should be banned from ruminant feed, and also from the feed stream in general, recommending “that the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds,” and that “all (specified risk material, or SRM) must be excluded from all animal feed, including pet food.”²⁷ The panel defined SRM more stringently than had the USDA in December, notably by including high-risk tissues from cattle older than 12 months, rather than 30 months.

In the subsequent report of the full advisory committee, released on February 24, 2004, concerns were expressed about inconsistencies between the subcommittee recommendations and findings from the Harvard study. The extent of the feed ban, not explicitly noted in findings of concurrence, is presumably an area of discord between the expert panel and the full committee.

The FY2005 budget proposal includes an increase of \$8 million for FDA’s Animal Drugs and Feeds program to expand administration of the feed ban.

²⁶ U.S. Department of Health and Human Services, “Expanded ‘Mad Cow’ Safeguards Announced To Strengthen Existing Firewalls Against BSE Transmission,” press release, Jan. 26, 2004. As of late February the rules had not yet been published.

²⁷ USDA, *The Secretary’s Foreign Animal and Poultry Disease Advisory Committee’s Subcommittee Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, Feb. 4, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

Compliance with the Feed Ban. FDA bases its compliance determinations on inspection of facilities, practices, and records. At this time there is no certified test that can be used on actual ruminant feed to determine if it contains prohibited material. FDA has commented that test methods are being studied for this purpose.²⁸ The agency also said that it was able to identify and hold all rendered material from the U.S. BSE-affected cow, and that none of it had gone into distribution as feed, obviating the need for a recall.²⁹

The GAO evaluated FDA's oversight of the feed ban, and reported a number of problems with administrative procedures, inspection, and enforcement. Many, including the GAO and the Harvard study, previously have noted that there are opportunities for non-compliance at many points in the feed chain, and that some may be difficult to detect, such as intermittent commingling of feeds on farms that feed cattle along with other livestock such as poultry.

Additional Concerns. The ban as originally designed permits rendering of ruminant by-products as long as they are not re-fed to ruminants. FDA's announced revisions would not alter this basic approach, but would merely expand the list of products that cannot be fed to ruminants. Proposals by others, including the international expert panel, that certain ruminant by-products should be banned from rendering up-front do not suggest alternate disposal routes for these products. Proper rendering practices kill most important human and animal disease organisms (including the Foot and Mouth disease virus, Salmonella, and the anthrax organism), and can reduce BSE infectivity, while complying with existing clean air and clean water regulations. Some assert that if the feed ban were bolstered by prohibiting additional high-risk materials in rendering, animals and by-products could be disposed of in ways that are unsafe, with adverse health, economic and environmental impacts. Some studies have concluded that there may not at this time be safe, legal, widely-available alternatives if certain cattle and their by-products cannot enter either the slaughter-and-food system, or the rendering-and-feed system. Alternative carcass disposal options, such as burial or burning on the farm, or disposal in a landfill, may be prohibited by state or federal law, or be unavailable.³⁰

The USDA expert panel (subcommittee) and full advisory committee concurred in their recommendations in the context of the downer ban (see later sections of this

²⁸ It is worth noting that such a test would determine only if prohibited species were present in the feed; it would not test for infectious BSE prions. No such prion test for feed exists.

²⁹ Comments of FDA Deputy Commissioner Lester Crawford during USDA, "Technical Briefing and Webcast with U.S. Government Officials On BSE Case," Dec. 30, 2003. This contrasts with the USDA recall of the BSE cow's meat that was sold for human consumption, in which it is believed some of the product was consumed — although USDA asserted that the meat posed an extremely low risk of danger and was being recalled out of an "abundance of caution." See also USDA, "FSIS Update Of Recall Activities," release, Feb. 9, 2004, at [<http://www.fsis.usda.gov/OA/recalls/prelease/update067-2003.htm>].

³⁰ See Jean E. Sander et al., "Selected Methods of Animal Carcass Disposal," *Journal of the American Veterinary Medical Association*, vol. 220, no. 7, pp. 1003-1005, Apr. 1, 2002, and Sparks Companies Inc, *The Rendering Industry: Economic Impact of Future Feeding Regulations*, June 2001.

report), also noting concerns about improper disposal methods. Quoting the report of the expert panel:

The subcommittee considered both the merits and the unintended consequences of the ban ... The goals for measures related to these cattle must be to (1) test them for surveillance purposes and (2) prevent potentially infective tissues from entering the food and feed chains. Given their exclusion from ... slaughterhouses, this important subpopulation may no longer be available for the BSE surveillance (program) at these locations. Therefore it is imperative that the USDA take additional steps to assure that facilitated pathways exist for dead and non-ambulatory cattle to allow for collection of samples and proper disposal of carcasses. This most likely would involve expending resources to assist with costs associated with sampling, transport and disposal.

In order to decrease the risk of these potentially infected cattle entering the normal slaughter process, supplemental measures to encourage compliance must be in place. These may range from financial incentives to a strengthening of ante-mortem inspections to identify questionable animals. To further prevent these cattle from being brought into the normal slaughter process, consideration may have to be given to the random sampling of appropriate subpopulations of aged cattle that have passed ante-mortem inspection on presentation at slaughter plant.

Congressional Role. If Congress reviews the feed ban and its role in preventing the spread of BSE in light of the finding of a BSE-positive cow in the United States, issues that it might consider could include: the effects of moving downer animals from slaughter to rendering on the safety of the feed supply; whether current oversight of the feed ban can accommodate this shift; the effect of changing market conditions that may result from the “downer” ban on the safety of both food and feed in the United States; and, processes to assure the safe disposal of animal remains as new regulations are implemented.

BSE Surveillance and Testing in Cattle

Overview. The goal of BSE surveillance is to ensure timely detection and response to cases of the disease in the United States. Because the clinical appearance of BSE is similar to other neurologic diseases, surveillance hinges on laboratory testing, including the decision of which animals to test and how many tests to conduct. Testing is hampered by the unique nature of the disease. Because it evokes no immune or inflammatory response, BSE cannot be diagnosed from blood, urine, or other noninvasive samples. And, because abnormal prions are found in abundance only in the brain and spinal cord, an animal must die or be killed to be tested.

Representatives of the USDA and some in industry have repeatedly stressed that BSE testing serves to support the surveillance program, and is not directly intended as food safety testing. Dr. Elsa Murano, USDA Under Secretary for Food Safety, has testified that the consistent removal of certain high-risk tissues from cattle at slaughter (described in greater detail in a subsequent section) is the relevant food

safety protection.³¹ For this reason, a BSE surveillance program does not have to test every animal slaughtered for food, but can instead use targeted sampling.

The U.S. BSE Surveillance Program. In 1990 APHIS instituted a surveillance program for BSE in U.S. cattle, in response to the British livestock outbreak. The program has grown steadily in scope, from a few thousand animals tested annually in the mid-1990's to about 20,000 animals each year in 2002 and 2003, out of about 35 million cattle slaughtered each year.³² The Washington state cow was the first BSE-positive animal detected by the program.

APHIS had targeted three high-risk groups of animals for surveillance: animals that die on the farm, animals exhibiting neurologic signs (including animals on the farm, at slaughter, sent for rabies testing, and submitted to diagnostic laboratories), and a sample of “downers,” animals presenting non-ambulatory at slaughter. All the groups except downers, while providing rich sample populations for screening, provided limited numbers for surveillance. The bulk of recent surveillance samples have come from the downer animals. While animals can be non-ambulatory for reasons other than neurologic disease, the sheer number of non-ambulatory animals available and concentrated at slaughterhouses, reported by USDA to be about 200,000 animals per year, offered a ready sample for targeted surveillance. USDA announced that it is weighing options to continue testing this population. These may include sampling at rendering plants (a likely new point of concentration for some “downers”), expanding on-farm outreach and testing, and offering economic incentives to encourage the submission of these animals.

Critics have argued that U.S. surveillance was inadequate to detect BSE in a timely manner, and that the positive cow found in Washington state may not be an isolated case. They propose that surveillance should approximate programs in European countries, where every adult animal is tested, or Japan, which claims to test every animal slaughtered. USDA argues that it tests many more animals than are recommended by the OIE, and that because surveillance targets animals with suspicious signs, it will detect BSE if it is present in the bovine population at a level of one in 1 million animals. (There are an estimated 96 million cattle in the United States.)

One complicating factor is that Japan — the top foreign customer — has been demanding that all cattle be tested for BSE as a precondition for again accepting U.S. beef. Some individual firms reportedly are considering whether to offer such testing in order to regain access to Japan, even though most U.S. government and industry officials believe that would be unscientific, expensive, and a bad trade precedent.

Proposals for Expanded Testing. On February 4, 2004, the Secretary of Agriculture’s advisory subcommittee of BSE experts recommended that USDA

³¹ Testimony of Elsa Murano, Under Secretary for Food Safety, USDA, before the U.S. Congress, Senate Committee on Appropriations, *Bovine Spongiform Encephalopathy (BSE)*, hearing, 108th Cong., 2nd sess., Feb. 24, 2004 (Washington: GPO, 2004).

³² Additional information on the APHIS BSE cattle surveillance program is available at [<http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>].

continue to focus its surveillance on high-risk animals, but that all such animals over 30 months of age be tested, along with a random sample of healthy animals over 30 months of age at slaughter. The subcommittee report did not state how many animals, in total, this proposal might encompass, but a USDA official estimates it at 600,000 per year. In its subsequent report to the Secretary, the full advisory committee also urged expanded surveillance but fell short of recommending that all animals of any subgroups must be tested, saying that USDA should:

Immediately develop and implement an enhanced national surveillance program for BSE to increase testing of high risk animals (cattle showing symptoms of central nervous system disease, non-ambulatory cattle, and cattle that die on farms); this action will further the scientific evaluation of risk for BSE in the U.S. and North America.³³

Prior to the finding of BSE in the United States, USDA had planned to nearly double surveillance to 38,000 animals tested per year, which was modified only slightly since the finding of BSE. The Administration's FY2005 budget proposes the testing of 40,000 animals. Since the budget proposal was released, USDA has announced that it plans to further expand the program, and will provide details of the plan in the future.

BSE Surveillance Program Costs. The cost of BSE tests and the infrastructure to support a testing program have been topics of discussion since BSE was announced in the United States. USDA currently uses immunohistochemistry (IHC), which takes at least one week to run but is the international "gold standard," or confirmatory test. The European Union has certified several commercial rapid BSE tests for use in surveillance programs. APHIS does not currently use any rapid BSE tests or certify any for commercial use, but has invited companies to submit applications for review of their test kits.³⁴

The cost of individual rapid BSE test kits has been reported to range from \$7 to \$25 per animal.³⁵ An APHIS spokesperson has said that considering overhead costs, tests could run \$25 to \$50 per animal. The USDA FY2005 budget proposal notes a unit cost per BSE test of \$425,³⁶ though this appears to have been derived merely by dividing the total surveillance program cost of \$17 million by the planned 40,000 tests. Given that the per-test cost is scalable (i.e., it depends on the number of tests performed), this estimate may be moot in light of statements subsequent to the budget release that BSE surveillance will be expanded.

³³ USDA, *Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States*, Feb. 23, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>].

³⁴ See USDA, "BSE Update," press release, Jan. 9, 2003.

³⁵ Dennis Normile, "First U.S. Case of Mad Cow Sharpens Debate Over Testing," *Science*, vol. 303, pp. 156-157, Jan. 9, 2004.

³⁶ USDA "FY2005 Budget Explanatory Notes for the House and Senate Committees on Appropriations," Feb. 2, 2005.

The Administration's proposed FY2005 budget increase for BSE includes \$17 million for BSE surveillance.³⁷ To further bolster testing capability for BSE and other threats, the budget proposal also includes \$178 million for completion of USDA animal health laboratories in Ames, Iowa.³⁸

Additional Concerns. USDA's announcement on December 30, 2003 of a ban on the slaughter of downer or non-ambulatory cattle for food is likely to have considerable impact on the BSE surveillance program. Some Members of Congress and industry representatives had previously expressed concern that "downer" bans, by removing economic incentives that brought animals into the testing program, could force this targeted surveillance population "under the radar" and compromise the nation's BSE control efforts. (The rationale for the ban, and its potential merits, are discussed below.)

On February 17, 2004, the House Committee on Government Reform held a hearing to question USDA officials and others, following a month-long investigation into the circumstances surrounding testing of the Washington state cow. The Committee Chairman and Ranking Member released a letter to the Secretary of Agriculture the same day, in which they questioned whether the cow was in fact non-ambulatory when it was selected for testing.³⁹ The investigation raises questions relevant to the design of an improved surveillance program. If in fact the animal were not a "downer," but rather an apparently healthy cow that nonetheless had BSE, is testing only abnormal animals adequate for surveillance? (Extensive testing in Europe has demonstrated that some animals can test positive without showing signs of illness.)

An affidavit from the plant owner indicates that he had initially declined to participate in USDA's surveillance program, suggesting that testing is voluntary. Can USDA conduct robust surveillance for BSE if plants can decline to participate? In November 2002, citing authority under P.L. 107-171, the Animal Health Protection Act of 2002, APHIS published a proposed rule allowing for the collection of blood and tissue samples at slaughter establishments to support disease surveillance programs, but the rule has not been finalized.⁴⁰

³⁷ USDA FY2005 Budget Summary, BSE Related Activities, Feb. 2, 2004, proposes \$17 million, an increase from \$8 million from the amount appropriated in FY2004. This excludes \$10.5 million in emergency funds transferred from the Commodity Credit Corporation to investigate and respond to the finding of BSE in December, 2003.

³⁸ See USDA, "Bush Administration Proposes Full Funding for Ames Animal Health Complex," press release, Jan. 13, 2004.

³⁹ Letter from Reps Tom Davis and Henry Waxman to Agriculture Secretary Veneman concerning "Mad Cow" Disease, Feb. 17, 2004, and related documents, available at [<http://reform.house.gov/GovReform/News/DocumentSingle.aspx?DocumentID=2497>].

⁴⁰ USDA, APHIS, "Blood and Tissue Collection at Slaughtering Establishments," proposed rule, 67 *Federal Register* 70864, Nov. 27, 2002.

Congressional Role. If Congress focuses on BSE surveillance efforts, it might be expected to review USDA proposals for enhanced BSE surveillance, including expanded outreach on farms and rendering facilities, the possible use of economic incentives for industry to ensure that targeted animals are not diverted from testing, and the scope of current USDA authority to conduct testing. Congress might also decide to consider options redefining the surveillance population, aimed at capturing other high-risk populations (such as older animals) at slaughter; to examine USDA’s proposed rule to establish a “test-and-hold” process for animals tested at slaughter, and to determine how these two measures might interact with each other and be affected by the availability and cost of different test methods.

Prevention Practices in Slaughter and Processing Instituted After the Finding of BSE: A “Fourth Firewall”?

USDA (FSIS) is responsible for safety of meat in facilities under federal inspection. In addition, under Memoranda of Understanding with FSIS, many states have programs to inspect meat for in-state sale only. State-regulated safety measures, including all BSE prevention measures, must be equivalent to those in federally-inspected plants. Therefore, all food safety measures announced by USDA to control BSE apply to state meat inspection facilities as well as federal facilities.

On December 30, 2003, USDA announced a number of new preventive measures. Since the “three firewalls” had been in place to prevent the emergence of BSE, most of the proposed new activities involve changes in meat inspection and human food safety protections, interventions believed by USDA to be unnecessary before BSE was known to be present in the United States. Officials and an advisory panel have subsequently noted that these measures, which remove all designated high-risk material from the food supply, regardless of test findings on specific animals or measures of BSE prevalence nationwide, represent the strongest actions to protect public health since the finding of BSE was announced.

Recall of Beef from the Positive Cow. On December 23, 2003, upon the announcement of a BSE-positive cow in Washington state, FSIS requested a voluntary recall of meat traced to the affected animal and others slaughtered and processed along with it.⁴¹ The agency announced that upon reviewing slaughter records for the BSE-positive cow, it had determined that high-risk materials — the animal’s brain, spinal cord and lower intestine (“distal ileum”) — had been removed at slaughter, and that the muscle meats that passed inspection posed an “extremely low likelihood that the beef contained the infectious agent that causes BSE.” Further, the agency states:

According to scientific evidence, the tissues of highest infectivity are the brain, spinal cord, and distal ileum. All were removed from the rest of the carcass at

⁴¹ USDA does not have explicit statutory authority to mandate meat recalls or to initiate recalls on its own. However, some believe that because USDA has the power to withdraw inspection, effectively keeping meat from the food supply, such mandatory authority is implied. For more information about meat inspection and slaughter practices, see CRS Issue Brief IB10082, *Meat and Poultry Inspection Issues*, by Jean Rawson.

slaughter. Therefore, the meat produced were cuts that would not be expected to be infected or have an adverse public health impact. The recall is being conducted out of an abundance of caution.⁴²

News reports indicate that some individuals already had consumed meat from the affected production lot, consisting of the positive cow and those slaughtered with it on December 9, 2003.

Ban on “Downer” Cattle. The most sweeping USDA action in response to BSE was the immediate ban on the use of non-ambulatory or so-called “downer” cattle in the food supply. “Downers” are defined as non-ambulatory or disabled animals that are unable to rise from a recumbent position or are unable to walk. USDA estimates that up to 200,000 “downer” cattle are slaughtered in the United States annually, less than 1% of roughly 35 million animals slaughtered. The action was based on the concern that animals could become non-ambulatory as a result of BSE.

The issue of whether to exclude downer animals from the food supply has received considerable attention in Congress. An amendment to the FY2004 agriculture appropriations bill (H.R. 2673), prohibiting USDA from spending any funds for the inspection of downed animals, narrowly failed in the House, but the Senate adopted an identical amendment. (Without federal or state equivalent inspection, meat from such animals could not be used for human food.) Conferees on the FY2004 agriculture appropriations measure did not adopt the Senate bill provision, so the bill, P.L. 108-199, FY2004 Consolidated Omnibus Appropriations, was signed into law without the downer ban.

Proponents of the ban have argued that downer animals pose numerous food safety hazards, not limited to BSE but including microbial hazards such as Salmonella; they have noted that some prominent fast-food chains already ban the use of these animals for the meat they accept. Opponents of the ban have expressed concern about the integrity of BSE surveillance if these animals are no longer brought to slaughter, and have questioned the scientific basis of the ban, in light of its economic impacts. (As noted earlier, USDA is exploring options to ensure that many downed animals will continue to be tested, even if they are diverted from slaughter for human food.)

Additional BSE Protections in Slaughter and Processing. Additional measures announced on December 30, 2003, include: a policy to hold meat from any animals tested for BSE until the test results are known; a ban on air-injection stunning, which is suspected to spread brain matter through the bloodstream and into meat; a ban on mechanically-separated meat, in which bones may be crushed to produce meat paste; and several provisions to keep certain high-risk materials out of the food supply, or out of Advanced Meat Recovery (AMR) systems, depending on the age of the animal. (AMR, as distinct from mechanically-separated meat, uses pressure to remove edible tissues from bone without crushing it. The resulting

⁴² USDA, “FSIS Update Of Recall Activities,” release, Feb. 9, 2004, at [<http://www.fsis.usda.gov/OA/recalls/prelease/update067-2003.htm>].

product can be labeled “meat,” and is typically incorporated into products such as hot dogs and sausages.) USDA published in the January 12, 2004, *Federal Register* three interim final rules and one notice to codify these actions, effective immediately.⁴³

One of the rules re-defines so-called “Specified Risk Materials,” (SRMs), those parts of a carcass where prions are believed to concentrate, and that are deemed inedible and cannot be inspected and passed as human food. The rule designates as SRMs, among other tissues, brain and spinal cord in cattle older than 30 months, but continues to permit such materials from younger animals (under 30 months) to be inspected and passed as human food.

Another of the rules prohibits the inclusion of certain parts in AMR meat. USDA has prohibited central nervous system tissue (brain, spinal cord and some other nerve tissues) from AMR meat in the past based on quality standards, not for food safety, but has found in tests of AMR meat that about one-third of it did contain prohibited material.⁴⁴ The GAO has asserted that, irrespective of USDA’s determinations of the safety of AMR meat, the public should be able to identify foods that may contain nervous system tissue. GAO recommended that USDA continue evaluating the safety of AMR meat, improve enforcement to keep prohibited nervous system tissue out, and consider labeling and other education efforts to advise consumers when they purchase products that may contain this tissue.⁴⁵

The USDA expert panel commented on February 4, 2004, that until a more aggressive BSE surveillance is in place, the SRM definition for parts excluded from food should be expanded, to exclude high-risk tissues from any animal older than 12 months of age (as they had also recommended for the feed ban). However, the report also included a seemingly contradictory statement that until a better understanding of BSE prevalence were established, the 30 month cut-off was “a reasonable temporary compromise.” The full advisory committee reported that the USDA action to ban SRM from animals over 30 months removed the highest-risk tissues from the food supply and was in accordance with international standards.

As part of its request for increased BSE funds, the Administration wants an increase of \$3 million in FY2005 for FSIS efforts to protect the food supply from BSE: for verification of slaughter plant designs for controlling SRMs; for testing animals that become non-ambulatory and disabled after they arrive at slaughter plants; and for increased testing of meat produced using AMR systems to help assure that SRMs are not entering the food supply.

⁴³ See also USDA, “USDA Issues New Regulations to Address BSE,” news release and related documents, Jan. 8, 2004, at [<http://www.fsis.usda.gov/oa/news/2004/bseregs.htm>].

⁴⁴ For further information on FSIS AMR standards and testing, see USDA, “Advanced Meat Recovery (AMR)” Web page at [<http://www.fsis.usda.gov/OA/topics/amr.htm>].

⁴⁵ GAO Mad Cow Disease report, p. 38.

Related Issues and Options

Animal Identification and Meat Traceability. Among the steps announced on December 30, 2003, by the Secretary of Agriculture was to “begin immediate implementation” of a national animal identification (ID) system. The Secretary added that USDA would offer its computer resources to support the system. A government-industry task force has been working voluntarily to develop the framework for such a system, which is aimed at helping authorities to determine more rapidly the origin of an animal disease outbreak and to contain it quickly. Presumably USDA now intends to expedite such a plan; a December 2003 draft did not anticipate full implementation for cattle until July 2005.⁴⁶

As noted, USDA has requested funds for animal ID as part of the President’s FY2005 budget. The Administration’s budget proposal includes \$33 million to be used to accelerate development of an animal ID system.

Many producers already keep records on the identities of each of their animals, primarily for herd management and marketing purposes. Though animals often may be identified individually as part of an animal disease program, no nationwide comprehensive U.S. animal ID system is in place.

Some observers have suggested that such a system, for example, would have enabled USDA to find more of the cows imported from Canada with the BSE cow. APHIS officials acknowledged that they had concluded their investigation of the U.S. outbreak after positively identifying only 28 of the 80 cattle that were imported with the BSE cow. “The limitations of the cattle identification system necessitated a more extensive tracing exercise than would otherwise have been necessary in order to identify the cattle to be culled in accordance with international standards, thus enabling the identification of some animals only by process of elimination,” the international panel of experts reported on February 4, 2004.⁴⁷

While most cattle and beef industry leaders appear to be supportive of an animal ID program (most major industry groups are represented on the task force), some also assert that animal ID should be viewed primarily as a potential tool in animal health and food safety assurance programs — not as another BSE preventive measure itself. Industry leaders also have pointed to a number of other policy issues that still remain unresolved, including: how much such an animal ID program will cost; how much government might contribute toward this cost; several questions regarding privacy of industry data and legal liability; and whether animal ID could or should be used for purposes besides animal disease management (also see Country of Origin Labeling, below).

⁴⁶ The U.S. Animal Identification Plan can be viewed at [<http://www.usaip.info>].

⁴⁷ USDA, *The Secretary’s Foreign Animal and Poultry Disease Advisory Committee’s Subcommittee Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, Feb. 4, 2004, at [<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>], p. 2. Earlier, the international team examining Canada’s BSE investigation also had observed that the lack of a mandatory ID system prior to Canada’s adoption of one in 2001, contributed to the need for “the extensive culling of animals.”

Conceptually, animal ID follows cattle from place of birth to the point of slaughter. That is only one segment of overall meat traceability, which extends further, generally through the marketing chain to the final consumer. Some policymakers have urged the adoption of this broader approach. For example, companion bills offered in 2003 (S. 1202 and H.R. 3546) would require USDA to establish a traceability system for all stages of production, processing, and distribution of both meat and poultry and their products, essentially from the birth of source animals to the ultimate consumer. Other pending bills that would require some type of animal ID system include S. 2007; H.R. 3714; S. 2008; H.R. 3787; S. 2070, and H.R. 3822.⁴⁸

Country of Origin Labeling. U.S. law requires most imports, including many food items, to bear labels informing the “ultimate purchaser” of their country of origin. Various raw agricultural products have been exempt. The 2002 farm bill (P.L. 107-171) requires many retailers to provide, starting September 30, 2004, country-of-origin labeling (COOL) on fresh fruits and vegetables, and unprocessed red meats, fish, and peanuts. The conference report on the omnibus FY2004 appropriation that includes USDA funding (H.R. 2673; H.Rept. 108-401) delays the effective date for mandatory COOL for two years, until September 30, 2006 (except for fish). The conference report passed both the House and Senate, and was signed into law on January 23, 2004 (P.L. 108-199).

Some Members strongly oppose this two-year delay. Among the reasons that COOL is needed, according to supporters, is that consumers have a right to know where their food is from, particularly in light of recent animal health and food safety concerns such as the two BSE cases in Canadian-born cows. COOL critics have countered that it is a thinly-disguised trade barrier intended to increase the costs of imports, and that it undermines U.S. efforts to reform world agricultural trade; moreover, they argue that, as designed, the mandatory program for industry will be extremely expensive to maintain, and might hold them legally accountable for inadvertent or minor mistakes in records.

Prior to enactment of mandatory COOL in 2002, industry leaders were seeking from USDA a voluntary program for labeling beef of U.S. origin. Although such labeling already is permitted so long as existing FSIS conditions are satisfied, presumably a newer, more specific origin program would have been more attractive to the industry.

Separately, after the May 2003 Canadian BSE discovery, Japanese officials said they would require proof, effective September 30, 2003, that beef shipped from the United States was of U.S. origin. Japan’s aim was to ensure that no products came from Canada. Hoping to satisfy Japanese (and Korean) demands, the Department unveiled in August 2003 a new “Beef Export Verification” (BEV) program as a voluntary, user-fee funded service. Exporters desiring to sell beef to Japan (or any other country that may request similar documentation) were to apply for BEV certification from USDA after satisfying a list of requirements so that the agency

⁴⁸ See CRS Report RL32012, *Animal Identification and Meat Traceability*, by Geoffrey S. Becker.

could verify that their beef is from cattle slaughtered in the United States. As noted, BEV is considered voluntary, even though at the time it was widely viewed as a minimum prerequisite for gaining access to the Japanese and perhaps other foreign markets. After the December 23, 2003, announcement of a U.S. BSE cow, Japan was among the first of what are now dozens of countries to suspend some or all imports of U.S. cattle, beef, and related products, so the future of BEV is clouded.

Observers anticipate that efforts to overturn the COOL delay could continue during the second session of the 108th Congress. For example, H.R. 3732, introduced January 27, 2004, would do so. Other proposed bills include H.R. 2270, to extend COOL to poultry and goat meat, and to exempt from coverage animals born prior to October 1, 2004; and H.R. 3083, to ease producer recordkeeping requirements and eliminate third-party audit provisions. (See also CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.)

Beef Labeled “Organic”. A USDA program, the National Organic Program (NOP), prohibits the feeding of “mammalian or poultry slaughter by-products to mammals or poultry,” if they are to be labeled “organic.”⁴⁹ Numerous news reports have suggested a safety benefit from beef grown using organic or other alternative practices, now that there has been a domestic BSE case. The NOP was developed to assure that labeling claims reflect defined and verifiable production and handling practices. USDA makes no claims that organically produced food is safer or more nutritious than conventionally produced food.

Chronic Wasting Disease. Chronic Wasting Disease (CWD), a TSE, is a fatal neurological disease of farmed and wild deer and elk in North America. CWD is generally similar to BSE, and is thought to be caused by a similar type of infectious prion protein, though CWD also differs from BSE in certain ways, including the types of tissues involved and its potential for transmission between animals in a herd.

The Centers for Disease Control and Prevention (CDC) says regarding the potential for CWD transmission to humans:

It is generally prudent to avoid consuming food derived from any animal with evidence of a TSE (a “transmissible spongiform encephalopathy,” or prion disease such as BSE and CWD). To date, there is no evidence that CWD has been transmitted or can be transmitted to humans under natural conditions. However, there is not yet strong evidence that such transmissions could not occur. To further assess the possibility that the CWD agent might occasionally cause disease in humans, additional epidemiologic and laboratory studies could be helpful. Such studies include molecular characterization and strain typing of the agents causing CWD in deer and elk and CJD (the human form of prion disease) in potentially exposed patients. Ongoing national surveillance for CJD and other neurological cases will remain important for continuing to assess the risk, if any, of CWD transmission to humans.⁵⁰

⁴⁹ 7 CFR 205.237, National Organic Program. For further information, see [<http://www.ams.usda.gov/nop/NOP/NOPhome.html>].

⁵⁰ Found at USDA APHIS, “Questions and Answers About Chronic Wasting Disease,” Sept. 2002, at [http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahcwd.html].

With regard to the potential for CWD transmission to cattle, possibly causing BSE or a related disease that could pose a food safety hazard, USDA says:

During the approximately two decades of monitoring, researchers have not found any evidence that CWD can be transmitted to domestic cattle under natural conditions. Ongoing experiments involving oral exposure and contact exposure on heavily CWD contaminated sites have not resulted in infection of cattle. These experiments, however, require additional time before they are completed. CWD has been experimentally transmitted by artificial means to mice, ferrets, mink, goats, squirrel monkeys, and calves.⁵¹

FDA prohibits the feeding of rendered deer and elk to ruminants. In addition, FDA prohibits the use of known-CWD positive animals in any animal feeds, and recommends against the use of rendered deer and elk material considered high-risk in any animal feeds.⁵²

The FY2005 budget proposal includes a \$1 million increase (to \$20 million) for APHIS BSE control programs. Proposed FDA programs for CWD control, slated to come from the funding base for its food programs, include research on the risk factors and mechanism for CWD. Additional FDA activities to strengthen the feed ban may include CWD control measures as well. Several bills to increase support for research and surveillance on CWD have been introduced in the 108th Congress, including H.R. 2057; H.R. 2430; H.R. 2431; H.R. 2636, and S. 1036.

Feline Spongiform Encephalopathy. Feline Spongiform Encephalopathy (FSE) was first identified in cats in Britain in 1990, and is believed to result from eating BSE-affected beef. When brain tissue from cats with FSE was inoculated into mice, the pattern of incubation periods and lesions in the mice was indistinguishable from that produced by BSE. There have been 87 cases of FSE diagnosed in the U.K., and a few in continental Europe.

The FDA feed ban both prior to and since the announcement of enhanced safeguards in January, 2004, permits beef by-products in U.S. commercial cat food (which is technically regulated as “feed”). Since the finding of BSE in the United States, some have expressed concern about the welfare of cats, and others about the fact that people have been known to eat cat food.

The Cornell Feline Health Center comments that “the risk of BSE-contaminated pet food is very small indeed,” for the following reasons: none of the rendered by-products from the BSE-positive cow were released into distribution; imports of rendered products prohibited from cattle feed but intended for pet food must originate from countries free of BSE; and, imports of pet food may not contain mammalian-derived material.⁵³

⁵¹ Ibid.

⁵² FDA, *Guidance for Industry #158: Use of Material from Deer and Elk in Animal Feed*, Sept. 15, 2003, at [<http://www.fda.gov/cvm/guidance/published.htm>].

⁵³ Cornell Feline Health Center, “Mad Cow Disease and Cats,” Feb. 25, 2004, at [<http://web.vet.cornell.edu/Public/FHC/madcow.html>].