

BSE among cattle consuming that feed. There is also a possibility that animal feed containing a TSE agent from the rendered protein of one species (e.g., scrapie in sheep) could cause development of disease in animals of another species consuming that feed (e.g., cause BSE in cattle). This is, in fact, the leading theory for how BSE originated in the United Kingdom.

Given this situation, the Animal and Plant Health Inspection Service (APHIS) wants to take steps to limit the potential pathways through which BSE could spread in U.S. animal populations, in case it is introduced despite efforts to keep it out of the United States.

#### *TSE Disease Surveillance*

Data from APHIS animal disease surveillance programs can be used to detect occurrences of disease, provide information for better policy decisions, and better understand the diseases. Most surveillance programs are based on data from live-animal tests; however, since such tests are generally unavailable for TSE's, in this area APHIS generally relies on observation of animals exhibiting signs of TSE's and tissue samples from dead animals. Since 1990, animals targeted for BSE surveillance by APHIS include cattle exhibiting signs of neurological disease in the field (i.e., prior to being brought to slaughter), cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories,<sup>3</sup> neurologic cases submitted to veterinary diagnostic laboratories and teaching hospitals, nonambulatory cattle ("downer cattle") over 24 months of age at slaughter, and adult cattle dying from unknown causes on farms. The primary reason we target downer animals is that surveillance data from European countries in which BSE has been detected indicate that downer cattle have a greater incidence of BSE.<sup>4</sup> If BSE enters the United States, downer

cattle testing programs are likely to first reveal it.

APHIS' current approach to BSE surveillance takes into account regional differences in the movement of animals, i.e., surveillance is scaled to take into account where most cattle are raised and where they are slaughtered. On this basis the United States is divided into eight regions<sup>5</sup> for BSE surveillance. For years, APHIS has calculated regional surveillance goals for BSE to exceed international standards recommended by the Office International des Epizooties, the world organization for animal health. APHIS continues to increase postmortem testing for BSE, with more than 19,990 cattle samples tested in fiscal year 2002 up from 5,200 during fiscal year 2001. Overall, our surveillance program targets the segment of the cattle population where BSE would most likely be found if it were to occur, i.e., downer animals and dead stock.

#### *Limiting Possible Pathways for Spread of BSE*

By their nature, downer animals and dead stock include many animals dead or dying from communicable diseases. They therefore represent a significant pathway for spread of disease if they are not handled or disposed of with appropriate safeguards. Over time, USDA and industry have developed methods to mitigate, if imperfectly, the risks presented by dead stock and downer animals affected by the older, better-known animal diseases.

With regard to limiting the potential pathways through which BSE could spread in U.S. animal populations if it were introduced, we believe that dead stock and downer animals represent the most significant potential pathway that has not been addressed in previous efforts to reduce BSE risks. The remainder of this advance notice of proposed rulemaking discusses why we think this is so and identifies topic areas

where we are seeking more information in order to develop rulemaking on the subject of dead stock.

#### *The Harvard Risk Analysis*

In April 1998, in order to better characterize the potential for BSE to be introduced and spread in the United States, and the potential threat to human health should this happen, USDA commissioned the Harvard Center for Risk Analysis to conduct a risk analysis (referred to below as the Harvard study). The Harvard study was completed and released on November 30, 2001.<sup>6</sup> The summary of the Harvard study stated its findings that the United States is highly resistant to any introduction of BSE or a similar disease. It also found that BSE is extremely unlikely to become established in the United States, and if introduced, it is likely to be quickly eliminated following its introduction.

The Harvard study investigated potential pathways by which BSE or other TSE's could enter U.S. cattle populations, using a quantitative simulation model to characterize how the introduction of BSE would spread over time, and the extent to which it could result in human exposure to contaminated food products. The study's model quantified some aspects of BSE's potential progress if introduced into the United States—e.g., the number of animals that would be infected over time, and the resulting quantity of the BSE agent in food that would potentially be available for human consumption—but it did not quantify the probability that BSE will be introduced, nor did it estimate how many people would contract vCJD if BSE were introduced. The study omitted quantitative treatment of both of these issues because the available information is inadequate.

The Harvard study has helped APHIS identify those risk management control options that most influence the introduction and spread of disease, and to identify those sources of uncertainty that have the greatest impact on our programs to control BSE risks. This information can be used to help identify the most important control measures and to prioritize data collection and research efforts.

The Harvard study finds that the United States is highly resistant to the introduction of BSE. In addition, should BSE occur in this country, measures taken by government and industry make

<sup>3</sup> We test rabies-negative cattle because these animals often have clinical signs that could be consistent with BSE. If the public health tests show the animal does not have rabies, the samples may be forwarded to APHIS for BSE testing.

<sup>4</sup> For instance, surveillance in Germany in 2001 showed that animals subjected to normal slaughter had a BSE incidence of 0.002 percent, while fallen animals (in the United States, these would be called dead stock, or animals not presented for slaughter for human consumption) had an incidence of 0.02 percent, and emergency slaughters (in the United States, animals presented for slaughter for human consumption and found to show signs of neurological illness) had an incidence of 0.48 percent. "Final Report of a Mission Carried Out in Germany from 28/05/2001 to 01/06/2001 in Order to Evaluate the Implementation of Protective Measures Against Bovine Spongiform Encephalopathy," available at [http://europa.eu.int/comm/food/fs/inspections/vi/reports/germany/vi\\_rep\\_germ\\_3302-2001\\_en.pdf](http://europa.eu.int/comm/food/fs/inspections/vi/reports/germany/vi_rep_germ_3302-2001_en.pdf).

<sup>5</sup> These divisions were established essentially for epidemiological surveillance reasons and are not intended for the purposes of Chapter 1.3.4 of the International Animal Health Code, i.e., "defining geographical areas of different animal health status within its territory for the purpose of international trade." The regions were established because State-by-State reporting did not provide very useful data, and caused underestimation and overestimation of States' cattle populations, due to the common practice of moving cattle interstate for feeding and slaughter. Often an animal actually comes from one state (e.g., New Jersey) but is slaughtered in another state (e.g., Pennsylvania), so therefore slaughter surveillance on a State-by-State basis would report the animal as originating from Pennsylvania. To make our estimations and calculations as scientifically sound as possible, we changed to a regional system, with States grouped into regions based on typical animal populations and their movement to regional slaughterhouses.

<sup>6</sup> Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States; Harvard University and Tuskegee University, November 26, 2001. Available at <http://www.aphis.usda.gov/oa/bse/>.