

the United States robust against the spread of BSE to animals or humans.

The report identified three pathways or practices that could contribute most either to increased human exposure to the BSE agent or to the spread of BSE if it should be introduced into the United States. The three pathways are:

- Noncompliance with the FDA feed ban, including misfeeding on the farm and the mislabeling of prohibited feed and feed products;
- Inclusion of high risk material, such as brain and spinal cord, in edible products;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed.

FDA and FSIS are taking action to address the first two pathways. FDA is enhancing its enforcement of the feed ban and is evaluating whether further rulemaking is needed. FSIS published a notice in the **Federal Register** on January 17, 2002 (67 FR 2399, Docket No. 01-027N) announcing the availability of a BSE Current Thinking Paper that discusses measures that it is considering implementing to minimize human exposure to bovine materials that could potentially contain the BSE agent. Measures under consideration by FSIS include prohibiting certain high risk materials, such as brain and spinal cord, from specified cattle for use as human food and prohibiting the incorporation of CNS tissue in boneless beef products, including meat from advance meat recovery (AMR) systems. Commenters on this advance notice of proposed rulemaking may wish to explore whether there are cross-cutting issues between safe disposal of these specified risk materials and safe disposal options for downer and on-farm dead animals.

Because APHIS has primary authority⁷ for animal disease risks

⁷ Generally, APHIS does not directly regulate businesses engaged in animal disposal through rendering, incineration, burial, or other methods. However, such businesses could be affected if APHIS regulates how the owners of animals may move or dispose of dead stock; e.g., disposal businesses could choose to alter their practices to provide the types of disposal APHIS requires the owners of animals to employ. See the Animal Health Protection Act of 2002 (Subtitle E of the Farm Security and Rural Investment Act of 2002, Pub. L. 107-171). Section 10406 states that the Secretary of Agriculture may prohibit or restrict "the movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock." Section 10409 states that the Secretary "may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock * * * including animals at a slaughterhouse, stockyard, or other point of concentration."

posed by both live and dead animals on the farm, including matters where carcass disposal may pose animal health risks, APHIS is publishing this advance notice of proposed rulemaking to open discussion concerning the third pathway, rendered material from animals that die on the farm and its possible inclusion in ruminant feed. We are publishing this notice to fulfill the Secretary's statement, upon release of the Harvard study, that "USDA will publish an advance notice of proposed rulemaking to consider disposal options for dead and downer animals, because such cattle are considered an important potential pathway for the spread of BSE in the animal chain."

The Harvard study considers dead stock to be an especially significant potential pathway for BSE. The base case for the Harvard study's model examined what would happen if 10 animals infected with BSE were imported into the United States, assuming current Government regulations and controls are in place. In this scenario, it could be likely that one or more of these animals will succumb to the disease on the farm, or become sick enough to be killed rather than sent to slaughter. The worst possible outcome at this point in the scenario would be for an animal with BSE to be rendered, and for the rendered product to be mixed into ruminant feed (in violation of the FDA feed ban). Rendering an animal that has reached the clinical stage of BSE introduces the maximum amount of infectivity into rendering and potentially into feed. This could result in many more cattle contracting BSE through consuming that contaminated feed, or consuming feed that was cross-contaminated during production or storage, if the feed ban was violated.

The Harvard study's model estimates that keeping this from occurring, by prohibiting the rendering of animals that die on the farm or by ensuring that no rendered product from such animals is ever mixed with ruminant feed, would greatly reduce the potential for contamination in the animal feed chain and reduce the average predicted new cases of BSE following introduction of 10 infected cattle from 2.9 new cases to 0.68 new cases. The Harvard study found that safely disposing of on-farm dead livestock is predicted to greatly reduce BSE spread due to the high levels of BSE agent expected in animals that die from BSE on the farm. It is important to keep such animals from directly entering animal feed chains (e.g., through using rendered products derived from them in feed), and it is important to dispose of their carcasses

in ways that keep other livestock and wildlife from contacting them.

Note that the Harvard study by design considered risk factors for BSE one at a time, not in combination. In other words, the prediction that keeping rendered dead stock out of ruminant feed would lower new cases of BSE following introduction of 10 infected cattle from 2.9 to 0.68 new cases does not take into account the marginal and cumulative effects of other BSE risk reduction activities. Other actions by Federal agencies and industry—e.g., more effective enforcement of the feed ban and import restrictions applied to countries with BSE—will also be acting to mitigate BSE risks, to a cumulative degree not calculated by the Harvard study.

The Harvard study suggests prohibiting rendering of dead stock as one way to mitigate this risk, but it does not go on to evaluate the associated negative effects such a policy could have on preventing the spread of BSE and other diseases. Eliminating rendering as a disposal option for dead stock would mean owners would have to find other disposal options, many of which pose their own risks of spreading disease. These risks are discussed later in this document.

Issues in Disposal of Downer Cattle and Dead Stock

Downer Cattle

Downer cattle—animals that cannot rise from a recumbent position due to injury or illness—may be sent for slaughter at plants inspected by FSIS.⁸ Sometimes the FSIS antemortem inspection reveals that the downer animal clearly is affected by a particular disease, but more often diseases are revealed only when characteristic lesions (e.g., of tuberculosis, swine erysipelas, or infectious anemia) are seen within the carcass after slaughter. However, TSE diseases do not cause grossly observable lesions, so FSIS inspectors instead observe the live downer animals for signs of a CNS disorder. FSIS has the lead role in ensuring that downer cattle presented for slaughter that exhibit clinical signs of BSE are diverted from slaughter. Cattle with clinical signs of a CNS disorder and cattle that died otherwise than by slaughter are already prohibited from use as human food. All downer cattle presented for slaughter are

⁸ Any FSIS-inspected facility may slaughter downer cattle if the animal passes ante mortem inspection. Although some slaughter facilities will not accept downers for slaughter, FSIS does not restrict or approve where downers may be slaughtered.