

### *Epidemiological Investigation*

Canada conducted an extensive epidemiological investigation after the one case of BSE in May 2003. This investigation included detailed tracebacks to identify possible herds of origin of the infected animal, traceforwards from the infected herd, and traceforwards of any possible feed or rendered material derived from the carcass of the infected animal. Fifteen premises were quarantined as part of the traceback and traceforward investigations, and cattle on the quarantined premises were slaughtered. Additionally, cattle that were determined to have moved from a quarantined herd to another herd were slaughtered.

The investigation included any possible exposure from the use of rendered material or feed that could have been derived from the carcass of the infected cow. Using a broad definition to include all possible exposures, the rendered material could have been distributed to approximately 1,800 sites, including sites with no ruminants. These included 600 facilities that receive bulk shipments of either rendered protein or feed, and 1,200 individual producers or consumers who purchased finished feed by the bag. A survey was conducted of those entities that were at some risk of having received such rendered material or feed. This survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle (96 percent of the sites) to the feed or only incidental exposure (3 percent of the sites). The remaining 1 percent represented limited exposures, such as cattle breaking into feed piles, sheep reaching through a fence to access feed, and a goat with possible access to a feed bag.

The investigation included a consideration of several possibilities for the source of the infected cow's exposure to BSE. Although it has not been confirmed, it is assumed, based on the age of the cow, that the infected cow was exposed through contaminated feed. The infected animal was born prior to the implementation of a feed ban within Canada and could have had exposure to contaminated feed at an early age.

The renderers and feed mills associated with the investigation had records of good compliance with the feed ban. The on-farm inquiries demonstrated a very small probability of exposure of ruminants to prohibited feed. Although the possibility exists that the original source of the BSE agent could have been imported, there was no evidence that this was due to an illegal

import. The BSE agent could have been from animals imported from the United Kingdom prior to import restrictions established in 1990. The surveillance program was sufficient to confirm the continued existence of adequate measures to prevent further introduction or spread of BSE.

### *Additional Risk Mitigation Measures*

Following the detection of BSE in Canada, a broad eradication program was followed during the epidemiological investigation, in which more than 2,700 head of cattle were culled. As part of the culling activity, more than 2,000 animals 24 months of age or older were tested (those animals less than 24 months of age were not tested), with no further evidence of BSE found in any of these animals.

### **Importation of Ruminant Commodities From a BSE Minimal-Risk Region**

Because we believe regions, such as Canada, that qualify as BSE minimal-risk regions based on the factors described above, would pose a minimal risk of introducing BSE into the United States, we believe it is warranted to allow the importation from such regions of some animals and animal products and byproducts that are prohibited importation from regions in which BSE exists and regions that present an undue risk of BSE. However, because BSE is a difficult disease to define experimentally with precision, epidemiological evidence suggests that risk factors are specific to the commodity, and multiple risk sources may be associated with a given commodity, we believe it is necessary to also apply individual risk mitigation measures to specified commodities intended for importation from BSE minimal-risk regions.

For example, as noted above and discussed further below, contaminated feed appears to be the most likely pathway of BSE transmission. However, it has not been established with certainty that contaminated feed is the only pathway. Furthermore, we cannot assume complete compliance with a ban on the feeding of ruminant protein to ruminants, which is the most effective mitigation for contaminated feed. Therefore, we believe it is necessary to apply certain other mitigation measures, in addition to implementation of a feed ban, to reduce the risk of the introduction of BSE into the United States. Each of these proposed mitigation measures is discussed below.

We are proposing to add the conditions for importing specified ruminant commodities from a BSE minimal-risk region to the regulations in

9 CFR parts 93, 94, and 95. The measures appropriate for specific commodities intended for importation would be determined by the presence or absence of factors that make it more or less likely the commodity might be contaminated or infected with the BSE. These factors are discussed in the following paragraphs.

### *Feed Source and Exposure*

Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE.<sup>3</sup> Thus, animals that have not ingested contaminated feed are unlikely to harbor the agent, so feed exposure influences risk. Animals, and the products derived from those animals, are unlikely to have infectious levels of the agent and will present a lower risk if the animals were (a) born after the implementation of an effective feed ban or (b) not fed risk material (e.g., wild animals or farmed animals that are not fed feeds containing meat-and-bone meal).

The risks associated with feed source and exposure can be mitigated by accepting for import only animals or products derived from animals that have not been fed commercial feed that is likely to be contaminated with infectious levels of the agent.

### *Animal Age*

Levels of infectious agent in certain tissues vary with the age of an animal, so the age of the animal influences risk. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have illustrated this.<sup>4</sup> Infectivity was not detected in most tissues until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was

<sup>3</sup> Prince, M.J., *et al.*; 2003; Bovine Spongiform Encephalopathy; Rev. sc. tech. OIE; 22 (1), pg 37–60.

Wilesmith *et al.*; 1988; 1991; 1992.

<sup>4</sup> Wells, G.A.H., *et al.*; 1994; Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy; Veterinary Record; 135 (2), pg 40–41.

Wells, G.A.H., *et al.*; 1998; Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): An update; Veterinary Record; 142, pg 103–106.

European Union Scientific Steering Committee (EU SSC), 2002; Update of the opinion on TSE infectivity distribution in ruminant tissues (initially adopted by the Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection, Food, and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.