

International des Epizooties (OIE) in its recommendations for a BSE minimal-risk country or zone. (The OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control.)

For example, according to OIE recommendations, a ban on the feeding of ruminant protein to ruminants should have been in place for a minimum of 7 years for a region to meet the criteria for BSE minimal risk, even though there is a significant level of variability in current estimates of the BSE incubation period, which should govern the recommended length of time of an effective feed ban. According to this criterion, a region could fail to be classified as a BSE minimal-risk region because it had not had a feed ban in effect for the precise period of time specified, even if it has excelled in surveillance and control mechanisms. We believe it is more appropriate to evaluate the overall combined effect of the factors described below when assessing the BSE risk level of a region.

#### **Definition of Bovine Spongiform Encephalopathy Minimal-Risk Region**

We propose to define *bovine spongiform encephalopathy (BSE) minimal-risk region* in § 94.0 to mean a region that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- a. Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

- b. Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and

- c. A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation

measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

Each element of this definition is explained below.

1. *The region maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease.*

This factor is important in determining those regions in which a BSE outbreak is unlikely to occur, or, if an outbreak does occur, in which it is likely to be limited. If a region maintains controls designed to minimize BSE introduction or exposure of animals, and, in those regions where BSE has been detected, if the region had such controls in place at the time of detection, it is more likely to present minimal risk than a region that does not have such controls in place. According to our definition of a BSE minimal-risk region, such measures would include importation restrictions, surveillance, and a feeding ban, as follows:

- 1a. *Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE.*

This factor addresses whether the region faces a high risk of initial or recurrent BSE outbreaks from multiple importations of animals or products that may spread BSE. In those regions in which BSE has been detected, it addresses whether the region's BSE outbreak was more likely the result of a point failure in its import controls or possible exposure prior to the implementation of such import controls. Because the incubation period for BSE is generally measured in years, the finding of a case of BSE reflects an exposure that occurred several years in the past.

A region that has prohibited the importation of high-risk animals and products from regions that are affected with or pose an undue risk of BSE will have minimized its possible exposure to the disease. Conversely, a region that continues to import high-risk commodities until a case of BSE is diagnosed has continued exposure and presents a more significant risk. Whether commodities are considered low-risk or high-risk can be based on the commodities' inherent lack of risk, the low risk level of the exporting region,

and/or controls on the movement and use of the commodities after entry.

- 1b. *Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE.*

This factor addresses whether BSE outbreaks are or would be likely to be quickly and reliably identified in a region, helping support a minimal-risk designation, or whether lack of effective surveillance suggests the possibility that BSE-infected animals may be overlooked and the scale of a BSE problem may be greater than is officially recognized.

As noted above, the OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control. The OIE Code provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country.

- 1c. *A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.*

The primary source of BSE infection appears to be feed contaminated with the infectious agent. Scientific evidence<sup>1</sup> shows that feed contamination results from the incorporation of ingredients that contain ruminant protein derived from infected animals. Standard rendering processes do not completely inactivate the BSE agent. Therefore, rendered protein such as meat-and-bone meal derived from infected animals may contain the infectious agent. Bans prohibiting incorporation of mammalian or ruminant protein into ruminant feed are imposed to mitigate risk.

This factor distinguishes between regions with effective feed bans and those without them. In a region in which BSE has been detected, if an animal with BSE was born after a feed ban was implemented, it is a sign that the feed ban may not be effectively enforced.

2. *In a region in which BSE has been detected, the region conducted an*

<sup>1</sup> Wilesmith, J.W., Wells, G.A.H., Cranwell, M.P., and Ryan, J.B.M.; 1988; Bovine spongiform encephalopathy; epidemiological studies; Veterinary Record; 123, pg 638-644.

Wilesmith, J.W., Ryan, J.B.M., and Atkinson, M.J.; 1991; Bovine spongiform encephalopathy; epidemiological studies of the origin; Veterinary Record; 128, pg 199-203.

Wilesmith, J.W., Ryan, J.B.M., and Hueston W.D.; 1992; Bovine spongiform encephalopathy: Case control studies of calf feeding practices and meat-and-bone meal inclusion in proprietary concentrates; Res Vet Sci; 52, pg 325-331.