Sample Size Estimate for BSE Ongoing Surveillance

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Purpose, rationale, and objectives of surveillance

Animal and public health concerns about bovine spongiform encephalopathy (BSE) have led to the establishment of active surveillance programs among other regulatory measures to monitor and prevent disease. Active surveillance for BSE was initiated in the United States in 1990. In response to identification of a BSE-affected imported dairy cow in December 2003, the U.S. Enhanced BSE Surveillance Program was implemented in June 2004. Through these efforts, two cases of BSE were identified through March 2006. Both cases were in beef cattle over 10 years old (born before the feed ban of 1997), one located in Texas and one in Alabama.

Based on data collected in the United States over the last 7 years, including over a half million samples from the Enhanced Surveillance program, the USDA has developed an estimate of prevalence of BSE among U.S. cattle that was extremely low, projected at less than one case per million animals in the standing adult cattle population at the 95 percent confidence level (APHIS 2006a). In addition, the USDA demonstrated that surveillance efforts to date far exceed the World Organization for Animal Health (OIE) "type A" surveillance recommendations. Prevalence is expected to decline as long as mitigation efforts that maintain low risk for introduction and spread of the BSE agent among U.S. cattle are equivalent to or better than those evaluated by the Harvard Risk Assessment (Cohen et al., 2001, 2003).

The principal purposes of ongoing BSE surveillance are:

1. To continue to monitor the BSE status of U.S. cattle.
2. To provide mechanisms for detection of BSE prevalence if it were to increase above 1 infected animal per million adults.

In addition, we aim to meet the objective of conducting ongoing surveillance at a level that meets or exceeds OIE surveillance recommendations. We believe this objective is reached by the following sampling strategy, which is sufficient to detect BSE at 1 infected animal per 1,000,000 adult cattle in the population with a high degree of confidence.

Sample Size to Meet OIE Surveillance Recommendations

APHIS is committed to maintaining BSE surveillance that at least meets OIE guidelines. The OIE surveillance guidelines for BSE recommend a target number of surveillance points for Type A surveillance based on the size of a country's cattle population. These points are accrued over 7 consecutive years, and are weighted according to the surveillance stream and age of the animal sampled. For a large cattle population, using the design prevalence of 1 case per 100,000 adult cattle and 95 percent confidence, 300,000 total points over 7 years, or 42,857 points per year, are required for Type A surveillance (OIE 2005).

The four surveillance streams identified in the OIE Code are clinical suspects; casualty slaughter; fallen stock; and healthy slaughter. OIE guidelines recommend sampling from at least three of the four surveillance streams. BSE surveillance efforts in the United States have always focused on the three surveillance streams where BSE is more likely to be found – clinical suspects, casualty slaughter, and fallen stock. During the 7 consecutive years prior to March 17, 2006, the United States collected 735,213 BSE samples from these surveillance streams and accumulated 2,973,804 OIE points (APHIS 2006b).

As shown in the calculation below, if the ongoing surveillance plan continues similar sample numbers from these surveillance streams, approximately 10,500 cattle per year would be sufficient to meet the OIE minimum number of sample points for Type A surveillance.

$$2{,}973{,}804 \text{ points} \div 735{,}213 \text{ samples} = 4.1 \text{ points per sample}$$

and

$$42{,}857 \text{ points required per year} \div 4.1 \text{ points per sample} = 10{,}453 \text{ samples per year}$$

Sample Size for BSE Prevalence Estimates

The OIE minimum number of samples as outlined would be sufficient for a design prevalence of 1 case per 100,000 adult cattle. However, in the interest of maintaining confidence in previous BSE prevalence estimates, a more sensitive design prevalence of 1 case per 1 million adult cattle will be adopted for ongoing surveillance. The BSurvE model (Wilesmith et al., 2004) can be used to help estimate the number of samples necessary to achieve this level of detection. This model determines sample point values based on a particular population's demographics.

The point tables described by OIE surveillance guidelines were designed using the BSurvE model to represent a conservative scenario (e.g., low point value and greater number of samples) of the characteristics of the cattle populations of all of its member countries. These demographic characteristics describe a hypothetic population that culls cattle very rapidly (mean age of approximately 4 years) and results in point values that are lower than the BSurvE model would calculate for cattle in most countries. In the United States, however, demographic data indicate 25 percent of the adult cattle population of approximately 42 million are dairy production type and 75% are percent beef cattle (NASS 2005). While the U.S. dairy population undergoes rapid culling similar to the characteristics used to develop the OIE table, beef cattle generally remain in the herd to a much older age until they no longer produce calves.

Because actual U.S. data are available regarding population characteristics, it is appropriate to base the sample size estimates on the points calculated through BSurvE given U.S. demographics (these points are hereafter referred to as "analytical points"). The higher average age at which beef cattle are culled influences the BSurvE output and results in substantially higher point values. Hence, sample values calculated with

BSurvE from actual U.S. data result in higher point values than the conservative OIE estimates. Each analytical point calculated by BSurvE corresponds to a single non-targeted sample (Wilesmith et al., 2004).

According to OIE, BSurvE and Cannon and Roe (1982) calculations, the required number of non-targeted samples needed to detect a prevalence of 1 case per million adult cattle with 95% confidence (given a population size of 42 million adult cattle) is 3,000,000, 2,995,730, and 2,891,389, respectively. Conservatively using the value of 3 million, we calculate that we will need to accumulate 428,571 analytical points (with negative results) per year across a period of 7 years to meet this objective.

$$3{,}000{,}000 \text{ analytical points} \div 7 \text{ years} = 428{,}571 \text{ analytical points per year}$$

The prevalence analysis conducted on U.S. surveillance data collected from March, 1999 through March 2006 reports 6,745,010 points resulting from 735,213 samples. The average sample was worth 9.5 analytical points.[1]

$$6{,}745{,}010 \text{ analytic points} \div 735{,}213 \text{ samples} = 9.5 \text{ analytic points per sample}$$

If USDA maintained an equivalent mix of surveillance streams during ongoing surveillance, then approximately 45,113 samples per year would be required to meet this objective.

$$428{,}571 \text{ analytical points per year} \div 9.5 \text{ analytical points per sample} = 45{,}113 \text{ samples per year}$$

However, greater than one half million of the samples from Enhanced Surveillance were collected from fallen stock – the surveillance stream that produced the lowest point values. Sampling efforts can be focused on higher value surveillance streams – clinical suspects and casualty slaughter – with a limited number of samples obtained from the fallen stock surveillance stream. This will substantially increase the average point value per sample. Therefore, we estimate that 40,000 samples collected from these three surveillance streams – with a focus on clinical suspects and casualty slaughter - will exceed the number of points necessary to maintain confidence that prevalence is less than one infected animal per million adult cattle. Further, since the data are analyzed over 7 consecutive years, the estimate of sample size may be adjusted each year as appropriate to assure a robust prevalence estimate.

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