In an effort to be as transparent as possible, USDA is providing answers to some common questions about the surveillance plan and the data that it will generate. A more detailed discussion of these issues is available at

http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf.

# What is the purpose of the enhanced BSE surveillance program?

The goal of the enhanced surveillance program is to test as many cattle as possible in the targeted population for BSE. The data obtained will be used to help determine parameters around the prevalence level of BSE in the United States. These prevalence estimates will allow USDA to determine whether risk-management policies currently in place are adequate or need to be changed.

## What assumptions or estimations were made in developing the surveillance plan?

USDA made certain assumptions and estimates in order to develop a feasible surveillance plan. Historical evidence has shown that BSE is more likely to be found in the targeted population – those animals exhibiting some type of clinical signs. USDA used this evidence and made the assumption that all cases would be found in the targeted population for the purpose of formulating a surveillance plan. In order to set goals for testing levels, USDA also estimated how many animals were in this targeted population. Data from multiple sources was used to develop the estimate, including foreign animal disease investigations and slaughter data from the Food Safety and Inspection Service.

### How did USDA choose its target population?

USDA has conducted an active BSE surveillance program in the United States since 1990. To design its surveillance activities, USDA examined historical evidence in Europe, focusing on the population where the disease is most likely to be found, if it is present. The targeted population has evolved over time as more is learned about BSE. In 1990, USDA's surveillance focused on animals reported as exhibiting either signs of a central nervous system disorder or classical clinical signs of BSE. In 1993, the program was expanded to include samples from non-ambulatory animals, and in 2001 the program was again expanded to include samples from animals that had died from unknown causes. While USDA understands that the disease is not necessarily limited to animals in this population, it is believed this is the population where the disease is most likely to be found, if it is present.

### How much of the U.S. cattle population fits the target population description?

The estimated adult cattle population in the United States is 45 million, with an estimated 446,000 of those animals fitting the targeted high-risk category. This means the target cattle population is approximately 1 percent of the overall cattle population.

## Why has USDA assumed that all BSE cases would be in the targeted population?

The assumption that all the cases would be found in the targeted population was a qualifying assumption made for purposes of designing a surveillance plan. Experience in Europe has demonstrated that targeting surveillance efforts at certain, high-risk populations is the most effective way to identify BSE if it is present. One way to explain this approach is that we are biasing our sampling toward the population where we are most likely to find the disease, thus helping to ensure that if disease is present at a certain level it will be detected. This approach is not necessarily limited to BSE – similar concepts are used in many disease control programs such as the brucellosis eradication program. In the case of BSE, the population in which we are most likely to find disease are adult animals that demonstrate some clinical abnormality that could be consistent with BSE, and therefore this is the population we continue to target in our surveillance.

Targeting the population where disease is most likely to be diagnosed, if it is present, is the most efficient way to approach surveillance. This approach requires fewer samples to reach similar conclusions, because it is based on the assumption that if you cannot find disease in the targeted, or most likely, population (i.e, animals with some type of clinical signs), it will be even more unlikely to be found in the non-targeted population (i.e., clinically normal animals). This approach has been evaluated and supported by Harvard, the International Review Team, and is consistent with OIE guidelines.

For a more detailed discussion about this topic, including statistical implications of the assumptions and data collected under the surveillance plan, see <a href="http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf">http://www.aphis.usda.gov/lpa/issues/bse/BSEOIG.pdf</a>.

#### Will the surveillance program provide prevalence data?

The enhanced surveillance program will provide data that will assist USDA in any estimations of prevalence specifically within the targeted cattle population. The data would need to undergo further calculations to extrapolate any information about the entire cattle population. There are ways to estimate prevalence rates applicable to the broader populations, but these methods have their limitations. USDA is considering which, if any, of these approaches would be used at the conclusion of the surveillance plan to estimate BSE prevalence.

#### Is the program a random sampling?

No. Truly randomized sampling means that every animal in the target population must have an equal chance of being selected for sampling. USDA is testing as many cattle as possible from the target population.

USDA is working hard to ensure appropriate access to all aspects of the target population. As part of the enhanced surveillance program, USDA is reaching out to producers, renderers, slaughter facility operators, and others to encourage participation from all levels of industry. Initial surveillance data in June and July 2004 suggest that we are maintaining appropriate access to the target population.

#### Why is the program voluntary?

The majority of USDA's enhanced BSE surveillance program is voluntary in nature. The exception is that collection of samples from cattle condemned prior to slaughter is mandatory. An entirely mandatory surveillance program would have required federal rule-making and would have inhibited implementation.

In order to reach the appropriate level of testing, USDA has built upon previous cooperative efforts with producers, renderers and others to obtain samples from the targeted populations. Initial testing levels indicate that the voluntary program is effective; an appropriate number of samples are being collected from different categories of cattle and a variety of testing sites.