USDA BSE Surveillance Plan: Background On Assumptions and Statistical Inferences

1. Surveillance history

Active surveillance for BSE has been conducted in the United States since 1990. Initially, surveillance was conducted by testing brain samples obtained from animals reported as exhibiting either central nervous system signs or classic clinical signs of BSE. In 1993, the surveillance was expanded to include samples obtained from non-ambulatory animals. This approach, criticized internationally as excessive at that time, was implemented to address concerns that an unrecognized TSE of cattle might exist in the US cattle population. In 2001, in response to the findings in the initial Harvard risk assessment, the surveillance program was again expanded to include additional samples obtained from animals that had died for unexplained reasons.

Total BSE tests conducted, fiscal year basis

Fiscal year	Total tests
1990	40
1991	175
1992	251
1993	736
1994	692
1995	744
1996	1,143
1997	2,713
1998	1,080
1999	1,302
FY 2000	2,681
FY 2001	5,272
FY 2002	19,990
FY 2003	20,543
FY 2004 ** Partial year, through May 2004	17,121

In 2001, a goal was established to detect one BSE-infected animal in a population of a million adult cattle. Given that the United States has an adult cattle population of approximately 45 million, if BSE were present in this cattle population at the one in a million level, we could assume that we would have 45 infected animals. To achieve a 95 percent confidence level in detecting at least one case from a random sample of adult cattle, we would have to randomly sample and test approximately 3 million animals from the population of 45 million.

However, based on the assumption of negligible detectable presence of BSE in the normally appearing adult cattle population, USDA has focused on a subset of the cattle population more likely to have BSE if it exists in the United States – adult cattle exhibiting some type of clinical sign that could be considered consistent with BSE. This allows us to conduct more efficient, targeted, and effective surveillance. At that time,

non-ambulatory cattle were defined as the primary targeted high-risk population. This definition was based on the surveillance experience of European countries that have BSE. Their experience and testing schemes have proven non-ambulatory cattle to be an appropriate and efficient population for active targeted surveillance. For example, in Switzerland, testing of fallen stock (dead cattle) and emergency slaughter cattle (cattle killed for reasons other than routine slaughter) revealed a BSE prevalence of 0.2 percent in 1999 and 0.12 percent in 2000. In comparison, Switzerland's BSE prevalence in routine healthy slaughter populations was 0.004 percent in 1999 and 0 percent in 2000.

BSE surveillance in France during 2001 identified 91 cases (19.4 percent of those tested) from cattle exhibiting central nervous system clinical signs, and 100 BSE cases (0.07 percent of those tested) from the 133,889 nonambulatory cattle tested. French testing of apparently healthy slaughter cattle found 83 BSE cases (0.003 percent of those tested) from the 2,382,225 tested. These data indicate the presence of infected cattle can be determined more efficiently by testing the population most likely to exhibit the disease, thereby supporting the decision to conduct a program of targeted surveillance rather than one of simple random sampling.

The expected number of animals in the targeted high-risk population was required to estimate an appropriate sample size. At that time, as stated, non-ambulatory animals were considered the primary targeted population, so an estimate of the number of nonambulatory cattle in the United States was needed. The American Association of Bovine Practitioners (Hansen et al., 1999) surveyed their members and estimated that 195,000 head of cattle become non-ambulatory per year.[1]

Initially, an assumption was made that the 45 potential cases of BSE (1 per million adult cattle population) would all be found in the high-risk cattle population. Dividing the potential cases into this estimate of the high-risk population (45/195,000) gives an assumed prevalence of 0.023 percent. This was the level of disease that needed to be detected in the high-risk population. Using Cannon and Roe's formula to determine the sample size required to detect disease at a prevalence of 0.023 percent with 95 percent confidence, a sample size of 12,500 was derived.[2]

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. The previous results giving no evidence of BSE in the United States, the low risk of BSE in the United States based on historical steps taken to mitigate risk, and the fact that current testing methodology can only detect the disease either a few months before or, more likely, after an animal begins to exhibit clinical signs all contributed to the decision to use this qualifying assumption.

It is important to note that no estimations of prevalence are done when designing these surveillance plans. The surveillance plans were designed solely to detect BSE if it exists in the U.S. cattle population at or above a specified prevalence with a specified degree of confidence. The objective of the surveillance plan is not to estimate prevalence of BSE in the U.S. cattle population. Certain assumptions of possible prevalence must be made

to assist in developing surveillance plans and establishing targets or goals. After sufficient data are obtained, then estimation of possible prevalence or bounds around the possible prevalence rate can be calculated.

Sampling at this level will not disprove that BSE may occur at a lower prevalence level, but it should allow detection of a case if BSE truly exists at a level of one or more cases per million in the adult cattle population given the underlying assumptions including:

1. the majority of cases of detectable BSE would occur in the targeted population
2. the samples collected are broadly representative of the targeted population
3. the testing system, as implemented, has a high sensitivity and specificity.

2. Current surveillance plan

On June 1, 2004, USDA launched an intensive surveillance program for BSE, with the goal of testing as many cattle as possible in the targeted population for BSE. This program is built on previous surveillance efforts, and is planned to be a one-time effort that will provide a snapshot of the domestic cattle population.[3]

The intent of this intensive surveillance effort is to provide sufficient data and information to assist in a determination of whether risk management policies – for both animal health and public health – are adequate or whether they need to be changed. The data obtained in this effort will be used to help determine parameters around the probable prevalence level of BSE in the United States. A specific, exact calculation of true prevalence of BSE is not necessary to enable us to make the determination of whether risk management policies need to be changed. These decisions can be made, for example, with information that simply estimates the upper bounds of a prevalence level.

We would like to clarify that, at this time, there have been no sampling-based, quantitative estimates of the prevalence of BSE in the United States. Certain assumptions have been made to assist in developing the surveillance plan, but this is very different from calculating or estimating the prevalence of BSE in the United States.

Experience in Europe, as described previously, has demonstrated that targeting surveillance efforts at certain 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 towards 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 the Harvard Center for Risk Analysis[4], the International Review Team[5], and is consistent with OIE guidelines[6].

One goal of the surveillance ***program*** may include determining estimates of what level of BSE could exist in the U.S. – i.e., determining parameters around a possible prevalence level - depending on the data obtained through this program. But the surveillance ***plan*** is a sample design that meets confidence level goals for detecting BSE if it is present at a specified level in the sampled population. It does not estimate prevalence. It is intended to help determine if BSE exists in the national herd and collect data for further analysis.

In order to develop the sample design in the surveillance plan, certain assumptions or estimations were necessary. One of these assumptions is that BSE is more likely to be found in the targeted population. Data from testing within the European Union in 2002 supports this assumption, with a conclusion that it is 29.4 times more likely to diagnose disease in the targeted population than in the clinically normal population.

Our surveillance plan is designed – and this has been confirmed by Harvard University's Center for Risk Analysis[4] – to detect the presence of BSE with 99 percent certainty if as few as five targeted high-risk cattle had BSE. The basis of this calculation is the same as described in the previous section, with the difference being the estimated number of animals in the targeted high-risk population. Clearly, if BSE were circulating in the U.S. cattle population, there might be infected animals that were not exhibiting clinical signs and therefore would not be included in our targeted high-risk population. Some such animals might have detectable BSE but most would not.

We appreciate the limits of our calculations and understand fully that there are additional calculations that would need to be done to extrapolate any assumptions or specifications about the targeted population to the entire U.S. cattle population. There are several ways to estimate or infer prevalence rates among the broader populations, each with advantages and disadvantages. Some examples of these approaches are described later in this document. As we gather data from our surveillance efforts, these approaches and others will be evaluated for their use in our calculations and decision-making processes.

Another approach to surveillance is focusing sampling on clinically normal animals. This is not an efficient way to conduct surveillance, if the intent of surveillance is to detect the disease if it is present. The following points explain the drawbacks and misleading assumptions of this type of approach:

The earliest point at which current testing methods can detect a positive case of BSE is approximately 3 months before the animal begins to demonstrate clinical signs. Also, the incubation period for this disease – the time between initial infection and the manifestation of clinical signs – is generally very long, on average about 5 years.

With current testing methodology, therefore, there is a long period during which testing an animal infected with BSE would produce a false negative result. This is

especially likely if the animal is clinically normal at the time samples are obtained for testing.

Based on these facts, and using the BSE simulation model as developed by Harvard[4], we can estimate the false negative rates for testing normal adult cattle. This model predicts that a testing program that tests all animals at slaughter would produce – when used on infected animals – a false negative test rate of 92 percent for clinically normal adult cattle, and a false negative test rate of greater than 99 percent for clinically normal young cattle under 30 months of age. In other words, if 100 infected clinically normal adult animals were tested, only 8 of them would test positive.

In comparison, current testing methodology is very sensitive when used in clinically affected cattle. Comparatively, a false negative rate in this population would be less than 1 percent. In other words, if 100 infected clinically affected animals were tested, more than 99 of them would test positive.

The exceedingly high rate of false negative results in the clinically normal population, in combination with its likelihood of extremely low disease prevalence, would impede statistical evaluation of the presence or absence of disease. More importantly, a testing program with such a high rate of false negatives would have negligible benefit from a public health standpoint and would be extremely misleading for the public and consumer, as it could provide false assurances of the absence of disease.

The key to surveillance is to look where the disease is most likely to be present and detectable. As outlined in the previous paragraphs, there is a significantly better chance of finding the disease if you look within the high-risk population. Our targeted surveillance program, focused on testing animals with some type of clinical signs, is the most efficient and effective way to detect the disease if it is present in the United States.

3. Statistical inferences and current plan

The current enhanced surveillance plan will provide data on the targeted population as described. Direct statistical inferences from these data can be made to the targeted population with the assumption that the animals tested are representative of the targeted population. For example, if 268,500 samples were obtained randomly from a target population of 446,000, and if no positives were found after completion of the testing plan, then we could state that we were 99 percent confident that there were less than 5 positive animals in the target population. Direct statistical inferences related to the remainder of the cattle population would require huge sampling efforts. For example, making a similar statistical inference using data obtained from sampling the apparently normal adult slaughter cattle population would require approximately 3 million random samples to be tested. Extrapolations of data from the targeted population may be used, however, to provide estimates of prevalence in the broader U.S. cattle population.

We made certain assumptions initially to assist in developing the surveillance plan and establishing general targets or goals. As addressed earlier, a qualifying assumption was made that all cases would be found in the targeted population for purposes of designing the initial surveillance plan. If another assumption was made – for example, that a certain number of cases would be found in the normal adult population – that too would

be simply an assumption for purposes of developing a plan. No statistical inferences could be drawn from such an assumption. All approaches in developing a plan are assumptions and none of them are known with certainty. After testing is complete, any assumption might be accepted, or it could be demonstrated to be completely wrong, depending on the data gathered in the surveillance effort. The validity of the underlying assumptions can and will be evaluated during the implementation of the surveillance plan and after the completion of the surveillance effort. However, the assumptions made to develop the surveillance system in the United States were based on the best current scientific knowledge of BSE and the cattle industry.

Additional details on specific aspects of the current surveillance plan that can impact the statistical calculations are addressed in the remainder of this section. These include descriptions of the target population estimates, the issue of random selection or access to animals, and finally a brief description of some approaches to extrapolating the data results from the targeted population to the broader U.S. cattle population.

Target population estimates:
For the purposes of developing the surveillance plan, we estimated the targeted high-risk population, based on data available to us at the time. We emphasize that this was an initial estimate; as we progress through the surveillance program, we will have better information and may be able to develop more accurate estimates.

Animals that fit our targeted population may be found in many different locations. If, for example, they exhibit clinical signs as described and subsequently die on the farm, they could then be transported to rendering facilities, salvage slaughter (3D/4D) plants, or other disposal facilities. Animals that initially exhibit subtle clinical signs may be sent to slaughter for human consumption or for salvage slaughter. As we attempted to estimate the targeted population, we had to make certain choices about data sources so as to avoid creating significant overlap, or double counting. For example, if we chose to use estimated numbers of animals picked up by rendering facilities and 3D/4D plants, these numbers could overlap significantly with any type of on-farm data available. Consequently, we chose to use NAHMS[7] data to estimate on-farm mortalities, reports of FAD investigations conducted by APHIS to represent on-farm CNS disorders, and FSIS slaughter data from 2002[8] to reflect the animals with perhaps earlier or more subtle clinical signs.

Table 1. – Summary of high-risk population estimate

High-risk population	Estimated number	Source of data
On-farm mortalities	251,532	NAHMS dairy and beef surveys[7]
On-farm CNS	129	FAD investigations
At slaughter	194,225	FY02 FSIS numbers[8]
Total	445,886	

When assessing FSIS data, certain codes for ante-mortem condemnation clearly needed to be included in our estimates. These included CNS signs, dead on arrival, moribund,

tetanus, and non-ambulatory (if specified). We recognized that the condemnation code for injuries was not so clear-cut, however, since it could represent different scenarios, including: animals condemned on ante-mortem inspection; animals condemned on post-mortem inspection; or part of the carcass passing post-mortem inspection after trimming. For the purposes of developing our estimate, we assumed that some cattle in this group could have injuries resulting from neurological deficits consistent with BSE, such as ataxia. This group would also include animals with injuries that are not likely related to BSE, for example bruising due to rough handling or a lesion associated with an old injury. Since there are no data available to help refine this group, we decided to include all of these animals in the high-risk population. Inclusion of all of these animals results in an overestimate, and this provides a more conservative (or larger) sample size than needed to meet our specified detection levels. We chose to err on the side of overestimation of the size of the high-risk population rather than underestimation.

Table 2. – At slaughter (high-risk categories) from FSIS data

Code	**Disposition**	**Number FY02**	**Number FY03**
Emaciation	Post-mortem condemn	3,275	4,488
Tetanus	Ante-mortem condemn	2	25
CNS Disorder	Ante-mortem condemn	135	133
Dead	Condemn	17,438	20,971
Injury	Passed	163,980	191,294
Injury	Post-mortem condemn	3,119	4,074
Injury	Ante-mortem condemn	19	17
Moribund	Ante-mortem condemn	6,257	6,154
ALL		194,225	227,156

The estimates of the high-risk population were based on 2002 FSIS data available at the time the plan was developed (Table 2). We continue to evaluate ongoing condemnation data to monitor our estimate, and will make adjustments as necessary. Recent monthly data for 2004 appear to indicate that the number of injuries and post-mortem condemns is declining, while ante-mortem condemns appear to be increasing. For example, in May 2003, a total of 31,077 injuries were reported, with 318 condemned post-mortem and none condemned ante-mortem. In May 2004, a total of 15,318 injuries were reported, with 75 condemned post-mortem and 6 condemned ante-mortem. Specifically for the injuries, this may indicate that the population that truly fits our target – *i.e.*, those animals that had neurological deficits sufficient to lead to injuries – are now being condemned ante-mortem or not being presented for slaughter.

Regulatory changes that have been implemented since the beginning of 2004 have also had an impact regarding categorization of high-risk cattle and movement of these animals. Monitoring the BSE surveillance data will help ensure that these changes do not result in relevant subpopulations being excluded from the BSE surveillance program. These changes may, however, result in adjusting the estimates of the high-risk population to reflect the current makeup of subpopulations.

We believe that our inclusion of these animal numbers in our estimates was appropriate. While we also recognize that it could be an overestimation of this segment of the population, choosing to err on the conservative side with an overestimation will not jeopardize the sampling plan – in fact, increasing the sample size increases the effective confidence level of the plan. We will monitor the ongoing condemnation data, our sample collection data, and testing results throughout the entire surveillance effort. If there is any indication that sampling should be done in other segments of the estimated population, we will be able to incorporate those changes as necessary.

The sub-population of cattle in the United States that was estimated as "high risk" for BSE consists of approximately 1 percent of the adult cattle population. In comparison, Eurostats data indicate that the sub-populations of cattle identified by European Union (EU) members for "high-risk" sampling (clinical signs of BSE, fallen stock, and casualty slaughter) range from less than 1 percent to approximately 4 percent of the adult cattle population[9]. The average was 1.87 percent of the population (Table 3). The differences result from a number of factors including management and production practices, data collection methods, and categorization of cattle. While it is difficult to make accurate comparisons given the differing management practices, our estimate nevertheless appears consistent with the range of what is seen in European countries.

Table 3. – High-risk cattle tested in EU, 2002[9]

Country	High-risk population tested	Percent of adult cattle population
Austria	9,513	0.95
Belgium	14,573	0.97
Denmark	22,093	2.45
Finland	12,020	3.01
France	133,889	1.22
Germany	276,748	4.19
Greece	1,653	0.55
Ireland	26,614	0.78
Italy	55,496	1.63
Netherlands	44,335	2.46
Portugal	2,630	0.33
Spain	52,293	1.54
Sweden	30,388	4.34
Switzerland	16,469	1.94
UK	73,417	1.39
Total	772,131	1.87

Randomness of selection and ensuring access to targeted animals: Randomized sampling is the basis for inference to a population of interest that helps reduce the

potential for bias. Randomized sampling depends on the availability of a list frame or some other method of randomizing the selection of sample elements (systematic sampling, area sampling, etc.). Every animal in the targeted population must have a known probability (non-zero) of being selected for sampling in a truly random scheme.

USDA weighed the options for randomized sampling in the targeted population, but decided that none of these were viable approaches for sampling this population. Consequently, there will be no random sampling but rather an attempted census of animals from the target population that are available for testing. Taking a census of the target population would eliminate any sampling error and make detection levels certain. However, not all animals in the target population may be available for surveillance, thus the census is expected to be incomplete.

It could be argued that inference to the entire targeted population without the randomization process and using a partial census introduces the potential for bias. However, the potential for bias cannot be assessed without more data about the targeted population and the population of tested animals. For example, if animal identification were in place, we could compare the tested group characteristics to the targeted population using criteria such as age, breed, and geographical location. However, because the United States does not yet have a completed national animal identification system, this is not feasible. Minimally, the geographic distribution of the tested animals could be compared to the distribution of the respective dairy and beef cattle populations. Further, the characteristics of the sampled population could be compared to generally expected distributions with regard to other demographic characteristics. If substantial gaps are apparent, resources can be moved and outreach efforts can be increased to remedy any apparent gaps in testing. These comparisons are being done on a routine basis with the data gathered in the surveillance effort, and outreach efforts or other approaches will be used to address any apparent gaps in distribution. Efforts are underway to learn more about the number, disposition, and distribution of portions of the target population. For example, VS is in the second year of a national probability based survey project to study the distribution of non-ambulatory cattle. Population based survey results such as these also could be used to assess the potential for bias in the target population surveillance.

The lack of availability of all targeted animals for surveillance and the potential for bias due to non-random sampling can potentially substantially affect the inference that can be made from the surveillance data. However, the effect of nonrandom sampling is minimized by our plan to test all available animals. Without regulatory requirements for reporting down or dead animals, we must focus on increasing our current efforts to identify and test the targeted population. The primary objective of the surveillance is to detect disease if it is present at a specified level with a desired confidence level. The impact of the sampling issues may result in unquantifiable changes in the detection criteria. If a BSE case is detected, then the impact will not be an issue. If no cases are detected, then the exact confidence we have that the disease is below the specified detection level will have to be based on the examination of the assumption that the animals tested are representative of the targeted population.

USDA is conducting significant efforts to ensure appropriate access to all aspects of the targeted population. We anticipate that a majority of the animals to be tested will come from animal disposal facilities, such as rendering facilities or salvage slaughter plants. We are also working to ensure that an adequate number of animals that are non-ambulatory or dead on the farm are available for testing. While a significant number of these will be available through the animal disposal facilities previously addressed, we are further enhancing efforts to encourage producers to contact authorities when they have a dead or non-ambulatory animal that meets our targeted population definition. As part of the enhanced surveillance program, USDA is reaching out to producers, renderers, slaughter facility operators, and others to encourage their participation. In addition, cost recovery options are also available to help address additional costs that may be incurred by participation in the surveillance effort. The combination of risk mitigation regulations promulgated in 2004 and their effect on the disposition patterns of animals, as well as our campaign to encourage reporting of high-risk animals for testing, means that samples may not follow the distribution of the high-risk population as reported in Table 1. Initial surveillance data in June and July 2004 suggest that we are maintaining appropriate access to the targeted population.

Approaches to extrapolate data to broader cattle population:
There are various methods that could be used to extrapolate the data obtained from our targeted surveillance program to the broader cattle population as a whole. While no decisions have been made about which, if any, of these approaches would be used, these examples can illustrate the options available.

One example of an extrapolation of collected data would be as follows. As previously mentioned, based on summary data from testing within the European Union in 2002[9], detectable cases of BSE were 29.4 times more common in targeted high-risk animals sampled than in apparently normal animals sampled. This ratio is based on detectable BSE. It is possible that BSE may be present but not at a detectable level. This discussion regarding approaches to estimating prevalence in the broader cattle population assumes detectable BSE.

The ratio based on European data can be used to extrapolate data on expected prevalence in additional populations. If we sample 268,500 targeted high-risk animals and find no cases of BSE, then we are 99 percent confident that at most there are not 5 or more cases in the targeted high-risk population of 446,000. Using the ratio of 29.4, we would then expect 0.15 detectable cases per 446,000 animals in the apparently normal population, or 2.2 cases in the 6.4 million adult animals slaughtered annually. This is an extremely low possible prevalence level, and detection of disease at this level in the apparently normal adult animal population would be extremely difficult. This would require sampling of approximately 4.5 million, 5.1 million, or 5.8 million animals to detect this prevalence level at a confidence level of 90 percent, 95 percent, or 99 percent, respectively.

Without testing a very large sample of normal adult animals, no statistical inferences can be made about the prevalence of BSE in the adult population. Any statements of prevalence after completion of testing of the high-risk population would have to be based on the extrapolation from the high-risk population to the normal adult population. For example, if we sample 268,500 high-risk animals and find no positive animals, then assuming at most 2.2 infected animals in the normal adult population, we could conclude there are no more than 7.2 positive animals in the adult population or about 1 per million (7.2 divided by 6.86 million).

The Harvard Center for Risk Analysis evaluated USDA's BSE surveillance plan, and described 2 approaches for extrapolating the data. These can be found on APHIS' web site at: www.aphis.usda.gov/lpa/issues/bse/BSE_Harvard03-12-04.pdf. The first approach described is similar to that outlined in the previous paragraph, using European data as a base for comparison. The second approach described utilizes the modified version of their computer simulation model initially developed in their 2001 risk analysis.

Yet another approach is a model, called BSurvE, developed by scientists in the United Kingdom and New Zealand. This model has been supported by the EU, and was submitted to the OIE for consideration in their amendments to the BSE chapter of the OIE Code. According to the developers, this model "estimates BSE prevalence in a national cattle population from surveillance data obtained by a country, accounting to the inherent biases and limitations of conducting surveillance only on animals after they are dead." As has been previously discussed in this paper, test results from BSE surveillance within various subpopulations of cattle (such as the U.S. defined high-risk population) cannot provide direct statistically valid estimates of the true prevalence of BSE in the national cattle population due to inherent biases and lack of random sampling. The BSurvE model makes use of historic data from European countries, combined with knowledge about BSE gained through research, to make an estimate of the true prevalence, with confidence limits around that prevalence, of BSE in the national standing cattle population. This prevalence estimate is based on a country's BSE surveillance data and demographic information of the cattle population in that country. The model also provides a way to evaluate the adequacy of the surveillance program within a country and guidance in efficient allocation of resources between various surveillance streams (clinical suspects, fallen stock, casualty slaughter, healthy slaughter) in terms of case detection success and cost effectiveness.

The BSurvE model shows promise of being an excellent tool to utilize within the US BSE surveillance program; however, it is still under evaluation and going through the international peer review process.

4. Sampling from the normal adult population

In accordance with the recommendations from the International Review Team, a limited number of samples will be obtained from the apparently normal adult cattle population presented at slaughter. The recommendation noted that some sampling in this population will help encourage disease reporting at the farm level.

Results from these samples are not used to quantify detection levels of the surveillance plan. Any estimates of possible prevalence levels in this population would be derived from alternative approaches or extrapolations of data about the normal adult population as described above.

In addition to these samples as outlined, there may be other samples obtained from animals that do not meet the definition of our targeted high-risk population. All samples that are of diagnostic quality will be tested. However, data from samples obtained from animals that do not meet the definition of the targeted population will not be used in any statistical analysis nor will they be used to help quantify any detection levels as described.

5. Actions if positives are found

The current surveillance plan is intended to detect disease if it is present at a certain prevalence with a specified degree of confidence. If cases of BSE are found through this effort, it may or may not invalidate assumptions or approaches we have taken. Investigation into the nature of the case, such as the type of animal and possible cause, would also provide information important to the future design of the surveillance plan. Depending on the specific findings, a decision would be required regarding the need to estimate prevalence. Depending on that decision, the surveillance approach may or may not be altered. If the surveillance program were altered, the assumptions would be re-evaluated and restated, the approach would be redefined, and appropriate detection levels would also be re-evaluated.

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