The meeting was hosted at the USDA-APHIS-VS Centers for Epidemiology and Animal Health, the OIE Collaborating Center for Animal Disease Surveillance and Risk Analysis. Thirteen participants from Argentina, Brazil, Canada, Colombia, Mexico, OIRSA, IICA, Panama and the United States attended the meeting.

The objectives of the meeting were to develop recommendations for the definition of and description of Type B surveillance for BSE and develop recommendations for guidelines to determine when a country should move from Type A surveillance to Type B surveillance.

Three broad questions were addressed:
• What constitutes adequate Type B surveillance?
• When is it time to change from Type A to Type B surveillance?
• When, if ever, might surveillance stop?

During the discussion, the following points were made and should be kept in mind regarding BSE surveillance.

- The points in the BSurvE model are not the same than those of the OIE Code. The OIE points table was generated based on a generic cattle population, making use of the BSurvE model with conservative assumptions.
- Given that adult clinical suspect animals are worth many more points than animals from any of the other surveillance streams, a critical aspect in surveillance is correctly classifying clinical suspects. The current code defines what constitutes a BSE clinical suspect animal.
- A country’s past history will be taken into account, including previous surveillance.
- Production management systems vary by county and are often different from what is seen in Europe. A country must focus surveillance on the compartments of their production systems where the risk is assessed to be greatest. Surveillance should be based on the epidemiologic factors found in a country.
- There is a difference between having a case of BSE and having a BSE “problem”. If a country detects a case of BSE in an animal born before their feed ban was implemented, or a case in an imported animal, it is not an indication that the country’s risk mitigations have failed and thus there is a BSE “problem” in the country. Rather, it is an indication that the system is functioning properly; the case was detected and must be dealt with. If, on the other hand, a country detects a case of BSE in an indigenous animal born after the feed ban was implemented, it is an indication that there might a BSE “problem” in the country in that mitigation measures in place may not be effective.
- It must always be kept in mind that there is a delay of 3 – 5 years before the impact of mitigation measures are seen due to the incubation period of BSE.
- Susceptibility to BSE is primarily during the first 12 months of life.
• OIE will only start assessing the BSE status of a country using the new code after May 2006.
• Surveillance conducted prior to the implementation of the new code can be utilized in determining compliance with Type A surveillance.
• OIE is developing criteria to define an effective feed ban.
• The OIE has developed guidelines for conducting risk assessment. The Terrestrial Code contains a section dedicated to risk analysis, as well as guidelines on risk release and exposure assessment within the BSE code chapter. In addition, two booklets on risk analysis have been published by the Central Bureau and guidelines for risk analysis in Spanish have been developed and published by the OIE Regional Office for the Americas. The OIE of the Americas ad hoc group for risk analysis has created a website on risk analysis available at: www.aphis.usda.gov/oieamericas/oieindex.htm
• The OIE code contains a chapter on disease status that can be referred to as guidance for BSE surveillance decisions.
• OIE should address the situation of diagnostic tests for BSE given the situation brought to light by the US case (i.e. a case that is negative on IHC and positive on Western Blot testing).
• From the current code, Type A surveillance includes the following points:
  - Design prevalence of 1/100,000,
  - 95% confidence level,
  - sampling should be representative of the national herd,
  - at least three subpopulations are sampled, and
  - points can be accumulated over seven years.

The following major issues or questions were discussed. Under each issue heading is a brief summary of the discussion along with any recommendations relevant to that issue.

• What does Type B surveillance look like?

From the current code Type B surveillance includes the following points:
- Design prevalence of 1/50,000,
- 95% confidence level,
- sampling should be representative of the national herd,
- at least three subpopulations are sampled,
- an emphasis should be placed on sampling clinical suspects,
- the number of clinical suspects sampled should be approximately the same as the number sampled annually while conducting Type A surveillance,
- points can be accumulated over seven years.

As is currently described in the code, Type B surveillance assumes the country’s risk analysis is reviewed annually and risk factors have not changed.

Over time, there will be a loss of confidence in BSE status at the level achieved during Type A surveillance. Type B surveillance is a means to restore that confidence. Doing so will require a lower level of surveillance than that conducted during Type A surveillance.

• What is the purpose of Type B surveillance?

Type B surveillance is about maintenance following achievement of negligible risk through an active process or through the inherent low risk of a country’s production methods. Upon
completion of Type A surveillance and conduction of a risk assessment with mitigation of any identified risk, a great deal is known about the status of BSE in a country. Conducting Type B surveillance, subsequent to these previously completed activities, does not result in significant additional knowledge of the disease. Rather, the purpose of Type B surveillance is to monitor mitigation measures and possible changes in BSE status. It is also an acknowledgement that upon completion of risk analysis, implementation of mitigation measures, and completion of Type A surveillance, continuation of a high level of surveillance does not provide additional useful knowledge. It should also be noted that a purpose of Type B surveillance is not to monitor BSE in a country that is continuing to detect cases of BSE.

- Should a country conduct Type B surveillance without having first conducted Type A surveillance?

Upon meeting the criteria for negligible risk status as outlined in the BSE code chapter, a country should implement Type B surveillance. A country that had no external challenge (e.g. did not import meat and bone meal or live animals from a BSE affected country) may be able to achieve negligible risk status without first having controlled risk status and thus could implement Type B surveillance without having first conducted Type A surveillance. A key component is the annual review of a country’s risk assessment as specified in Article 2.3.13.2 in order to confirm that risk has not been introduced since obtaining negligible risk status. The annual review also includes confirmation of the continuation of lack of internal risk, for example, a 100% pastoral system without the use of meat and bone meal as a feed ingredient.

**Recommendation:** A country can go directly to negligible risk status without having first completed Type A surveillance (i.e. did not go through controlled status). However, while this is implied in the current code, it is not clearly stated. If the BSE ad hoc group agrees, the code should be modified to clearly state that a country can go directly to negligible risk status without having first completed Type A surveillance in Article 3.8.4.3, paragraph 2 “Maintenance (type B) surveillance”.

- A discrepancy exists between conducting Type B surveillance at a 1/50,000 design prevalence level and testing the number of clinical suspects that was established as a baseline during Type A surveillance.

Maintenance surveillance for BSE should be similar to that which is conducted for other foreign diseases, such as FMD surveillance in an FMD free country. This comprises an ongoing surveillance system targeted towards high risk animals, in the case of BSE, those animals that meet the definition of clinical suspects. When such animals are found, they should be tested for BSE. The level of sampling needed to reach the points target for a design prevalence of 1/50,000 can be used as a minimum, but only as a minimum. The discrepancy comes because the described level of sampling of clinical suspect animals (the approximate number as taken annually during the country’s Type A surveillance program) will most likely earn many more surveillance points than is needed for the prescribed design prevalence. However, clinical suspects should not stop being tested once that year’s surveillance goal towards achievement of the points target is met. The historic level of the number of clinical suspects found in a country provides a better annual goal for the level of surveillance needed to maintain confidence in a country’s BSE status.

**Recommendation:** To resolve this discrepancy, the text in Article 3.8.4.3, paragraph 2 “Maintenance (type B) surveillance” should be edited to reflect the appropriate emphasis on
on-going surveillance of clinical suspects. The points target needed to achieve a design prevalence of one case per 50,000 adult cattle could be kept as a minimum required level of maintenance surveillance. However, it is suggested that this reference be removed entirely. A more preferable minimum level of surveillance be that level that is needed to maintain confidence in a country’s BSE risk status based on the level of depreciation of knowledge gained via surveillance each year (see discussion point below).

- A discrepancy exists between emphasis on sampling clinical suspects for Type B surveillance and requirement to sample three of the four surveillance streams.

A discrepancy exists between Article 3.8.4.3 and Article 3.8.4.4. Article 3.8.4.4 states that countries should sample at least three of the four subpopulations and applies to both Type A and Type B surveillance. In the text regarding Type B surveillance, the code emphasizes focus on sampling clinical suspect animals and that the number of clinical suspect samples taken annually should approximate the number of clinical suspect samples taken annually during the country’s Type A surveillance program. The code also defines the level of sampling, and thus the number of surveillance points needed, at a design prevalence of one case per 50,000 adult cattle. The discrepancy comes because the described level of sampling of clinical suspect animals (the approximate number as taken annually during the country’s Type A surveillance program) will most likely earn many more surveillance points than is needed for the prescribed design prevalence. This will likely lead a country to collecting only token numbers of samples from the other surveillance streams.

The clinical suspect subpopulation is where BSE is most likely to be found if the disease does exist in a country. Therefore, emphasis in Type B surveillance should be on clinical suspects, with less emphasis on fallen stock and casualty slaughter.

**Recommendation:** The code text directing countries to sample at least three of the four subpopulations should be moved out of article 3.8.4.4 and placed in Article 3.8.4.3, paragraph 1 “Implementation of type A surveillance”. This maintains the appropriate emphasis in Type B surveillance on clinical suspects.

- The design prevalence of 1/50,000 for Type B surveillance was not in the draft code sent out to countries for comment prior to the General Session. Why was it included in the code?

The group was informed that this language was added during the general session as a compromise to make Type B surveillance have a lower defined level of required sampling.

- Should surveillance be conducted evenly over a seven year time period, or is it acceptable for it to be completed in a shorter time period, for example, over two years?

Maintenance (Type B) surveillance for BSE should be similar to that which is conducted for other foreign diseases, such as FMD surveillance in an FMD free country. This comprises an on-going surveillance system targeted towards high risk animals, in the case of BSE, those animals that meet the definition of clinical suspects. When such animals are found, they should be tested for BSE, regardless of how many animals have already been tested for BSE that year. This provides an continuity with a steady, ongoing BSE surveillance approach through each year and over the years.
After Type A surveillance has been completed such that one is 95% confident the prevalence is less than 1/100,000, over time, how does this change? How does knowledge about confidence or prevalence threshold change or deteriorate over time? Has anything happened which might have changed the situation or allowed prevalence to expand? This is the issue of how information, or data or the accumulated number of surveillance points, accumulated depreciates over time.

One purpose of Type B surveillance is to maintain a 95% confidence level that the prevalence of BSE in a country is less than 1 case per 100,000 adult cattle by replenishing the value of sampling information that depreciates across time. Such depreciation occurs, for example, because undetected infection below the threshold prevalence may transmit during subsequent years. The possibility that prevalence could increase across time gradually erodes our confidence that prevalence is below the 1 case per 100,000 adult cattle threshold. Confidence in surveillance evidence also depreciates because the likelihood of newly introduced infection is not zero for most countries. In order to maintain the level of confidence gained during Type A surveillance, Type B surveillance should focus on the clinical suspects surveillance stream as previously described. Additionally, the risk assessment must be reviewed annually to ensure no increases in risk, external or internal, have occurred.

**Recommendation:** The points target derived from a design prevalence of 1/50,000 should be removed from the code for maintenance surveillance. Rather, the code should define the level of surveillance needed annually to maintain confidence gained during Type A surveillance. The amount of sampling currently required in the code implies that the number of sampling points accumulated in Type A surveillance (e.g., 300,000) will depreciate to 150,000 points during the following seven years. Thus, Type B surveillance currently requires that 150,000 points be accumulated across those following seven years. This level of replacement implies that BSE surveillance evidence will depreciate at a rate of 1/14th per year. To remain consistent, the current code could be modified to instruct countries applying Type B surveillance to collect 1/14th of their original Type A target points during each year of their Type B surveillance period. However, the BSE ad hoc working group should address this issue by determining an appropriate level of confidence lost each year, and thus what level of surveillance is needed to regain that confidence.

- Article 2.3.13.3, under the definition of negligible BSE risk, is worded to focus on when the last case of BSE was reported in a country. The date of finding and reporting the most recent case of BSE is less epidemiologically relevant. More epidemiologically relevant is when the case was born.

**Recommendation:** In Article 2.3.13.3, under negligible risk, change “the last indigenous case of BSE reported more than 7 years ago” to “was born” more than 7 years ago or “was born before implementation of a feed ban”. This editing should also be done in Article 2.3.13.4 regarding controlled BSE risk.

- Can compartmentalization within a country be applied to BSE risk based on risk factors such as production systems, age, implementation of mitigation measures, or birth cohort?

Where appropriate, focus should be on compartments rather than countries as a whole if groups of animals can be shown to have different epidemiologic characteristic that result in differing levels of BSE risk. Current OIE code addressing compartmentalization should be
used to provide guidance. An example of compartmentalizing by production type for BSE would be a country which has beef cattle that are 100% pastoral. Compartments of this type may or may not coincide with a geographic compartment. An example of compartmentalizing by age would be animals that were born before and after a change in production that resulted in a change in risk level.

Compartments within a country must be clearly defined, including definition of all terms and aspects of the compartmentalization. Risk analysis is critical to demonstrate differing levels of risk between compartments. It has to be clearly demonstrated that compartments are epidemiologically distinct and that one has a lower risk.

Another aspect that must be taken into account with compartmentalization for BSE risk is the lag time of five to seven years between implementation of a risk mitigation and when the resulting decline in risk can be demonstrated via surveillance.

Application of the compartmentalization concept to BSE risk does complicate the system. But should be noted that use of compartmentalization is an option, not an obligation. A country must decide if the benefit gained from compartmentalization outweighs the increased cost incurred in demonstrating and maintaining compartments.

**Recommendation**: The BSE ad-hoc group should discuss this concept and provide clear guidance for establishment of zones or compartments relative to BSE.

- What is the result of detecting a few cases of BSE when a country is in controlled risk status?

It is important to consider this situation relative to when mitigation measures were put in place, e.g. was the case(s) born before or after the implementation of a feed ban.

Scenario A: A case of BSE is detected in an animal born before the feed ban was implemented. In this situation, there should be no negative implications in terms of BSE risk status of the country in that controlled risk status is maintained. Detecting the case does not indicate that there is a lack of efficacy of mitigation measures. It should be noted that verification of the age of the infected animal will be critical.

This situation does indicate that the surveillance system is effective in detecting disease. Type A surveillance should continue, without having to reset to year 0, i.e. surveillance conducted prior to detection of the case continues to be applied to completion of the Type A surveillance goal. However, the point target needed to gain (or regain) 95% confidence that the prevalence is less than a design prevalence of 1/100,000 will increase above what is listed in Table 1. A country in this situation does not need to go to the extreme of determining true BSE prevalence. This is not consistent with Article 3.8.4.5 as currently written.

**Recommendation**: Article 3.8.4.5 should be edited to take this situation into account and provide guidance regarding additional point targets. Drs. Aaron Scott and Vicki Bridges have completed analyses regarding this issue making use of the BSurvE model and will provide that input to the BSE ad hoc working group.

Scenario B: A case of BSE is detected in an animal born after the feed ban was implemented. This situation implies there has been a failure of mitigation measures, specifically that an
effective feed ban is not in place. The date of claimed effectiveness of the feed ban should be moved at least to the year determined that exposure of the case took place.

A country in this situation will need to audit their system to identify the failure point which resulted in a case of BSE born after the feed ban. Included in the audit of the system, should be an analysis by age cohort to determine when the fracture to the system took place. The country will need to be able to show that the failure has been addressed and is now controlled. If they can do so, controlled risk status is maintained. If the country can not show that the situation is under control, it indicates mitigation measures are not effective and therefore the risk status should change to undetermined BSE risk.

Under this scenario, a country might consider using compartmentalization based on age cohorts. A lower risk compartment might include animals younger than the case, born after the new year of demonstration of effectiveness of a feed ban. Animals of the same age cohort or older than the case would constitute a higher risk compartment.

This scenario will result in an impact to the surveillance plan. The system audit will help determine at what year surveillance points need to be reset to zero. Additional surveillance will be needed to indicate risk factors are under control and to reestablish confidence in the maximum prevalence level. Tools such as the BSurvE model might also be useful under this scenario to redefine surveillance goals and to help target future surveillance.

In both scenarios, it will need to be demonstrated that the feed ban became effective after the case was born.

- Can surveillance for BSE in animals ever be stopped? If a country can demonstrate negligible risk, what value does surveillance in animals provide? Can risk mitigations such as SRM removal or feed bans be decreased over time?

The questions raised address the issue of what is the most efficient method to assess effectiveness of mitigation measures. Perhaps there are better ways to do so than testing animals for disease. One alternative method discussed was an existing method used in the feed mill industry that uses inert pellets to differentiate types of feed. This method could be used to differentiate on-farm feed containing meat and bone meal from that which does not. HACCP analysis is another alternative method to assess effectiveness of mitigation measures. An advantage of making use of methods other than testing for disease in animals would be elimination of the approximately five year delay in being able to demonstrate effectiveness of mitigation measures.

Surveillance in animals should always continue as it does for foreign animal diseases in any country. In this respect, a country should always test clinical suspects for BSE. Methods other than testing animals could be used in conjunction with surveillance in animals.

Being able to decrease surveillance in animals is strongly linked to the risk analysis. If no risk is identified or identified risks have been overcome via mitigation measures, and this has been demonstrated with surveillance, it should be acceptable to decrease surveillance in animals to the level of only sampling clinical suspects as is done for any other foreign animal disease surveillance. Also based on the risk analysis, mitigation measures may change or decrease over time. Mitigation measures may shift from within a country to its borders, maintaining compliance with WTO guidelines.
Changes from the current guidelines for surveillance and mitigation measures will depend on the world BSE situation and how it evolves over the near future.

**Recommendation:** This topic should be considered and discussed by the BSE ad hoc working group. Current OIE code regarding historical freedom and disease freedom declarations without conducting active surveillance should be consulted for guidance.

- If a country has no external challenge, e.g. no imports of live animals or meat and bone meal, is a feed ban necessary?

This is a situation where the risk assessment has shown negligible BSE risk. In such a case, a country must examine the composite effectiveness of their risk mitigations. The point may be reached when one or more of the risk mitigations can be removed because other risk mitigations in place provide adequate assurance of safety. As long as a country can show equivalence of risk mitigation measures, as measured by risk analysis, risk mitigations should be allowed to be altered from current requirements. For example, if risk analysis indicates negligible risk from external challenge and SRMs are being removed, perhaps a feed ban does not add any additional risk mitigation but does add significant cost.

An analogy for this situation is vaccination for an infectious disease. It is not required to have 100% vaccination for a disease not present in a country, even when other countries still have the disease. A country does not wait to stop vaccination until the disease has been eradicated from every country of the world.

A country can never be 100% confident that no BSE risk exists within that country. Therefore, mitigation measures such as feed bans and SRM removal are safety nets. However, the issue of what level of intensiveness of risk mitigations are truly required needs to be explored. Various risk mitigations provide varying levels of risk reduction. This should be taken into consideration when determining the composite effectiveness of risk mitigations and what level of total risk mitigation is needed based on the level of risk determined to exist from the risk assessment conducted.

**Recommendation:** This topic should be considered and discussed by the BSE ad hoc working group.

- The rational behind the tables and derivation of the point targets in current OIE code is not clearly stated.

**Recommendation:** Background documentation such as the notes from the BSE ad hoc working group should be made available to member countries.

- Does there need to be another category for risk in addition to negligible, controlled, and undetermined?

It is not appropriate for this group to address this issue. Rather, a group of CVOs should do so as it is in reality a political and trade issue.

- Most countries have not historically recorded data on their cattle populations based on the four surveillance streams as currently defined in the surveillance appendix. While
it is possible in many cases to categorize historic surveillance samples into these four surveillance streams, it is not possible for all countries and for all data.

**Recommendation:** The ad hoc group should provide guidance regarding the interpretation of historic surveillance data based on the current definitions of surveillance subpopulations.

Knowledge of the epidemiology of BSE increases and changes over time. In addition, diagnostic tests are developed and improved. Based on these changes in knowledge and diagnostics, surveillance goals and approaches might also need to change over time.

**Recommendation:** Periodically, the BSE ad hoc working group should review the point tables in the BSE surveillance code. Changes in knowledge and diagnostics should be incorporated into the BSurvE model, potentially resulting in changes to the point table.