The attached appendix contains the Food Safety Commission's views concerning the following reports, published by the USDA in July 2006, which analyzed data on the surveillance over the last seven years, including the Enhanced Surveillance program.

1.   Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan
2.   An Estimate of the Prevalence of BSE in the United States
3.   Peer Review of the Estimation of Bovine Spongiform Encephalopathy (BSE) Prevalence in the United States
4.   APHIS Response to Peer Review of the Estimation of BSE Prevalence in the United States
5.   Sample Size Estimate for BSE Ongoing Surveillance
6.   Peer Review of the Estimation of the Ongoing Surveillance Plan for Bovine Spongiform Encephalopathy in the United States
7.   APHIS Response to Peer Review of the Sample Size Estimate for BSE Ongoing Surveillance in the United States

(Appendix)

(Tentative Translation)

December 2006

The Prion Expert Committee's Views
On the Revised BSE Surveillance Program
In the United States

1. Estimate of the BSE Prevalence

The Prion Expert Committee assumes that the USDA's result of the estimate that "the prevalence of BSE in the United States is less than one infected animal per million adult cattle" does not differ significantly from our own estimate of the prevalence of approximately one per million, which was made based on surveillance data in the Report, " Risk assessment concerning the comparability between risks of consuming beef and internal organs regulated by the beef export verification program of the United States/Canada and risks of consuming beef and internal organs of Japanese cattle" published in December, 2005.

However, the Committee notes that the following suggestions and questions about the revised surveillance program in the United States should be taken into consideration so as to estimate the accurate BSE prevalence :

    For the BSurvE model used to estimate the prevalence, the appraisal has not yet

been determined; it is still under discussion in the OIE;

Uncertainty lies in the age estimate method for cattle tested, classification of categories, and size or head of cattle population; the question therefore arises as to whether an adequate sampling was carried out;

The surveillance data in the last seven years should be divided into two groups one collected before and the other after Western Blotting was introduced so that each group may undergo a more accurate analysis, depending on individual sensitivity to detect prions;

Impact of sample handling methods on testing sensitivity should be taken into account, including such factors as time-lag between sample collection and actual BSE testing as well as timeframe of cold storage, etc.;

The difference of the used IHC testing method from the OIE protocol (with no formic acid applied) may have an effect on testing sensitivity; and

The possibility cannot be precluded that BSE infected cattle have been unscreened, because quality control was inadequate for the testing method itself including primary screening test.

It is difficult to predict exactly without making an actual estimate. But the Committee presumes the prevalence of less than one infected animal per million adults is unlikely to increase greatly, e.g. to 10 or more, even if re-evaluation is carried out with the aforementioned suggestions taken into consideration.

2. Forthcoming (Ongoing) Surveillance

The concept of the revised BSE surveillance program in the United States released recently is understandable in that it focuses more on high-risk cattle in light of its goal to detect one infected animal per million adult cattle. Therefore, the Committee conceives the reduced number of samples in this context will not always pose a problem by itself.

However, as regards the practicability of the surveillance program and the reliability of surveillance data, the Committee has the following concerns:

Validity should be demonstrated of the sampling plan, which was devised based on the BSurvE model. A question arises whether it is appropriate that the model be applied to such low BSE prevalence countries as Japan and the United States;

To ensure a fair application of the sampling scheme in farms, a more specific approach should be made clear, e.g. establishments of cooperative ties with practicing veterinarians and a new compensation system, etc.;

Though the members of the expert committee, who are responsible for the determination of testing results, are not announced to the public, specialists from various areas of expertise should be involved to make a comprehensive evaluation

of results from the ELISA, WB, and IHC methods.

As stated in our own the report of the risk assessment concerning beef and internal organs imported from the United States, the Committee presumes that, under the present feed regulations, the possibility of cross-contamination remains at a certain rate in the future. In this situation, the Committee suggests the following proposal, which seems like a useful way to obtain a clearer state of BSE prevalence and implement appropriate management measures in the United States:

> To verify the effectiveness of control measures in low BSE prevalence countries, sampling efforts should be focused more on high risk regions while conducting a nationwide survey. For example, the efficacy will be increased by maximizing the sampling number of culled cattle in apparently high-risk regions where many dairy cows have been imported from the Province of Alberta, Canada or where dairy farming is commonly practiced.