

FINAL REPORT
JAPAN-UNITED STATES BSE WORKING GROUP
July 22, 2004

Introduction

Pursuant to the agreement reached between the Government of Japan and the Government of the United States (U.S.) at the Third Japan-U.S. Consultation on Bovine Spongiform Encephalopathy (BSE) held on April 24, 2004, the Japan-U.S. BSE Working Group (WG), which is composed of experts and working-level officials, conducted discussions on the following seven topics from the technical and expert viewpoints toward the resumption of beef trade between Japan and the U.S. The WG also conducted inspections of relevant facilities in Japan and the U.S., with a view to gaining an understanding of BSE surveillance and risk mitigation measures.

- (i) Definition of BSE and the method of testing
- (ii) Definition of Specified Risk Materials (SRMs) and the method of removal
- (iii) Appropriate surveillance
- (iv) Appropriate feed ban implementation
- (v) Risk categorization/status of countries
- (vi) Cattle month-age identification
- (vii) Other

The WG hereby reports on the BSE measures implemented by Japan and the U.S., as clarified through its discussions and technical reviews of relevant facilities, and on its deliberations.

1. DEFINITION OF BSE AND ITS TESTING METHODS

(1) *Japan's BSE Measures*

(i) *Screening*

Japan indicated its use of the following 2 rapid screening tests: "Platelia" ELISA-kit (Bio-Rad Laboratories) and the Enfer BSE test (Enfer).

(ii) *Confirmation*

The diagnosis of BSE consists of a positive result by either Western Blot (WB) (Japanese version) or Immunohistochemical (IHC) examination in the confirmation test.

(iii) *Enabling Legislation and testing system in abattoirs*

Abattoirs Law, Law Concerning Special Measures for Bovine Spongiform Encephalopathy.

Based on Article 14 of the Abattoirs Law, only animals that pass ante-mortem and post-mortem inspections are approved for slaughter and dressing for use as edible meat. These inspections are conducted by meat inspectors (veterinarians) who are public officials of prefectures or cities with established health centers.

Under the Law Concerning Special Measures for Bovine Spongiform Encephalopathy, cattle of 0 months or older (all ages) are subjected to BSE testing during this post-mortem inspection.

The Abattoirs Law prohibits producing meat from cattle affected with BSE, and cattle diagnosed with BSE are incinerated and the processing facilities are then disinfected.

(iv) Testing system

As of October 18, 2001, BSE testing is required for all meat inspections at all abattoirs where cattle are slaughtered.

Slaughter is prohibited for all cattle which present neurologic symptoms or signs compatible with BSE. In addition, if an animal tests positive during a BSE screening test, confirmation of test results is conducted at the National Institute of Infectious Diseases, Obihiro University of Agriculture and Veterinary Medicine, or Hokkaido University and final diagnostic results are given by the "Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare (MHLW)."

Testing has been conducted on 3,159,408 animals as of May 8, 2004. There are 162 abattoirs where cattle are slaughtered and dressed (as of February 2004) and 2,657 meat inspectors (as of March 31, 2003).

(v) Process of diagnosis and BSE cases in Japan (including an atypical case)

Diagnosis of BSE testing based on the Abattoirs Law is implemented by the "Expert Committee for BSE Diagnosis, MHLW" established in MHLW. Positive cases from the BSE screening test are diagnosed conclusively based on the results of confirmation tests.

The criteria of BSE diagnosis consist of a positive confirmatory result by either WB or IHC examination. Two (eighth [23 months] and ninth [21 months]) of the 11 cases diagnosed as BSE in Japan tested positive by WB, and negative by IHC methodology. One [23 months] of these cases was considered atypical. Furthermore, histopathological tests are also conducted in the confirmation test, and 5 animals of the 11 diagnosed with BSE did not show spongiform changes in their brain tissues.

A small amount of the abnormal prion protein (PrP^{Sc}) with an electrophoretic profile different from that of a typical BSE-associated PrP^{Sc} was seen in WB testing for the one animal slaughtered on September 29, 2003, and the results were published. Japan determined that this case was BSE because an abnormal prion protein was confirmed by the WB test.

(2) *The United States' BSE Measures*

The U.S. provided its procedures for the laboratory diagnosis of BSE. The definition of BSE in the laboratory will be accomplished if one of the following criteria is fulfilled:

- A. Positive results by Rapid test and IHC;
- B. Positive results by Rapid test and WB (The United Kingdom (U.K.) version) - in the event that a sample is not suitable for IHC or the brain stem architecture is not evident; or
- C. Positive result by IHC only - in the event that no appropriate fresh brain tissue is available to employ either a Rapid or WB test.

The U.S. also provided information on how BSE-specific diagnostic tests are employed for surveillance of cattle for the presence of the BSE agent. Testing will be completed by use of the U.S. Department of Agriculture (USDA)-approved rapid tests as well as a confirmatory WB reference or IHC method.

The rapid tests will be run at the respective BSE contract laboratories (State/University Diagnostic Veterinary Laboratories) and the National Veterinary Service Laboratory (NVSL-APHIS). Confirmatory IHC or WB analyses will be applied as described above and will be only performed at the NVSL in Ames, Iowa.

The IHC test is considered the method of choice for the detection of PrPSc in the central nervous system (CNS) of affected cattle. According to the World Animal Health Organization (OIE) Manual of Standards for Diagnostic Tests and Vaccines, IHC is the method of choice for both confirmatory diagnosis and surveillance in countries with low BSE incidence.

It should be noted that the scheme of sampling and testing implemented in the U.S. since June 1, 2004, is in accordance with OIE guidelines and was reviewed by the head of the International Review Team for the U.S. BSE case (Dr. Ulrich Kihm) and the Harvard Center for Risk Analysis.

(3) Working Group Deliberations

(i) Objectives of BSE testing

Japan asserts that the objective of BSE testing is for the elimination of infected cattle from the food chain, ensuring the safety of meat. The U.S. asserts that the OIE recognized objectives of BSE testing are to help define whether BSE is present in the U.S. cattle population, and if so, provide estimates of the level of BSE, and monitor the effectiveness of BSE prevention and control measures.

Japan states that taking into account the fact that the detection of abnormal prion protein under a certain age in months is difficult through BSE testing, a double check is being implemented by removing SRMs from all cattle in order to compensate for technical limitations of the testing (fail-safe).

Also, the U.S. asserts that the best way to protect consumers from exposure to BSE at slaughter is removal of specified risk material (SRM). Carcasses tested at slaughter as part of surveillance are held until a negative result is returned. By U.S. law, carcasses of all diseased animals, including BSE positive animals, are condemned avoiding the difficulty of recalling beef product.

(ii) BSE testing methods

Japan and the U.S. agree that accumulated abnormal prion protein in younger animals is unlikely to be detected using current testing methods. Japan and the U.S. agree that at present any relationship of such undetectable levels of abnormal prion protein in CNS tissues to consumers' risk is unclear.

Japan asserts that both Japan and the U.S. are countries with low frequency of BSE incidence and they need to adopt testing methods (i.e., WB in parallel to IHC) which are more sensitive than the testing methods utilized in countries with a higher prevalence of BSE.

The U.S. states that its testing of high risk animals with an internationally recognized testing scheme addresses concerns of low prevalence BSE detection in the U.S. The U.S. contends it is important to use OIE recommended methodology.

(iii) Cases of BSE-infected young cattle in Japan (eighth and ninth cases)

Japan reported the following results.

- The infection was in the incubation period.
- These cases of confirmed abnormal prion protein should be identified as BSE.
- A possible cause of the infection was contaminated feed that was given before the feed ban was effective.
- Attempts to amplify BSE prions by transmission are underway.

The U.S. looks forward to the results of these important amplification experiments.

2. DEFINITION OF SRMS AND METHOD OF REMOVAL

(1) Japan's BSE Measures

(i) Enabling Legislation

- (a) Based on Article 6 of the Abattoirs Law and Section 2, Article 7 of the Law Concerning Special Measures for Bovine Spongiform Encephalopathy, owners or managers of abattoirs are required to retain bovine heads (except for tongues and cheek meat), spinal cords and distal ileum (2 meters from connection to caecum) in a special waste container for incineration.
- (b) Similarly, based on Article 9 of the Abattoirs Law and Section 3, Article 7 of the Law Concerning Special Measures for Bovine Spongiform Encephalopathy, slaughter businesses have been required to process bovine heads (except for tongues and cheek meat), spinal cords and distal ileum (2 meters from connection to caecum) so that contamination of the dressed carcass and edible intestines is prevented as of October 18, 2001. Related documents have been provided by the Ministry of Health, Labour and Welfare.

- (c) In addition, the use of the vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae, the wings of the sacrum and the vertebrae of the tail) for food in meat processing and other food businesses has been prohibited based on Section 1, Article 11 of the Food Sanitation Law since February 16, 2004.
- (ii) *Method of SRM Removal, Monitoring and Incineration*
 - (a) In abattoirs, the removal, disposal and incineration of SRMs are implemented under the supervision of meat inspectors who are public officials of prefectures and other local authorities. In addition, it is also accepted that licensed, industrial waste processing businesses must incinerate outside the abattoirs' property.
 - (b) Meat processing facilities and butcher's shops, food inspectors of prefectures and other local authorities must conduct regular inspections to confirm compliance.

(2) The United States' BSE Measures

In determining which materials of cattle should be removed from the human food supply, the U.S. considered the findings of pathogenesis studies conducted in the U.K., and data on the age distribution of confirmed BSE cases in the U.K.

BSE infectivity has been confirmed in the brain, spinal cord, eyes, trigeminal ganglia, tonsils, dorsal root ganglia, and distal ileum of the small intestine of cattle infected either under field conditions or experimentally.

After considering the internationally validated scientific factors known, the U.S. decided to designate the brain, skull, trigeminal ganglia, eyes, spinal cord, dorsal root ganglia (DRG) and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declare them inedible, and prohibit their use for human food. To ensure effective removal of the distal ileum, in the U.S., the entire small intestine shall be removed.

Although the skull or vertebral column of cattle infected with BSE has not demonstrated infectivity, the skull contains the eyes, trigeminal ganglia, and brain, and the vertebral column contains DRG and spinal cord. Thus, because they contain high-risk tissues, the USDA included skulls and vertebral column. Unlike other parts of the vertebral column, the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum do not contain spinal cord or DRG. Therefore, the U.S. excluded these parts of the vertebral column from the materials designated as SRMs. Head meat, cheek meat, and tongue may continue to be used for human food, provided they are not contaminated with SRMs.

The U.S. requires that establishments that slaughter cattle and process the carcasses or parts develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. The U.S. does not prescribe specific procedures that establishments must follow because it believes that establishments should have the flexibility to implement the most appropriate procedures that will best

achieve the requirements of this rule. USDA inspection personnel verify that written SRM procedures are followed and effective.

Although the U.S. has designated the distal ileum and tonsils of cattle of all ages as SRMs, the other tissues are designated as SRMs for cattle that are 30 months of age and older. The U.S. decision was based on studies in the U.K., and experiences in the U.K. and Europe. In the rare instances of cattle demonstrating BSE before 30 months of age, it is thought these cattle received heavy exposure to the BSE agent as calves. The U.S. has every reason to believe that if BSE is present at all, it is present at such a low level that calves would not receive heavy exposure. In the estimation of the U.S., designating SRMs in cattle at 30 months of age and older is the right decision based on circumstances in the U.S.

(3) Working Group Deliberations

(i) Definition of SRMs

(a) Japan and the U.S. agreed on the following points.

- Removal of SRMs is extremely important for protecting public health.
- The scientific foundation of initiatives for determining SRMs implemented by both Japan and the U.S. is based on pathogenesis studies performed in the United Kingdom.
- As per international guidelines, the tissues and ages of SRMs will be determined by the BSE risk in the respective country.

(b) There were divergent views on the following points.

- Regarding pathogenesis studies test data from the U.K., Japan stated that since a relatively small number of animals were tested, the data was insufficient and therefore, removal of SRMs should be implemented for cattle of all ages. The U.S. stated that since the risk of BSE in the U.S. is low, removal should be implemented only for cattle 30 months of age and older as per international guidelines.
- SRMs are excluded from the food chain in both Japan and the U.S. Japan excludes their use in all animal feed while the U.S. excludes them from use in ruminant feed.
- The U.S. stated that as a result of pathogenesis studies conducted in the U.K. and the reaffirmation of this laboratory data on the age distribution of clinical cases in the U.K., 30 months of age is appropriate for SRM removal for a low prevalence country like the U.S.

(ii) Removal of SRMs

(a) Japan and the U.S. agreed that SRMs should be removed in such a manner as to avoid cross contamination of edible tissue during slaughter, dressing, and processing. Removed SRMs should be disposed of according to respective laws.

(b) The U.S. explained that the Agriculture Marketing Service's (AMS) quality systems verification program is used to provide independent verification of industry management

systems and other quality standards. This program could provide assurances that U.S. beef exported to Japan meets requirements. This system can be used to certify that the exported meat and meat products meet conditions required by Japan in addition to the U.S. regulatory requirements.

3. APPROPRIATE FEED BAN IMPLEMENTATION

(1) Japan's BSE Measures

(i) Feed ban on meat and bone meal

The government has issued, by means of administrative guidance, the prohibition of the use of meat and bone meal originating from ruminant animals as feed for ruminant animals from April 1996 onward. After the domestic detection of BSE in September 2001 this ban was established as a regulation pursuant to the Law Concerning Safety Assurance and Quality Improvement of Feed (Feed Safety Law). As of October 2001, a complete ban was implemented on the use of meat and bone meal as feed. All meat and bone meal originating from ruminant animals and produced through rendering is to be disposed of through incineration.

(ii) Measures for prevention of cross contamination

The results of the epidemiological investigation on BSE-positive cattle detected in Japan indicate that there is a high probability that the infection was caused by cross contamination. Therefore, in order to implement effective measures for prevention of cross contamination, feed for ruminant animals is separated from other types of feed, and specialized handling of feed is implemented at each stage of the process: from import of raw materials to manufacturing and distribution and marketing in the use of feed. Dedicated feed manufacturing lines are to be introduced by the end of March 2005.

(iii) Implementation of Feed Inspections

Pursuant to the Feed Safety Law, the Fertilizer and Feed Inspection Services implement inspections and monitoring on feed manufacturers and other entities. Penalties are applied for violations of the standards and specifications for these are stipulated in the Law. In FY 2002, on-site inspections of 667 manufactures were conducted, 1,618 samples of feed and feed additives were tested with only one case of animal protein-related violations recorded (chicken substance in imported fish flour) was detected.

(2) The United States' BSE Measures

The U.S. issued guidance to industry in 1994 regarding not using ruminant products from BSE countries in FDA regulated products. In 1997, the U.S. issued a legally binding regulation imposing the current feed ban which meets or exceeds OIE recommendations. The effectiveness of the feed ban is based on a) enforcement mechanisms supported with legal penalties, b) methods for monitoring compliance that include inspection by state and Federal authorities on a regular basis, c) sampling

products for the presence of prohibited material, d) an extensive training program for Federal and state inspectors that perform the feed ban inspections, e) outreach and education efforts to assist industry, and f) the publication of all inspection results and the availability of these results to all interested parties. No indigenous BSE has been detected in the U.S. and the one case identified in the U.S. was born in Canada, before the implementation of its feed ban. The U.S. announced its intention on July 9, 2004 to publish a proposed rule removing SRMs from animal feed and asked for comments on other measures to further address the small possibility of cross contamination. In light of the 2 BSE cases detected in Canadian cattle, the increased surveillance announced on March 15, 2004 and the legal process involved in implementing regulations, the U.S. is beginning the process that will enable it to implement these additional measures rapidly should surveillance detect multiple cases of BSE in U.S. cattle.

(3) Working Group Deliberations

- (i) Japan and the U.S. agreed on the following points.
- BSE studies indicate that ingestion by animals of even small amounts of infected feed materials may result in a case of BSE after an extended incubation period. It is important to establish effective ruminant to ruminant feed bans and measures which control the cross contamination of feed.
 - Japan asserted that it had stopped importing meat and bone meal from BSE suspect countries in 2001 and imposed a complete feed ban in October 2001 (accompanied by punitive provisions) on the use of meat and bone meal originating from ruminants, and had established measures for their disposal through incineration. As per international guidelines, the U.S. bans the use of meat and bone meal of ruminant origination as feed for ruminant animals but permits the use of feed to swine, poultry and other non-ruminants.

(ii) *Issues pointed out by Japan and the U.S.*

Japan pointed out that the U.S. feed ban did not eliminate the possibility of cross contamination, and in order to ensure appropriate controls on meat and bone meal, it is necessary to implement measures for prevention of cross contamination through segregation, and establishment of separate and dedicated lines at feed processing plants.

In response, the U.S. explained that measures other than segregation could be used to control cross contamination such as cleaning, flushing and sequencing. The U.S. also noted that since Japan has had 11 cases of BSE and is predicting another possible 50 or 60 cases, their approach to addressing cross contamination may be appropriate for their situation, and the same methods may not be appropriate for mitigation of risk associated with cross contamination in the U.S. system. In addition, the U.S. indicated it was considering options for reinforcement of the current feed ban.

In response to this, Japan explained that its epidemiological investigations of BSE-infected cattle had produced no evidence that meat and bone meal had been directly fed to infected cattle.

Japan pointed out that there was a discrepancy between the premise and the actual effectiveness of the Harvard BSE Risk Assessment. The Assessment indicates that as a result of trial calculations with a labeling error of 5%, the BSE risk in the U.S. for 2002 is negligible, but in fact the labeling error until 2000 was 15%. This and other cases indicate a low level of compliance with regulations. Therefore, it cannot be ascertained that BSE risk in the U.S. is negligible.

The U.S. replied that it believes the mislabel calculation (5%) is more appropriate than the reported rate of 15% for the purpose of determining the actual performance of the feed ban in the U.S. While use of higher mislabeling rates increases the estimated probability that BSE would persist in the U.S. after introduction, the estimated probability that the disease would die out remains high. First, the higher reported mislabeling rate of 15% reflects both actual mislabeling and non-material paperwork violations. Moreover, the reported mislabeling rate is not adjusted to reflect the sizes of the facilities involved. Harvard conducted a mass balance calculation. Based on that calculation, 5% is a better estimate of the mislabeling rate for use in the risk assessment. The U.S. reported compliance rates with the feed ban in 2003 of over 99%.

(iii) Issues for further deliberation

The two sides confirmed that they would continue to review the validity of feed bans by both Japan and the U.S. based on the results of future surveillance.

4. SURVEILLANCE MODALITIES

(1) Japan's BSE Measures

(i) BSE testing and surveillance

Japan asserts that its BSE testing is implemented for all cattle in abattoirs (launched on October 18, 2001) and on all dead cattle at farms (launched in April 1996, with its scope gradually expanded to eventually cover all dead cattle 24 months of age and older as of April 2004). The test results are incorporated into the surveillance data for surveillance. The methods of testing are the same as the methods stipulated under "Definition of BSE and the method of testing" section above.

(ii) Testing of dead cattle

Pursuant to the Special Measures Law Concerning Bovine Spongiform Encephalopathy, all dead cattle on farms must be notified by the veterinarians to the prefectural governor. Pursuant to the Domestic Animal Infectious Diseases Control Law, sampling and BSE testing are carried out on the dead cattle by a veterinarian at the livestock hygiene service centers. If the results of the tests on the dead cattle are BSE-positive, the entire animal is incinerated. If the results are BSE-negative, rendered-processed meat and bone meal is incinerated.

(iii) *Surveillance results*

Since testing in Japan is implemented in a comprehensive and almost all-inclusive manner, it is possible to accurately keep track of the status of BSE. In the three-year period from FY2001, the nine cases of BSE-positive cattle were detected through abattoir inspections of approximately three million animals, and two cases of BSE-positive cattle were detected through the testing of fallen stock or CNS suspects at farm of approximately 50,000 animals. Five cases of nine BSE-positive cattle detected through abattoir inspections were ordinary healthy cattle, and it is thought that they would not have been detected through surveillance applied only on "BSE high-risk" cattle populations.

(2) *The United States' BSE Measures*

The U.S. reemphasized the goals of BSE surveillance (see 1.(3)(i)). These goals do not include the use of BSE testing as a food safety test, given (a) SRM removal is used to assure that the U.S. beef supply is safe; (b) there is currently limited scientific evidence to suggest the time at which the various diagnostic tests are effective in detecting BSE infection in cattle; and (c) BSE surveillance since 1990 has not detected BSE in the U.S. native cattle.

USDA leads an interagency targeted surveillance program for BSE that has been in place in the U.S. since May 1990 and is targeted on testing the high risk cattle sub-population. These surveillance samples include field cases of cattle exhibiting signs of neurologic disease, cattle condemned at slaughter, rabies negative cattle, neurological cases submitted to diagnostic laboratories, and samples of nonambulatory cattle and adult cattle dying on farms.

The U.S. explained that, as a result of the detection of the BSE agent in North America, as of June 1, 2004, the BSE surveillance program in the U.S. has been significantly enhanced for 12-18 months in the "high-risk for BSE" cattle populations over 30 months of age in order to estimate the magnitude of the problem, if it exists. Surveillance systems targeting these high risk sub-populations have been shown to be the most efficient at identifying BSE cases. Laboratory diagnostics will consist of decentralized labs screening with rapid diagnostics and confirmatory testing at USDA.

The U.S. recognizes that a surveillance program on its own cannot guarantee BSE status and should be determined by, and be commensurate with, the outcome of a risk assessment referred to in the OIE International Terrestrial Animal Health Code Article 2.3.13.2. and should take into account the diagnostic limitations.

(3) *Working Group Deliberations*

- (i) The two sides agreed that the goals of BSE surveillance are to determine whether BSE is present in a country or zone, and if the disease has been detected, to monitor the evolution of the epizootic, and to direct control measures and monitor their effectiveness.

Both countries also agreed that limited scientific data suggests that, in experimental and naturally infected cattle, infectivity accumulated in the CNS at a later time point in the incubation period than at the mid-point. This is an issue that must still be addressed

experimentally to evaluate the time at which the various currently approved diagnostic tests are effective in detecting BSE-infected cattle (at this time, globally, we are limited to the estimating the prevalence of BSE-detection rather than the prevalence of BSE-infection in cattle).

(ii) Issues pointed out at the Working Group

(a) *Effectiveness of surveillance*

Japan explained that it implemented BSE testing in all cases of dead cattle 24 months of age and older and at all abattoirs. As a result of testing at the abattoirs, it confirmed BSE even in clinically ordinary healthy cattle. Japan therefore contends it is important to test healthy animals as well as high risk animals.

In response to this, the U.S. explained 1) that its surveillance which was implemented in 1990 has evolved based on changing science and surveillance data from affected countries; 2) surveillance which has exceeded the OIE standards since 1996; and 3) as of June 2004, based on the recommendation of the International Review Team the BSE surveillance program has been significantly enhanced.

(b) *Scope of BSE testing*

Japan requested the U.S. to explain the downer cow issue in the State of Washington and the handling of the CNS suspect cow in the State of Texas.

In response, the U.S. stated that the BSE surveillance plan accomplished its objectives by detecting the BSE-positive cow in Washington State. The U.S. explained a USDA VMO in charge determined the cow was in sternal recumbency (down on its chest) after his ante-mortem inspection.

Furthermore, while the animal in Texas was not tested, this incident resulted in a new USDA policy for BSE inspection and testing. Also USDA provided field personnel with the training and guidance to effectively implement this policy.

The U.S. explained that its BSE surveillance strategy was based on OIE guidelines and targets the cattle sub-population with the highest risk for BSE. This expanded surveillance program was reviewed and sanctioned by the International Review Team.

Japan contends it is difficult to sufficiently grasp the prevalence of BSE infection by a one-time effort of 12-18 months considering the incubation period of this disease. The U.S. explained that the 12-18 month surveillance period was recommended by the International Review Team.

(iii) Issues for further deliberation

The two sides confirmed that they would continue discussions regarding the modalities of appropriate surveillance in their countries and any possible revised OIE standards.

5. RISK CATEGORIZATION/STATUS OF COUNTRIES

The two sides acknowledged the OIE was currently deliberating revisions to its international standards.

Risk categorization of the United States

The U.S. presented documentation that addressed the criteria identified by the OIE for countries to be categorized as "BSE Provisionally Free." The U.S. explained that it fulfills the OIE requirements for being Provisionally Free of BSE for the following reasons: 1) the U.S. has conducted risk assessments in accordance with OIE guidance and found that there is no significant risk of BSE in the U.S.; 2) the only case of BSE found in the U.S. was found to have originated in an imported cow and progeny of the BSE-affected cow have been destroyed; and 3) the U.S. has an effective program in place to prevent the introduction of BSE into the U.S. cattle population since 1989 and measures to prevent amplification through feed since 1997.

The U.S. will submit its risk categorization document when the OIE concludes its categorization scheme. In addition, the U.S. contends that it is imperative that any agricultural trading nation complete a basic risk analysis as indicated in the OIE Code.

Japan pointed out several issues of concern, such as the surveillance efforts implemented, the short duration of the feed ban, and the fact that the U.S. had yet to be recognized as a "BSE Provisionally Free Country" by the OIE.

Furthermore, Japan pointed out several issues of concern with regard to the Harvard BSE Risk Assessment, based on the U.S. emphasis that it is a low-risk country, including the way of setting premises in this assessment and the fact that the assessment does not take into consideration the existence of potentially BSE-infected cattle. The U.S. noted that the Harvard Risk Assessment is a quantifiable model which evaluates the possible prevalence of BSE based on varying assumptions. For example, the models looked at what would have happened if there had been 1 to 500 BSE-infected cattle in the U.S.

Issues for further deliberation

The two sides confirmed that they would continue necessary discussions on the OIE standards and the results of surveillance and other control mechanisms implemented by both Japan and the U.S.

6. CATTLE AGE (BY MONTH) IDENTIFICATION METHOD

(1) Japan

Japan has introduced a traceability system that records information on cattle births so a precise age in months can be determined.

(2) United States

The U.S. provided scientific documentation which clearly demonstrated that cattle could be accurately

aged to 30 months of age or above. In addition, the U.S. is embarking on a National Animal Identification System by which month-age of cattle and precise identification can be captured. The U.S. explained that for the purposes of BSE mitigation the 30 month cut-off was more than sufficient to meet its needs and as a result dentition served as an appropriate means for age determinations.

(3) Working Group Deliberations

The AMS quality systems verification program can be used to certify that exported beef and beef products meet conditions required by Japan in addition to the U.S. regulatory requirements.

7. EXPORT OF JAPANESE BEEF TO THE U.S.

(1) Japan's Food Safety System

USDA considers Japan's food safety system to be equivalent with the U.S. system. The U.S. explained that it would resume annual audits to confirm the continuing equivalency status of the Japanese system.

(2) Rule formulation process in the U.S.

The U.S. provided an explanation of the Administrative Procedures Act (APA) which lays out the basic framework for rulemaking by all U.S. government agencies. The process by which USDA and FDA promulgate rules is deliberate and transparent but lengthy.

(3) Working Group Deliberations

At the third Japan-U.S. consultation on BSE held in April this year, the Governments of Japan and the U.S. shared their recognition that the two sides would actively engage in consultations, including a working group. The two sides would respectively pursue domestic discussions and make efforts to reach a final conclusion on the resumption of the importation of both U.S. and Japanese beef by sometime around summer.

The U.S. expressed that it placed a high priority on resuming trade in beef with Japan. In this regard, the U.S. explained the three available options for the importation of Japanese beef to the U.S. The options discussed were: enacting a new rule for Japan imports, submission under the minimal BSE risk rule, and the current administrative permits process. The final proposal will be developed on an accelerated schedule.

In this connection, in order to reach a final conclusion by sometime around summer on the resumption of trade of Japanese beef, the U.S. would make the maximum efforts in operating its regulations and systems concerned.