PROTOCOL

BETWEEN THE DEPARTMENT OF AGRICULTURE OF THE UNITED STATES OF AMERICA AND THE STATE ADMINISTRATION FOR ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA ON QUARANTINE AND HEALTH REQUIREMENTS FOR BOVINE SEMEN IMPORTED FROM THE UNITED STATES TO THE PEOPLE'S REPUBLIC OF CHINA

- 1. The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), shall be responsible for quarantine and inspections of the donor bulls, teaser animals, semen, and issuance of veterinary health certificates.
- 2. The Chinese side shall send veterinarians to the artificial insemination (AI) centers for export of semen and the related testing laboratories to cooperate with U.S. veterinarians in conducting quarantine and inspections, or may approve AI centers for continuous collection of semen which will be supervised by USDA.
- 3. The United States of America is officially recognized as free from foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, lumpy skin disease.
- 4. Whenever any outbreak of diseases in paragraph 3 occurs in the United States, APHIS shall employ the following actions immediately:
 - 4.1 Notify SAIQ with the details of the outbreak within 24 hours, including the name of the disease, name and address of the farm in which the outbreak occurs, number and species of the animal involved in the outbreak, and the control measures that have been taken by APHIS; and
 - 4.2 Refrain from exporting bovine semen to China.
- 5. The AI centers for the export of semen shall be located in those States where:
 - a. there has been no clinical evidence of bluetongue in any ruminant; and
 - b. for the past 12 months, no bluetongue virus has been isolated from any ruminant. The States are Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland, West Virginia, Pennsylvania, Ohio, Michigan, Indiana, Wisconsin, Minnesota, North Dakota, Alaska, Hawaii and Western Washington. The donor bulls and teasers shall be negative to an AGID test or ELISA prior to entry into the AI centers. The donor bulls and teasers at the AI centers for export of semen shall be born and reared in the above mentioned states. Donor bulls or teasers born in states other than those

mentioned above, must be negative to bluetongue by AGID test or ELISA prior to movement to one of the above mentioned states. They must be a resident of that state for six months and be negative for bluetongue by the AGID test and ELISA, and by virus isolation prior to entry into the AI center.

- 6. The AI centers for export of semen shall meet the Certified Semen Services (CSS) standards (January 1997) and be under regular supervision and examination by a USDA accredited veterinarian. The donor bulls have resided in the AI centers for at least 6 months and have not been used for natural service since entering the centers.
- 7. The AI centers for export of semen are recognized as free of tuberculosis and brucellosis by USDA.
- 8. According to records, no animals in the AI centers for the export of semen have had any clinical signs of enzootic bovine leucosis during the 3 years prior to the first collection of semen for export to China by clinical examination. There was no swelling of lymph glands during the collection period.
- 9. All donor bulls and teasers in the AI centers for export of semen shall be negative to an AGID test or ELISA for bluetongue prior to entry into the center and be negative on the centers semiannual tests thereafter. For semen to be eligible for export, the donor bull must be negative to an ELISA at least 40 days after the last collection of semen included in the shipment. During the collection period, there has been no clinical evidence of bluetongue disease in the AI center.
- 10. All animals in the AI centers for export of semen shall be free of clinical signs of epizootic hemorrhagic disease (EHD). For semen to be eligible for export, the donor bulls must be negative to an AGID test for EHD at least 40 days after the last collection of semen included in the shipment.
- 11. During the 12 months prior to the first collection of semen for export to China, there have been no clinical signs of IBR/IPV in the animals in the AI centers for export of semen; and
 - 11.1 All bulls and teasers in the AI centers producing semen for China shall be negative to the SN test at a 1:2 dilution or ELISA for IBR/IPV on a semiannual basis. Results of the tests shall be shown on the health certificate.
 - 11.2 Semen will be tested in China by virus isolation procedures as follows: semen shall be taken for isolation of virus by three passages in fetal bovine kidney cells with negative results.
- 12. If the donor bulls producing semen for export to China in a mixed population (IBR seronegative and seropositive bulls) the following procedures must be followed:

- 12.1 The seropositive animals shall be negative to IBR by virus isolation on serum at intervals of 6 months within the last 12 months prior to the first collection of the semen for export to China. Bulls that have only been tested in the last six months must have one additional negative virus isolation test conducted within 30 days prior to the first collection of semen.
- 12.2 The donor bulls producing semen for export to China shall be negative to the SN test at a 1:2 dilution or ELISA within 30 days prior to the first collection of the semen; and the same test shall be repeated with negative results within 21-60 days after the last collection of the semen
- 12.3 In the case of bulls of beef breeds which have been vaccinated against IBR using an inactivated vaccine, the following procedures shall apply:
 - 12.3.1. During the 30 days prior to the first collection of the semen, the donor bulls producing semen for export to China shall be tested twice using SN tests or ELISA at least 21 days apart using undiluted serum as the initial dilution, and the results are considered negative if there is no increase in antibody titers.
 - 12.3.2. Three (3) straws from each ejaculate of the semen for export to China shall be tested for IBR by virus isolation with negative results.
- 12.4 Each ejaculate of the semen for export to China shall be tested for IBR by virus isolation with negative results. *
- 13. During the 12 months prior to and during the collection of semen for export to China, there have been no clinical signs of BVD/MD in the animals in the AI centers; and
 - 13.1 The donor bulls shall be tested for persistent BVD/MDV infection prior to entry into the AI center using virus isolation techniques on blood serum or semen with negative results.
 - 13.2 A sample of 0.1 ml of fresh semen or three straws of semen from each ejaculate shall be cultured by two passages (at least 6 days for each passage) in fetal bovine kidney cells for isolation of virus with negative results.*
- * Note: For tests conducted on each ejaculate, "each ejaculate" refers to the first ejaculate collected each week during the collection period.
- 14. The semen for export to China shall come from an AI center which is annually tested for M. paratuberculosis by fecal culture. An ELISA shall be conducted on donor bulls with negative results, whose semen is included, at least 40 days after the last collection of any of their semen in the shipment.

- 15. During the previous 12 months, all animals in the AI center have been free from clinical evidence of leptospirosis; and within 30 days prior to the first collection of semen for export to China and at least 40 days following the last collection of semen for export to China, the donor bulls shall be tested for bovine leptospirosis 5 serotypes: L. canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae, and L. pomona with negative results (negative at a 1:100 dilution on the microtiter agglutination test) and the interval between the tests shall be not less than 60 days nor more than 120 days.
- 16. There has been no occurrence of vesicular stomatitis in the State in which the AI center is located during the 12 months prior to the first collection of semen for export to China nor within 30 days after the last collection of semen for export to China.
- 17. From the time of semen collection to the time of shipment of the semen, donor bulls were free from any sign of infectious or contagious diseases.
- 18. During the period of semen collection and for 30 days thereafter, the United States of America has been free from the diseases listed under paragraph 3 of this protocol and the AI centers have been free of clinical signs of infectious or contagious diseases.
- 19. The health certificates for the export of semen shall include the following information for each collection of semen:

19.1 The donor bulls:

- (a) do not exhibit any genetic defects and there is no record of genetic defects in their predecessors or offspring;
- (b) have not produced any progeny exhibiting recessive lethal genes or possible signs of carrying such genes;
- 19.2 The amount and quality of the semen;
- 19.3 The components in the diluent (including antibiotics), and the proportion of the various elements;
- 19.4 The date of the semen collection for export, specifications of packing, and marking of each dose;
- 19.5 That every batch of semen was packed and containers were sealed under the supervision of a USDA veterinarian.

On November 18, 2004 at the 1st U.S.-China Animal Health Technical Bilateral Meeting held in Honolulu, HI USDA APHIS and AQSIQ's Department for Supervision on Animal and Plant Quarantine agreed to amend the current import protocols for U.S.-origin bovine semen and bovine embryos.

BSE-related references in Article 3 of the April 1999 bovine semen protocol have been removed. The following statements have been added in lieu of BSE-related references in Article 3.

- 1. Semen collection centers are located in the areas which are within the U.S. national surveillance program which operates in accordance with OIE guidelines as related to prevention, control and eradication of BSE.
- 2. There have been no suspected or confirmed cases of BSE in the semen collection centers.
- 3. Donor animals were born after implementation of the August 1997 feed ban and have not been fed any materials prohibited under the ban.
- 4. Donor animals can be imported into the United States from countries with equivalent or lower BSE risk levels and an equivalent feed bans. Imported donor animals were born after the feed ban was implemented in the country-of-origin. The birth farms of the imported donor animal have had no suspected or confirmed cases of BSE for the previous six (6) years.
- **5**. Donor animals are not the progeny or birth cohorts of animals suspected or confirmed to be BSE positive.