

Quarantine Requirements for the Importation of Fetal Bovine Serum from Canada
(TRANSLATION)

(In case of any discrepancy between the English version and the Chinese text of these Requirements, the Chinese text shall govern.)

Promulgated by Council of Agriculture on June 29, 2011

1. The importer shall apply to the Bureau of Animal and Plant Health Inspection and Quarantine for an import permit prior to import. Only the applicant from research institute or manufacturer of biological products for animal use is allowed to apply for importation.
2. The sera shall be allowed to use only for in-vitro test or production of biological products for poultry or swine, and shall not be allowed to use for in-vivo test or production of biological products for ruminants, dogs, cats or human.
3. The disease-free countries as stated in this requirements refers to a country that has been recognized by the Council of Agriculture, Executive Yuan as free of foot and mouth disease, rinderpest, contagious bovine pleuropneumonia, and bovine spongiform encephalopathy.
4. The imported fetal bovine serum shall be in compliance with the following requirements:
 - (1) The serum was derived from bovine fetuses collected from dams born and raised in a disease-free country, or from dams that were of Canada origin.
 - (2) The dams which have passed ante-mortem and post-mortem inspection by competent authority of the country of origin.
 - (3) The serum was processed in a premise which has been approved by Canada government and the premise processes sera only from the disease-free country or Canada.

- (4) The serum has been filtered through filter of 0.22μ m or less, or has been irradiated with γ -ray at the dose of 25 kGray (2.5MRad) or more, and has been tested and found free from mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and bluetongue.
5. The imported fetal bovine serum shall be accompanied by an original veterinary certificate issued by the animal quarantine authority of Canada and the certificate shall state the following detailed information in English:
- (1) Authority of issuance of the certificate, province or district
 - (2) Product name, quantity, and lot number
 - (3) Country of origin of the dams
 - (4) Name and address of serum processing premise
 - (5) Name and address of exporter
 - (6) Means of transportation, identification of means of transport (flight number, vessel name or seal number of container)
 - (7) Destination including country, name and address of importer
 - (8) Results of quarantine inspection attesting that the health status of the imported fetal bovine serum is in conformity with Article 4 of the Requirements
 - (9) Official stamp of animal quarantine authority, name and signature of the veterinary officer, date and place
6. Packaging, labelling and documentation of fetal bovine serum for transportation shall be pursuant to the Guidance on Regulations for Transport of Infectious Substances of World Health Organization (WHO).