

Quarantine Requirements for the Importation of Fetal Bovine Serum from Paraguay (Draft)

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

1. The “Quarantine Requirements for the Importation of Fetal Bovine Serum from Paraguay” (hereinafter these Requirements) regulate the importation of serum derived from fetus of animals of the Subfamily Bovinae.
2. Testing referred to in these Requirements must be conducted by laboratories owned, designated or approved by the government of the exporting country using methods listed in these Requirements; or prescribed, recommended or considered suitable by the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (hereinafter the OIE Manual) for confirmation of population or individual animals being free from infection with pathogens of corresponding diseases. For diseases with no such testing methods prescribed, recommended or considered suitable in the OIE Manual, methods that have been published in international scientific journals may also be used.
3. Paraguay must have no confirmed case of foot and mouth disease and contagious bovine pleuropneumonia occurring during the 5 years prior to the manufacturing of fetal bovine serum (hereinafter FBS) for export.
4. For FBS from the Paraguay, only that which is manufactured by designated serum processing facilities is eligible to be imported. In addition, only government institutions (agencies), publically operated companies, private companies, academic institutions, and legal persons, are allowed to import such products.

The list of designated serum processing facilities named in the preceding paragraph must be provided by the government of Paraguay, after confirming their compliance with Article 5, to the animal quarantine authority of Taiwan for approval and publication on its website.

5. The FBS must comply with the following requirements:
 - 5.1 The FBS is derived from bovine fetuses collected from dams that are of Paraguay origin.

- 5.2 The dams have passed ante-mortem and post-mortem inspection by the competent authority of Paraguay.
- 5.3 The sera was extracted by cardiac puncture of the fetus; and then aseptically obtained and collected in sterile bags of containers.
- 5.4 The FBS must be processed in serum processing facilities approved by the government of Paraguay and the facilities processing sera only from the slaughterhouses which have been inspected and passed the inspection by the animal quarantine authority of Taiwan according to the Quarantine Requirements for the Importation of Deboned (chilled or frozen) Beef from Paraguay into the Republic of China.
- 5.5 The FBS has been filtered through filter of 0.22 μ 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 diarrhoea, infectious bovine rhinotracheitis, and bluetongue.
6. The consignment must be accompanied by an original veterinary certificate issued by Paraguay's competent authority. The certificate must specify the following information in English or Chinese:
 - 6.1 Origin:
 - 6.1.1 Name of consignment, total quantity and lot number;
 - 6.1.2 The exporting country;
 - 6.1.3 Name and address of the serum processing facilities; and
 - 6.1.4 Name and address of the exporter.
 - 6.2 Destination:
 - 6.2.1 Country of destination; and
 - 6.2.2 Name and address of the importer.
 - 6.3 Result of the quarantine:
 - 6.3.1 Specify explicitly that the consignment complies with Articles 3 and 5;
 - 6.3.2 Manufacturing date of the consignment.
 - 6.4 Date of issuance, name and official stamp of the issuing authority, and name and signature of the issuing officer.