Attachment 17-1: Quarantine Requirements for the Importation of Bovine Serum from the United States

1. The quarantine requirements regulate the importation of serum of cattle of the subfamily of Bovinae (hereinafter referred to as “bovine serum”).
2. The disease-free countries or zones as stated in this requirements refers to countries or zones recognized by the central competent authority of the importing country as being free from foot and mouth disease (FMD) and contagious bovine pleuropneumonia (CBPP).
3. For bovine serum, only that which is manufactured by designated serum processing facilities is eligible to be imported into Taiwan. In addition, only government agencies, publically operated enterprises, private enterprises, academic institutions, and corporations are permitted to import such products.
   The list of designated serum processing facilities named in the preceding paragraph must be provided by the government of the United States, after confirming their compliance with Articles 5.4 and 5.5, to the animal quarantine authority of Taiwan for approval and publication on its website.
4. Bovine serum is prohibited from being used for the production of biological products for ruminants use, or for *in-vivo* tests/research purposes.
5. For the importation of bovine serum, the following requirements shall be complied with:

5.1 The serum must be collected from cattle that, at the time of collection, are resident in disease-free countries (zones).

5.2 For the serum is collected at slaughter, it must be collected from cattle which passed ante-mortem inspection and dressed carcasses passed post-mortem inspection by the competent authority of the country where the slaughterhouse is located. In addition, prior to slaughter, the cattle must not be subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity nor to a pithing process.

5.3 For the serum is not collected at slaughter, it must be collected from cattle which are found to be clinically healthy by physical evaluation.

5.4 The serum must be manufactured in designated serum processing facilities which are located in the United States and under the supervision of the government of the United States. In addition, appropriate measures must be taken to effectively segregate the serum for export to Taiwan from ineligible materials if these designated facilities also handle bovine blood materials which are not compliant with Articles 5.1 to 5.3.

5.5 The serum must be filtered through a filter with mesh size 0.22μM or less, or irradiated with γ-rays at a dosage of 25 kGray (MRad) or more. In addition, it must be tested and found free from pathogens of mycoplasma, bovine viral diarrhea,

infectious bovine rhinotracheitis and bluetongue.

5.6 The serum must be produced, stored and transported in such a manner as to prevent contamination by communicable animal disease pathogens transmissible through the product.

5.7 The information presented on the inner package label must include product name and lot number.

5.8 The government of the United States is required to publish on its website the transportation of bovine serum from the United States to Taiwan must meet relevant regulations of the International Air Transport Association (IATA).

6. Each consignment shall be accompanied by an original veterinary certificate issued by the animal quarantine authority of the United States, and the certificate shall state the following information in English or Chinese:

6.1 Origin of the animal:

6.1.1 Name of consignment, quantity and lot numbers;

6.1.2 Name and address of the processing facilities; and

6.1.3 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 quarantine:

6.3.1 Statement attesting that the bovine serum fulfills the requirements stipulated in Articles 5.1 to 5.6.

6.3.2 Countries (zones) in which the cattle were resident at the time of serum collection.

6.4 Date of issuance, name and official stamp of the issuing authority, name and signature of the issuing officer.