

Draft Amendments to the Quarantine Requirements for the Importation of Bovine Serum from the United States

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

1. 自美國輸入牛血清，其來源以特定血清加工廠為限，且其輸入人以試驗研究機構或動物用生物製劑製造廠為限。

前項特定血清加工廠之名單，由美國政府提供，經輸出入動物檢疫機關審核後公布於網站。

For bovine serum from the United States, only that which is manufactured by designated serum processing facilities is eligible to be imported into Taiwan. In addition, only research institutes and manufacturers of biological products for animal use 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 to the animal quarantine authority for its reviewing. Those approved will be published on the website.

2. 自美國輸入牛血清，其用途以體外試驗研究、家禽或豬用生物製劑製造為限，且不得使用於反芻動物、犬、貓或人體用相關生物製劑產品之製造及體內試驗研究。

Bovine serum imported from the United States is permitted only for in-vitro tests/research purposes or for the production of biological products for poultry or swine use. It is prohibited to be used for the production of biological products for ruminants, dogs, cats or human use, or for in-vivo tests/research purposes.

3. 本條件所稱非疫區，指經中央主管機關公告為口蹄疫、牛瘟及牛接觸傳染性胸膜肺炎非疫區，且非牛海綿狀腦病之發生國家(地區)。

The term “disease-free countries (zones)” used in the Requirements refers to countries/zones recognized by the central competent authority as: 1) being free from foot and mouth disease, rinderpest and contagious bovine pleuropneumonia and 2) where no cases of bovine spongiform encephalopathy (BSE) have ever been reported.

4. 自美國輸入牛血清，應符合下列條件：

To import bovine serum from the United States, the following requirements shall be complied with:

- (1) 供應血清之來源牛隻，以出生並飼養於非疫區，或美國國內經中央主管機關公告為口蹄疫、牛瘟及牛接觸傳染性胸膜肺炎非疫區之地區為限。

The serum must be collected from cattle that are born and raised in disease-free countries (zones), or in zones within the United States that are recognized by the central competent authority as being free from foot and mouth disease, rinderpest and contagious bovine pleuropneumonia.

- (2) 以屠宰方式採集血清者，應採自屠宰場所在國政府主管機關執行屠前及屠後檢查合格且非以空氣槍注射或穿刺腦腔方式致昏後屠宰之牛隻。

If the serum is collected during slaughtering, it must be collected from cattle which pass ante- and post-mortem inspections 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.

- (3) 非以屠宰方式採集血清者，應採自經臨床檢查健康情形良好之牛隻。

If the serum is not collected during slaughtering, it must be collected from cattle which are found to be in healthy conditions after clinical examinations.

- (4) 血清產自受美國政府監督之血清加工廠，且該血清加工廠僅加工來自非疫區或美國之牛隻血液原料。

The serum must be manufactured in designated serum processing facilities which are under the supervision of the government of the United States. In addition, the facilities are restricted to processing only raw serum materials collected from cattle originating from disease-free countries (zones) or the United States.

- (5) 血清經 0.22 μm 以下孔徑之濾膜過濾，或經 25kGray(2.5MRad)以上劑量之加瑪射線照射，且經檢測無黴漿菌、牛病毒性下痢、牛傳染性鼻氣管炎及藍舌病等病原之污染。

The serum must be filtered through a filter with mesh size 0.22 μm or less, or irradiated with γ -rays at dosage of 25 kGray (2.5MRad) or more. In addition, it must be tested and found free from pathogens of mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and bluetongue.

- (6) 其包裝、標示及運送，應符合世界衛生組織(World Health Organization, WHO)「感染性物質運輸規範指引」(Guidance on Regulations for the Transport of Infectious Substances)及國際空運協會(International Air Transport Association, IATA)之規定。

The packaging, labeling and transportation of the serum must comply with the “Guidance on Regulations for the Transport of Infectious Substances” of the World Health Organization (WHO) and relevant regulations of the International Air Transport Association (IATA).

5. 自美國輸入牛血清應檢附美國政府動物檢疫主管機關簽發之動物檢疫證明書正本(英文)，並詳細記載下列事項：

The bovine serum consignment from the United States must be accompanied by an original veterinary certificate issued by the animal quarantine authority of the United States. The certificate must state the following information in its full detail in English:

- (1) 產品名稱、數量及批號。

Product name, quantity and lot number.

- (2) 供應血清之牛隻來源國。

Origin country of the cattle from which the serum is collected.

- (3) 血清加工廠之名稱、地址及國別。

Name, address and country of the designated serum processing facility.

- (4) 目的地：包括目的地國家、輸入人姓名或公司名稱及地址。

Destination country and the importer or the importing company's name and address.

- (5) 檢疫結果：證明血清符合前點第一款至第五款之規定。

Compliance with subparagraphs 1 to 5 of the preceding article.

- (6) 動物檢疫證明書發證日期、地點、機關名稱、戳記、簽發者姓名及簽章

Date and place the certificate was issued, name and official stamp of the issuing authority, and name and signature of the certifying officer.

6. 美國政府動物檢疫主管機關應先將動物檢疫證明書樣本及戳記送輸出入動物檢疫機關確認。

The animal quarantine authority of the United States must submit a sample veterinary certificate with official stamp for the animal quarantine authority's confirmation in advance.