Export of Fetal Bovine Serum to Taiwan

(This article is three pages long- please be sure to read all three pages.)

The following is based on Taiwanese import requirements. These are not APHIS-VS requirements.

Requirement for inspection: The processing/exporting facility must be inspected by APHIS/VS at least annual to verify that the facility meets the requirements to export, and provide USDA supervision.

Countries of origin for eligible material: In order to be eligible for export to Taiwan, fetal bovine serum and products must have been collected from fetuses from animals slaughtered in the United States or the following countries that have been recognized by the Council of Agriculture, Executive Yuan as free of foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, and bovine spongiform encephalopathy:

Australia, New Zealand, Iceland, Norway, Mexico, Panama, Honduras, Costa Rica, Hungary, and Nicaragua.**

**This list is based upon the most recent information provided to APHIS by BAPHIQ (animal health authorities in Taiwan). As always, the exporter is responsible for having their importer confirm, prior to shipment, that Taiwan will accept the exported materials.

Requirement for import permit: The Taiwanese importer is required to apply and obtain an import permit from the Taiwanese Bureau of Animal and Plant Health Inspection and Quarantine prior to import. Only the importer from a Taiwanese research institute or manufacturer of biological products for animal use is allowed to apply for the import permit (the US exporter may not). The exporter is responsible for confirming prior to export that his importer has obtained the required import permit. APHIS will not verify the issuance of the Taiwanese import permit.

Restrictions on use: Taiwanese regulations limit the use of the serum to: use only for in-vitro test or production of biological products for poultry or swine. Products may not be used in Taiwan for in-vivo purposes or to produce biological products for use by/in ruminants, dogs, cats, or humans.

Restriction on materials that can be handled in US processing facilities: Materials may only be processed or handled in facilities in the US which do not handle materials derived from bovines **other than** those resident, at the time of slaughter, in the US, or the following countries: Australia, New Zealand, Iceland, Norway, Mexico, Panama, Honduras, Costa Rica, Hungary, and Nicaragua.** Facilities may not handle materials derived from animals slaughtered in Canada.

Documents required to be presented to APHIS office with certificate for endorsement: In addition to meeting other APHIS-VS requirements regarding issuance of zoosanitary (animal health) export certificates, the exporter must present the following with the draft VS Form 16-4 to the APHIS office:

- A proper notarized affidavit containing all certification statements appearing in the additional declaration area of the VS Form 16-4 (your APHIS area office can provide you with details on how to prepare a proper notarized affidavit).

- For materials derived from cattle slaughtered in a country other than the United States: A certificate*** (for the specific lot of raw material that the exported materials are derived from) endorsed by a full-time salaried veterinarian of the agency responsible for animal health in the country of origin stating:
  - **A.** That the materials are derived from cattle that were, at the time of slaughter, resident in (insert one of the following: Australia, New Zealand, Iceland, Norway, Mexico, Panama, Honduras, Costa Rica, Hungary, and Nicaragua.**)
  - **B.** That the materials are derived from fetuses collected from cattle which have passed ante-mortem and post-mortem inspection by the competent authority of <insert name of country of origin>.
  - ***C.*** That the materials has been filtered through a filter of 0.22µm or less, or has been irradiated with gamma-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 exotic bluetongue. *(If this testing is done in the US**, laboratory results must be presented with the certificate** showing that the materials have been tested (with negative results) for the following: mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and exotic bluetongue.*

*** An easily read copy is acceptable.

Certification statements to appear on the VS Form 16-4: The following exact text must appear in the additional declaration section of the VS Form 16-4. No additional text may be added.

*The below described bovine serum product was processed at the following facility, a premises which is under the supervision of the United States government: **[insert name and address of processing/exporting facility in the US]** in the United States.*

This office has on file a notarized affidavit from [insert name of company] verifying the accuracy of the statements below.

The above referenced processing facility processes bovine sera only from cattle (or fetuses collected from cattle) that were, at the time of slaughter, resident in [insert <the

United States> and/or <country name or names>], a country that has been <or countries that have been> recognized by the Council of Agriculture, Executive Yuan as free of foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, and bovine spongiform encephalopathy". *(Purple text should be deleted if facility only handles material from US slaughter houses).*

In the case of fetal bovine serum products, the serum is derived from fetuses collected from cattle that were, at the time of slaughter, resident in [insert <the United States> and/or "<country name**>], a country that has been <or countries that have been> recognized *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. (Purple text should be deleted if materials only include those supplied by US slaughterhouses.)*

In the case of fetal bovine serum products, the serum is derived from fetuses collected from cattle which have passed ante-mortem and post-mortem inspection by the competent authority of <insert name of country of origin>.

The serum has been filtered through a filter of 0.22µm or less, or has been irradiated with ã-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 exotic bluetongue.

Information to be included in the "PRODUCT (quantity, unit of measure, and kind)" block of the VS Form 16-4:

Product name, quantity, and lot number. (must state that products are fetal bovine serum products).

Information to be included in the "NAME AND ADDRESS OF CONSIGNEE" block of the VS Form 16-4:

Destination including country, name, and address of importer in Taiwan.

If you have questions about any of the above information, you should contact your APHIS-VS area office for assistance.