TAIWAN - QUARANTINE REQUIREMENTS FOR BOVINE SERUM FOR TECHNICAL USE AMENDED

(*Note another update to these requirements below)

Taiwan recently amended their Quarantine Requirements for Bovine Serum for Technical Use to Taiwan, which are currently in transition and scheduled to enter into force on January 1, 2019. The biggest changes to these requirements include the following:

- APHIS will be required to inspect and approve all facilities manufacturing bovine serum for technical use. Upon approval of a facility, the Export Products staff in Riverdale will need to forward the facility name, address and APHIS approval date to Taiwan for publication on their website. Taiwan has indicated that a facility may begin exporting once the APHIS approval has been issued (i.e. they do not need to wait for publication to the Taiwanese website). These inspections will be required annually.
- Bovine serum may now be collected from animals at the time of slaughter, or from live donor animals. If the serum is collected from live donor animals, they must be found clinically healthy by physical evaluation at the time of collection.
- Facilities may utilize any of the following processing options:
    1) Facility dedication;
    2) Line dedication; or
    3) Measures to effectively segregate serum for export to Taiwan from ineligible materials if these designated facilities also handle ineligible materials.

  Accordingly, APHIS will need to certify that the serum was produced, stored and transported in such a manner as to prevent contamination by communicable animal disease pathogens transmissible through the product.
- The serum must be collected from cattle that, at the time of collection, are resident in countries free of FMD and contagious bovine pleuropneumonia (as recognized by Taiwan).
- The product name and lot number must be included on the inner package label.

The following IREGS have been updated reflecting these changes – please review them at your earliest convenience to familiarize yourself with the new requirements and updated certification language and share them with your stakeholders.

Serum for Technical Purposes: General Information - November 2018 (pdf 277kb)

Bovine serum albumin (BSA) and cell culture media containing BSA -November 2018 (pdf 189kb)

Bovine Serum and Derivatives (Excluding Fetal Bovine Serum) - November 2018 (pdf 269kb)

Fetal Bovine Serum - November 2018 (pdf 244kb)

Additionally, an inspection checklist has created and shared with the APHIS field to facilitate inspectors with facility inspections. This checklist is available upon request from a facility's pertinent VS Service Center. Upon completion of inspection, this checklist must be forwarded to the Export Products staff in Riverdale for final review and approval. If the facility can be approved, the facility information will be listed in APHIS' internal database. A facility is not permitted to begin exporting until their name and Taiwan-specific approval information is listed in VSPS.

The Taiwanese government has indicated that **all facilities currently manufacturing/processing and exporting bovine serum (or fetal bovine serum) to Taiwan must be in compliance with these new regulations by January 1, 2019**. This means facilities currently manufacturing/processing bovine serum for Taiwan must have a current completed facility checklist on file in Riverdale with information listed in our APHIS internal database by January 1, 2019. If the inspector can verify the checklist based on their most recent inspection, a new inspection is not required. Please have all facilities manufacturing or processing bovine serum (or fetal bovine serum) for Taiwan in the last 3 years contact their VS Service Center endorsing certificates immediately for the steps necessary to ensure compliance with these new requirements.

*IMPORTANT UPDATE TO THE ABOVE INFORMATION

APHIS has just been informed by Taiwan that a facility may not begin exporting bovine serum until BAPHIQ approval has been issued and the facility has been posted to the Taiwanese website. BAPHIQ assures us that these updates will be made within 2-3 business days of submission of facility information by APHIS to Taiwan, but that only product produced after the date of BAPHIQ approval may be exported to Taiwan. (This should only be applicable for new facilities not presently on the list included in the original message below or facilities requesting name/address updates.)

After submission of the inspection checklist to the Export Products staff in Riverdale and review, Riverdale will submit the facility name and address to Taiwan. Once Taiwan issues their approval and posts the facility on their website (within 2-3 business days of submission), BAPHIQ will notify Riverdale who will notify the Service Center that submitted the checklist. The Service Center and/or veterinary inspector is responsible for notifying the facility of their formal Taiwan approval and the date after which products may be produced for export to Taiwan. A new facility will be listed as inactive in the APHIS internal database until the formal BAPHIQ approval is received.

It remains the exporter's responsibility to ensure their information is correctly published on the BAPHIQ website.