

Bovine, Ovine and Porcine Bile and Bile Salts for Manufacturing Uses (including Pharmaceutical) or for Research for Export to Mexico

The bilingual certification statements below are for bovine, ovine and porcine bile and bile salts intended for use in manufacturing products such as pharmaceutical products or for diagnostic and/or research uses and should be provided in the Additional Declarations section of the Export Certificate for Animal Products (VS Form 16-4) and continuation page VS form 16-4A as needed. A notarized affidavit from the manufacturer is required to support these statements on the export certificate issued by APHIS Veterinary Services.

Mexico SENASICA requires certain traceability information for animal products offered for importation. For bovine, ovine and porcine bile and bile salts intended for use in manufacturing or diagnostic and/or research uses, the export certificate should present the product lot number in the identification block. Additional information concerning origin plant, date of manufacture, and any expiry date should be provided in a manufacturer's addendum. An original and a copy of a quality control certificate or a lot-specific laboratory report, issued by the manufacturing company, must be presented with the product. Border quarantine personnel will retain the copy after comparing it with the original.

Certification statements:

This office has on file a notarized affidavit from [company name] verifying the accuracy of the statements below. / *Esta oficina mantiene en archivo una declaración notarial de [nombre de la compañía], verificando si lo detallado abajo es lo preciso.*

1. The animals from which the product derives are from the United States and/or the animal ingredients were legally imported from countries free of foot-and-mouth disease and classical swine fever. / *Los animales de los que procede el producto son originarios del país indicado en este documento como de origen y/o los insumos de origen animal fueron importados legalmente a los Estados Unidos de países libres de fiebre aftosa y fiebre porcina clásica.*

Certify statement 2 for product containing bovine-origin bile and bile salt ingredients as necessary:

2. For bovine product the country of origin is classified by the OIE as a country with BSE controlled or negligible risk status. / *Para producto de origen bovino, el país de origen está clasificado por la OIE como de riesgo controlado o insignificante para la encefalopatía espongiiforme bovina.*

3. The product is approved for industrial use or research purposes. / *El producto está aprobado para uso industrial o investigación.*

4. The product derives from animals subjected to ante-mortem and post-mortem inspection and were slaughtered in an establishment under official controls. The official

USDA FSIS establishment numbers are as follows:_____. / *El producto procede de animales sanos inspeccionados ante y pos mortem y que fueron sacrificados en establecimientos bajo control oficial, señalando los números de establecimientos.*

5. The product was subjected to the following physical treatment designed to destroy, inactivate or eliminate viruses, bacteria or causal agents presenting zoonotic risk: _____ (indicate time, temperature and drying). / *El producto fue sometido a un tratamiento (indicar tiempo y temperatura y condiciones de secado en su caso), el cual permite la destrucción, inactivación o eliminación de cualquier virus, bacterias o agente causal que represente algún riesgo zoonótico.*