

## **Blood and Blood Products Including Fetal Bovine Serum for Use in Diagnostics or Research for Export to Mexico**

The bilingual certification statements below are for animal blood and blood products, including fetal bovine serum, intended for diagnostic and/or research use 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 blood and blood products for use in diagnostics and in research, 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.

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 product originated in the United States of America, or was legally imported from \_\_\_\_\_ (indicate country of origin). / *El producto es originario de los Estados Unidos de América, o fue importado legalmente del país indicado.*
2. The animals from which the product derives were inspected at the time of collection of the product in an establishment under the control of the official sanitary authority and were found to be free of infectious contagious diseases. / *Los animales de los que procede el producto fueron inspeccionados en un establecimiento bajo control de la autoridad oficial sanitaria correspondiente, y se encontraron sin evidencias clínicas de alguna enfermedad infecto-contagiosa al momento de la recolección del producto.*
3. The product was collected and processed in establishments under the control of the official sanitary authority in the country of origin and the final product has been approved for use in research and/or diagnostics. / *El producto fue colectado y procesado en establecimientos bajo control de la autoridad sanitaria oficial de país de origen y el producto final ha sido aprobado para su uso en investigación y/o diagnóstico.*

(Choose appropriate option for statement #4) / *(Elija la opción apropiada para la declaración #4)*

4. The product was subjected to the following treatment (indicate the appropriate option): / *El producto fue sometido al siguiente tratamiento (indique la opción apropiada):*  
( ) Physical treatment (ultrafiltration or triple filtration to 0.1  $\mu\text{m}$ ) / *Un tratamiento físico (ultrafiltración o filtración triple a 0.1  $\mu\text{m}$ ): \_\_\_\_\_*

- ( ) Chemical treatment / *Un tratamiento químico:* \_\_\_\_\_  
( ) Radiation treatment / *Un tratamiento radiante:* \_\_\_\_\_  
( ) Thermal treatment / *Un tratamiento térmico:* \_\_\_\_\_

which is designed to destroy, inactivate or eliminate any viruses, bacteria or causal agents that can cause animal health risk / *el cual permite la destrucción, inactivación, o eliminación de cualquier virus, bacterias, o agente causal que represente algún riesgo zoonosario.*

4. For defibrinated blood - that the blood was derived from healthy animals subjected to a veterinary examination at the time of the collection and was handled in a manner that assures that the product was not contaminated with viruses, bacteria or causal agents that can represent an animal health risk. / *Para el caso de sangre desfibrinada, que se obtuvo de animales sanos, los cuales fueron sujetos a un examen veterinario al momento de la colecta, y que la sangre se manejó de tal manera que se asegure que no está contaminada con virus, bacterias o agentes causales que representen algún riesgo zoonosario.*
5. Blood products derived from laboratory animals meet the following conditions:

(Certify the following if from laboratory animals.)

[The animals were clinically healthy at the time of collection of the serum product. The collection of the serum product was carried out under aseptic conditions. / *Los animales se encontraron sanos al momento de la extracción del suero y que este proceso de obtención fue llevado a cabo completamente en condiciones asépticas.*]

(Certify the following if from rabbits.)

[The product derives from rabbits raised in facilities free of any evidence of rabbit haemorrhagic disease and myxomatosis. / *El producto procede de conejos originarios y procedentes de explotaciones libres de la enfermedad hemorrágica viral de los conejos y de mixomatosis.*]

(Certify the following if bovine blood or fetal bovine serum from slaughtered animals)

6. The animals from which the product was obtained were not stunned before slaughtering by means of compressed air or gas injection in the cranial cavity or cutting of the spinal cord (by laceration of the central nervous tissue by means of introducing a sharp cutting instrument into the cranial cavity). / *Para el caso de sangre obtenida de bovinos que hayan sido sacrificados: Estos no fueron aturdidos mediante inyección de gas en la cavidad craneana o por corte de la médula espinal (por laceración del tejido nervioso central, mediante la introducción en la cavidad craneana de un instrumento punzo cortante).*