

Processed Bovine-Origin Bone Products for Biomedical Use

This document is for the export to Mexico of processed bovine bone intended for use in humans (biomedical). Animal-origin ingredients used for manufacturing the product must originate from the United States or have been imported legally.

Please note that importers will be asked to present an original and copy of a quality control certificate or a report of analysis of the product lots issued by the manufacturing company.

For product of the United States, provide the following bilingual certification statements in the Additional Declarations section of the certificate 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.

This office has on file a notarized affidavit from [company name] verifying the accuracy of the following statements: / *Esta oficina cuenta en su expediente con una declaración notariada de [nombre de la compañía] que verifica la exactitud de las siguientes declaraciones:*

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 product was processed in an establishment under official control. / *El producto se procesó en un establecimiento bajo control oficial.*
3. The raw animal origin ingredients (bovine) used in the preparation of the product derive from a country recognized by the OIE as Negligible Risk or Controlled Risk for BSE (bovine spongiform encephalopathy, United States or Canada). / *Los insumos de origen animal (bovino) utilizados en la elaboración del producto son originarios de un país clasificado por la OIE como de riesgo insignificante y/o controlado de EEB (Estados Unidos y/o Canadá).*
4. The product is intended for human use in the biomedical industry. / *El producto está destinado para uso humano biomédico.*
5. Raw animal-origin ingredients with which the product was manufactured originated from a country free of foot-and-mouth disease or they were processed to reach an internal temperature of at least 70°C for no less than 30 minutes. / *Los insumos de origen animal con los que se elaboró el producto son originarios de un país libre de fiebre aftosa o bien que fueron sometidos a un tratamiento térmico con el que alcanza una temperatura interna de por lo menos 70°C durante por lo menos 30 minutos.*

For product from Canada offered for reexport from the United States: Follow indications in IREG instructions for [Animal Products Offered for Re-Export](#) and provide authenticated copy of

the origin export certificate that provides certification in line with the mentioned document and the following additional statements:

1. 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. / *Los animales de los que se obtuvo la materia prima para elaborar el producto, no fueron aturdidos, mediante inyección de gas en la cavidad craneana o por corte de médula espinal (por laceración del tejido nervioso central, mediante la introducción en la cavidad craneana de un instrumento punzo cortante).*
2. The following specified risk materials were removed from the ruminant animals serving as the source of the product: brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, dorsal root ganglia, bone marrow, tonsils and small intestine. / *En los rumiantes sacrificados de los que se obtuvo el producto no corresponden a materiales específicos de riesgo: cerebral, cráneo, ojos, ganglio trigémino, médula espinal, columna vertebral, cadena dorsal ganglional, médula ósea, tonsilas e intestino delgado.*
3. The ruminant-origin raw materials used in the product do not correspond to or contain the following specified risk materials: brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, dorsal root ganglia, bone marrow, tonsils and small intestine. / *Los insumos de origen rumiante empleados en la elaboración de los productos no corresponden a los siguientes materiales específicos de riesgo: cerebral, cráneo, ojos, ganglio trigémino, médula espinal, columna vertebral, cadena dorsal ganglional, médula ósea, tonsilas e intestino delgado.*
4. In the country of origin of the product there exists health regulations currently in force that prohibit the feeding of animals with meat and bone meals or greaves of ruminant origin, in accordance to the OIE guidelines. / *En el país de origen del producto existe reglamentación zoonosanitaria vigente que prohíbe alimentar a los rumiantes con harinas de carne y hueso o chicharrones (greaves) de origen rumiante de acuerdo a los lineamientos de la OIE.*