

Porcine Bile and Similar Products for Pharmaceutical, Surgical or Industrial Purposes for Export to Ecuador

This document outlines the requirements for porcine products such as bile intended for pharmaceutical, surgical or industrial purposes.

AGROCALIDAD Ecuador requires that the product intended for export must be registered with the U.S. competent authority. A free sale certificate or document demonstrating product registration at the State or Federal level should be available.

AGROCALIDAD Ecuador requires that biological products intended for export must be packaged in appropriate materials that meet any current international guidance. The packages must be labeled such that the product is identified as to country and establishment of origin and with appropriate production and expiration/best by dating or coding as appropriate. Biological products should be shipped refrigerated or frozen as appropriate.

Porcine products that have not been heat treated and that are imported for pharmaceutical, surgical or industrial uses must derive from animals raised in a country free of swine vesicular disease, African swine fever and Teschen's disease (porcine enterovirus encephalomyelitis).

Product description (product box on VS Form 16-4) should include the species of origin (porcine) and the quantity of product being exported.

The laws of Ecuador require that certificates should also be in Spanish. A translation of the VS form 16-4 to Spanish may be required. Any required translation should be provided by a certified translation service.

The bilingual certification statements provided below should be made in the Additional Declaration section of a VS Form 16-4, Export Certificate for Animal Products, and VS Form 16-4A, Export Certificate for Animal Products Continuation Page, as necessary.

The VS office has on file a notarized affidavit from [company name] verifying the accuracy of the statements below. / *La Oficina de Servicios Veterinarios tiene en sus archivos una declaración juramentada de [nombre de la compañía] certificando la veracidad de las afirmaciones enunciadas a continuación:*

1. The product does not derive from animals that were culled as a result of a transmissible swine disease control or eradication program. / *El producto no deriva de animales desechados o descartados como consecuencia de un programa de control o erradicación de una enfermedad porcina trasmisible.*

2. The products derive from animals raised from birth in a country free of the swine vesicular disease, African swine fever and Teschen disease (enterovirus encephalomyelitis). / *Los productos proceden de animales que permanecieron desde su nacimiento en un país libre de enfermedad vesicular porcina, peste porcina Africana y encefalomiélitis por enterovirus.*