

VS Guidance 13809.1

Importation of Cell Culture Material and Diagnostic Kits

1. Purpose and Background

This guidance provides information on importing test kits, cell cultures, cell lines, and products of cell cultures and cell lines (such as monoclonal antibodies) into the United States.

This guidance document represents APHIS' position on this topic and is intended solely as guidance. It does not have the force and effect of law, does not create or confer any rights for or on any person, and does not bind the U.S. Department of Agriculture (USDA) or the public. Language suggesting that this guidance is mandatory (e.g., "shall," "must," "required", or "requirement") should not be construed as binding unless the terms quote from a statutory or regulatory requirement. The information this document contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

2. Document Status

- A. Review date: 12/30/2026.
- B. This document replaces Veterinary Services Memorandum 593.1, which is hereby canceled.

3. Reason for Reissuance

This document reflects updated references and product import information.

4. Authority and References

- A. Authorities (*Code of Federal Regulations* (CFR)):

- [7 CFR 371.4](#)
 - [9 CFR part 94](#)
 - [9 CFR part 95](#)
 - [9 CFR part 122](#)

- B. References:

- [Guideline 1120, Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products \(for in vitro use\)](#)
 - [Guideline 1121, Self-Contained Test Kits Containing Animal-Derived Ingredients](#)
 - [VS Form 16-3, Application for Permit to Import Controlled Material, Import or](#)

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[Transport Organisms or Vectors](#)

- [VS Form 16-7, Additional Information for Cell Cultures and their Products](#)

5. Audience

VS employees, other State and Federal agencies, and accredited veterinarians.

6. Guidance

A. General

- 1) VS policy requires a VS veterinary import permit for importation of animal derived materials and products that do not adhere to the criteria outlined by [Guideline 1120, Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products \(for in vitro use\)](#) or [Guideline 1121, Self-Contained Test Kits Containing Animal-Derived Ingredients](#).
- 2) VS previously modified the list of products requiring a VS veterinary import permit to reflect deregulation of animal derived materials in fully-finished, self-contained test kits and of cultured cells, cell lines, and products of cultured cells and cell lines under certain criteria (e.g., for *in vitro* use). These products had been previously regulated because of concerns that animal origin components could introduce exotic disease, such as foot-and-mouth disease (FMD) and highly pathogenic avian influenza (HPAI), into livestock and poultry. However, the Animal and Plant Health Inspection Service (APHIS) deregulated these products after it performed risk analyses that showed the risk to animal health in the United States associated with these products was minimal.

B. Permitting

- 1) The VS Permitting Assistant may be used to determine VS import requirements and to submit a VS veterinary import permit application if needed (see links below). If a VS veterinary import permit is required, an applicant must submit a completed [VS Form 16-3, Application for Permit to Import Controlled Material, Import or Transport Organisms or Vectors](#) in eFile to obtain a VS veterinary import permit. If the material is a cell culture, cell line, or product of cell culture or cell line, [VS Form 16-7, Additional Information for Cell Cultures and their Products](#), must also be submitted.
 - a. VS Permitting Assistant:
<https://efile.aphis.usda.gov/s/vs-permitting-assistant>
 - b. eFile permit application instructions:
<https://www.aphis.usda.gov/help/eFile/guidance-submit-vs16-3-permit-app.pdf>

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- 2) VS Animal Product Import staff needs the information requested in the VS veterinary import permit application form to properly evaluate the permit request. Incomplete information will result in denials or delays in processing the application while staff obtains more information.
- 3) Applicants must pay a permit application user fee before VS processes the veterinary import permit application. The fee will be listed in eFile during the application process.
- 4) If VS Animal Product Import staff determine that the risk associated with import of a controlled material cannot be mitigated, then safety testing at a USDA National Veterinary Services Laboratories (NVSL) laboratory will be required. In these cases, VS Animal Product Import staff will inform the applicant that testing is needed and will guide the applicant through the subsequent permitting process.
- 5) Importers must provide a copy of the VS veterinary import permit with each shipment of the permitted animal derived material. If Customs and Border Protection Agriculture Specialists at U.S. ports of entry identify shipments of controlled material that do not have an accompanying VS veterinary import permit, the shipment will be placed on hold until an On Hold Shipment Notification application (VS 16-79) is submitted in eFile, a compliance fee paid, and appropriate supporting documentation is provided to the VS Animal Product Import staff. If the VS Animal Product Import staff determines that the risk to animal health associated with import of the controlled material is acceptable, the material may be released.
- 6) A VS veterinary import permit is generally valid for one (1) year, and the permit may be renewed on a yearly basis. Applicants can apply in eFile for renewal of the permit weeks in advance of the expiration date and pay a user fee.

7. Inquiries

Please contact the following office with questions concerning this guidance document:

USDA APHIS Veterinary Services
Strategy and Policy
Animal Product Import and Export
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