VETERINARY SERVICES
REQUIREMENTS FOR ANIMAL RELATED MATERIALS, INCLUDING PATHOGENS

Kathleen Jan Akin, DVM
Assistant District Director
District 5, Veterinary Services
April 2014
Veterinary Services
Reorganization of Infrastructure 2014

VS Field Organization

Hub Locations
NIES Service Centers
SPRS Districts
District 1
District 2
District 3
District 4
District 5
District 6

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service collected the data displayed for internal agency purposes only. These data may be used by others; however, they must be used for their original intended purpose.
Veterinary Services

- Complete Redesign of Website for APHIS
- Work in progress
Veterinary Services

- **Importation**
  - Includes certain organisms and vectors
  - Risk determination – mitigation
  - Disease Status of Country of Origin

- **Exportation**
  - Animals and animal products
  - Country of Destination Determined
  - International Regulations – IREGS by country on web

- **Interstate movement**
  - Certain agents have restrictions
Veterinary Services

- **Importation and Interstate movement**
  Import permits issued by National Center for Import-Export
  (located in Riverdale, Maryland – DC suburb)

- **Exportation**
  Export Certification endorsed by local office (National Import-Export Services (District Service Center and/or branch office of Service Center))
Authorities (laws/regulations)

- **Animal Health Protection Act 2002**
  - Broad authority for interstate and importation of animals and articles

- **Virus-Serum-Toxin Act**
  - Importation permits, inspections and licenses for viruses, serums, toxins and products

- **Title 9 Code of Federal Regulations, Parts 93, 94, 95**
  - Codified importation of certain animals and animal materials

- **Title 9 Code of Federal Regulations Part 122**
  - Codified importation and interstate permit requirements of organisms and vectors or derivatives which may introduce or disseminate disease of animals
Importation and Interstate transfer

- VS permit is required for interstate transfer and importation of organisms or their derivatives which may introduce or disseminate any contagious or infectious disease of animals (including poultry).
Importation and Interstate transfer

VS permit is required for interstate transfer and importation of specimens inoculated with or known to be infected with known infectious organisms of livestock and poultry.

Includes mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, etc. which have been infected or inoculated with infectious organisms of livestock or poultry (VECTORS).
Permit Issuance

- Permit approval is risk based and depends on:
  - Agent involved
  - Proposed use
    - *In vitro* at a lower BSL (bio-safety level) might be appropriate.
    - *In vivo* in susceptible species may require higher BSL or additional enhancements.
Review Process for Permit

- Case by case requests
- Documentation needed
- Similar process for Select Agents and Non-Select agents
- Biosafety facility inspection may be needed
  - prior to permit
  - Select Agent Inspection

- User Fee cost associated with application

EXCLUSION OR EXEMPTION FOR ORGANISMS
ePermits

- Web-based system
- Apply for permits on-line, check status, distributed electronically
- View permits on-line
- eAuthentication
- User Fee
Accessing ePermits

Last Modified: Jul 25, 2013

To access ePermits, and submit a Plant Protection and Quarantine (PPQ) permit application, you must have a level 2 e-Authentication account. e-Authentication is a registration process that enables customers to access USDA Web applications and services via the Internet.

The USDA eAuthentication system supports different levels of authentication. ePermits currently supports Level 2 users for all permit application types and Level 1 users for selected permit application types.

Account Restrictions:

- After 180 days with no login, your USDA eAuthentication password will expire. To use the system again, you will need to unlock your password.
- After 400 days with no login, your USDA eAuthentication account will be disabled. To unlock your account, please contact the eAuthentication Helpdesk via email eAuthHelpDesk@ftc.usda.gov or call 600-457-3642. You may also visit the eAuthentication Help website http://www.eauth.gov.usda.gov/eauthHelp.html.
- To learn more about USDA eAuthentication password rules, see http://www.eauth.gov.usda.gov/USDA%20eA%20Registration%20Job%20Aid_v2.0.pdf.
- Each person who uses USDA eAuthentication must use his or her own user id. No sharing is allowed. USDA reserves the right to terminate any account if this policy is violated.

Create eAuthentication Account to access ePermits
No Import Permit Required

Last Modified: Mar 17, 2014

These materials do not require a USDA import permit, but will be reviewed at the port of entry.

1100 Human Pharmaceuticals and Human Vaccines Containing Animal Components
1101 Human and Non-Human Primate Material (excluding cell cultures)
1102 Feline and Canine Material
1103 Live Laboratory Mammals and Their Material (for research purposes)
1104 Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom) Revised June 2011
1106 Chemically Synthesized Materials
1110 Microbially Produced Materials
1114 Recombinant Microbes and Their Products
1116 Non-pathogenic Microorganisms
1118 PET CHEWS / TREATS made of ANTLERS or RAWHIDE
1120 Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
1121 Test Kits
1122 Vitamins and Minerals
Accessing ePermits

Last Modified: Jan 8, 2014

Some of the many advantages of having an ePermits account include:

- Notifications of permits about to expire
- Amend, renew, and copy your applications with minimal data entry
- Reprint permits at any time
- Securely submit credit card payments online
- Manage your own information to prevent transcription errors
- A single place to view and manage all of your applications, permits, letters of no jurisdiction, denials, and other permit related correspondence.

How to Register to Use ePermits

ePermits uses a USDA-wide system for login called USDA eAuthentication. For more information, go to the Register to Use ePermits page. To use ePermits, you will need to register for an eAuthentication account with Level 2 access for most application permit types.

Please click here to apply for a Level 2 eAuthentication account.

Login to ePermits

Registered users may access the ePermits system at https://epermits.aphis.usda.gov/epermits.

Applications that can be submitted online through ePermits:

<table>
<thead>
<tr>
<th>Application Form</th>
<th>Application Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPQ 525A</td>
<td>Application for Permit to Receive Soil</td>
</tr>
<tr>
<td>PPQ 526</td>
<td>Application and Permit to Move Live Plant Pests or Nöxious Weeds</td>
</tr>
<tr>
<td>PPQ 546</td>
<td>Agreement for Postentry Quarantine State Screening Notice</td>
</tr>
</tbody>
</table>
UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS

TRADE AND ADDRESS OF SHIPPER:
Various shipments within the UNITED STATES

NAME AND ADDRESS OF PERMITTEE INCLUDING ZIP CODE AND TELEPHONE NUMBER:
Jane Doe
XYZ CORPORATION
1234 Old Mill Road
Riverdale, MD 20707
(301) 754-9460

AS REQUESTED IN YOUR APPLICATION YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS:

BACILLUS ANTHRACIS

RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES:

This permit is issued under authority contained in 7CFR Chapter 1, Parts 351 and 352. The authorized materials or their derivatives shall be used only in accordance with the restrictions and precautions specified below. Violations of this permit are subject to penalty, in addition to any penalties imposed by USDA, APHIS.

- Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease.
  - *** THIS PERMIT IS INVALID WITHOUT PERMITTEE'S SIGNATURE ***.
  - "I, Jane Doe, certify that this material will be used in accordance with all restrictions and precautions as are specified in this permit.
  - *** signed: ____________________________ " ***
- All studies must be conducted in Biosafety Level 3 facilities inspected and approved by the USDA. This facility shall be reinspected every 3 years.
- Permittee shall notify USDA, APHIS, Veterinary Services within 48 hours of failure of receipt of a shipment of materials. Permittee to contact [1-866-994-LOST (5678)].
- Registration for possession, use, and transfer of Select Agents and toxins is required pursuant to Chapter 9 of Part 121 of the Code of Federal Regulations. Registration applications are available at the following website address: http://www.aphis.usda.gov/programs/ag_selectagent/index.html.
- Select agent program registration application number ASA000000.
- Work with these Agents is limited to personnel with an approved Security Risk Assessment (SRA).

TO EXPEDITE CLEARANCES AT THE PORT OF ENTRY, BILL OF LADING, AIRBILL OR OTHER DOCUMENTS ACCOMPANYING THE SHIPMENT SHALL BEAR THE PERMIT NUMBER.

SIGNATURE: Max Yeh
TITLE: Senior Staff Veterinarian
NO. LABELS: National Center - Import-Export

APHIS
Safeguarding Animal Health
Veterinary Services

VS FORM 16-6A (MAR 95) Replaces VS Form 16-3A and 16-20 which are obsolete.
### UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS

<table>
<thead>
<tr>
<th>PERMIT NUMBER</th>
<th>SAMPL 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE ISSUED</td>
<td>Research</td>
</tr>
<tr>
<td>DATE EXPIRES</td>
<td>09/06/2005</td>
</tr>
</tbody>
</table>

**NAME AND ADDRESS OF SHIPPER(S):**

Various shippers within the UNITED STATES

**NAME AND ADDRESS OF PERMITTEE INCLUDING ZIP CODE AND TELEPHONE NUMBER TO:**

Jane Doe  
XYZ CORPORATION  
1234 Old Mill Road  
Riverdale, MD 20707  
(301) 734-5960

**CC:**

Transport Permit  
CDC, Atlanta, GA  
AVIC, VS, Annapolis, MD

**U.S. PORT(S) OF ARRIVAL:**

N/A

**MODE OF TRANSPORTATION:**

ANY

AS REQUESTED IN YOUR APPLICATION YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS

**BACILLUS ANTHRACIS**
United States Veterinary Permit for Importation
and Transportation of Controlled Materials and
Organisms and Vectors

Permit Number: SAMPL 1
Research

Date Issued: 09/06/2005
Date Expires: 09/06/2006

Name and Address of Shipper(s):
Various shippers within the United States

C C:
Transport Permit
CDC, Atlanta, GA
AVIC, VS, Annapolis, MD

Name and Address of Permittee Including Zip Code and Telephone Number:
To: Jane Doe
XYZ Corporation
1234 Old Mill Road
Riverdale, MD 20707
(301) 734-5960

U.S. Port(s) of Arrival: N/A

Mode of Transportation: ANY

As requested in your application you are authorized to import or transport the following materials:

Bacillus Anthracis
RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES

- Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease.
  
  **"I, Jane Doe, certify that this material will be used in accordance with all restrictions and precautions as are specified in this permit,"**
  
  **signed: ____________________________"**

- All studies must be conducted in Biosafety Level 3 facilities inspected and approved by the USDA. This facility shall be reinspected every 3 years.

- Permittee shall notify USDA, APHIS, Veterinary Services within 48 hours of receipt of a shipment of materials. Permittee to contact [1-866-994-LOST(5678)].

- Registration for possession, use, and transfer of Select Agents and toxins is required pursuant to Chapter 9 of Part 121 of the Code of Federal Regulations. Registration applications are available at the following website address: http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

- Select Agent Program registration application number AGR00000.

- Work with these Agents is limited to personnel with an approved Security Risk Assessment (SRA).

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TO EXPEDITE CLEARANCES AT THE PORT OF ENTRY, BILL OF LADING, AIRBILL OR OTHER DOCUMENTS ACCOMPANYING THE SHIPMENT SHALL BEAR THE PERMIT NUMBER

<table>
<thead>
<tr>
<th>SIGNATURE</th>
<th>TITLE</th>
<th>NO. LABELS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Yeh</td>
<td>Senior Staff Veterinarian National Center - Import-Export</td>
<td>Copy of Permit</td>
</tr>
</tbody>
</table>

VS FORM 16-6A (MAR 95) Replaces VS Form 16-3A and 16-25 which are obsolete.
RESTRICTIONS AND PRECAUTIONS: (continued from Permit Form VS 16-5)

- Importer is responsible for obtaining any required authorization (letter or permit) from the U.S. Public Health Service. Importer to contact [(404) 498-2260].

- This permit does not exempt the permittee from responsibility for compliance with any other applicable federal, state, or local laws and regulations.

- This permit DOES NOT authorize direct or indirect exposure of domestic animals, including poultry, cattle, sheep, swine, horses, etc.

- All laboratory animals which are to be exposed to the material must be hold only in isolated insect & rodent-proof facilities.

- Packaging, containers, and all equipment in contact with these materials shall be sterilized or considered a biohazard and be disposed of accordingly.

- Pens, cages, bedding, waste, and dead animals in contact with these materials shall be sterilized or considered a biohazard and be disposed of accordingly.

- This permit is valid only for work conducted or directed by you in your present U.S. facilities. (MATERIALS SHALL NOT BE MOVED TO ANOTHER U.S. LOCATION, OR DISTRIBUTED WITHIN THE U.S., WITHOUT USDA, APHIS, VS, NCIE AUTHORIZATION.)

- On completion of your work, all permitted materials and all derivatives therefrom shall be destroyed.

- The restrictions on this permit remain in force as long as the material is in the United States.

- A copy of this permit should be included with the shipping documents.
Restrictions and precautions for transporting and handling materials

- Certification requirements
- *In-vitro* and *in-vivo* work (BSL and Animal BSL)
- Specific building and room numbers
- Movement restrictions
- Other agent specific restrictions
Permit Compliance

- Inspections to verify Permitee following Restrictions and Precautions for transporting and handling materials and all derivatives.
Permit Compliance

- Compliance Inspection Checklist
- Permit number ____________
- Name of individual present during compliance check ________________
- Title of individual present during compliance check ________________
- How many shipments have been received this year? ________
- Are conditions/restrictions on permit being met? ________
- Is the permittee in compliance? Yes or No (circle response)
- If no, explain deficiencies or discrepancies ____________________________
- ________________________________________________________________
- ________________________________________________________________
- ________________________________________________________________
- ________________________________________________________________
- ________________________________________________________________
- Signature of inspector ___________________ Date of inspection ____________
- Printed name of inspector ___________________ Title of Inspector __________

Please fax or mail this completed form to:
- Organisms and Vectors Staff
- USDA, APHIS, VS, NCIE, TTST
- 4700 River Road
- Unit 2, Mail Stop 22, Cub 1A07
- Riverdale, MD 20737
- Fax: (301) 734-3652
Contact

- National Center for Import and Export
  - Call Center: 301-851-3300
  - Select Agents, Organisms and Vectors:
    - Fax: 301-734-3652
    - AgSAS@aphis.usda.gov
    - OV@aphis.usda.gov

- Nebraska Service Center (sub-section of District 5 Service Center)
  - 402-434-2300
  - vspsne@aphis.usda.gov
Exportation

Export Certification endorsed by local office
(National Import-Export Services - District Service Center and/or branch office of Service Center)

Nebraska Lincoln Office - 402-434-2300
vspsne@aphis.usda.gov

- Animals and animal products –
  - agents could be subject to State Department rules -
- Country of Destination Determined
  - Research materials may have special conditions
- International Regulations – IREGS by country published on web
Import Export

Last Modified: Feb 25, 2014

APHIS plays a vital role in ensuring the free flow of agricultural trade by keeping U.S. agricultural industries free from pests and diseases and certifying that the millions of U.S. agricultural and food products shipped to markets abroad meet the importing countries' entry requirements. APHIS makes sure that all imported agricultural products shipped to the United States from abroad meet the Agency's entry requirements to exclude pests and diseases of agriculture.

APHIS also keeps export markets open for American agricultural products by working to eliminate unjustified sanitary or phytosanitary (SPS) barriers - that is, concerns involving plant and animal health - raised by U.S. trading partners. APHIS' team of technical experts, based in the United States and abroad, includes scientists, veterinarians, pathologists, and entomologists that advocate on behalf of U.S. agriculture. They build relationships with their agricultural health and regulatory counterparts in other countries and use scientific principles to make the case for American agricultural exports, explaining to foreign officials why U.S. commodities are safe to import. APHIS played a direct role in opening new markets and retaining and expanding existing market access for U.S. agricultural products worth billions of dollars annually.

What are you IMPORTING into the United States?

- **Food and Agricultural Products** (Fact sheet)
  This factsheet is available in Armenian, Arabic, Burmese, Simplified Chinese, Traditional Chinese, Japanese, Korean, Lao, Polish, Russian, Spanish, Vietnamese >> more.
- **Animal or Animal Product**
- **State Regulations and Import Requirements**
- **Plants or Plant Products**
  - **View Electronic Manuals**
    This website contains an alphabetized list of Plant Protection and Quarantine manuals in electronic format
- **Veterinary Service Forms**
Animal and Animal Product Export Information

Last Modified: Mar 10, 2014

Export a Live Animal (includes semen, embryos...) or Animal Product - International health certificates for the export of animals from the United States are completed by an accredited veterinarian who certifies herd and animal health status, conducts tests, and records test results for the individual animals being exported. Complete and signed international health certificates for the export of animals from the United States must be endorsed by a Veterinary Services area office in order to be valid.

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has created the International Animal Product Export Regulations (IREGS) to provide exporters with our best understanding of importing countries requirements for certain animal-origin products.

Export Requirements for...

Live Animal - Export requirements frequently change, obtain the current export requirements from the Veterinary Service office in your area before each shipment.

Animal Product - Zoonository (animal health) product certificates endorsed by APHIS are sometimes required by the importing country for exported products. The exporter should obtain any required certificates prior to shipping any product.

Pets - APHIS is one of three Federal agencies that you will encounter as you travel with your pet. Learn More.

Biologics - View the process for obtaining an export permit for biologics.
Website for APHIS