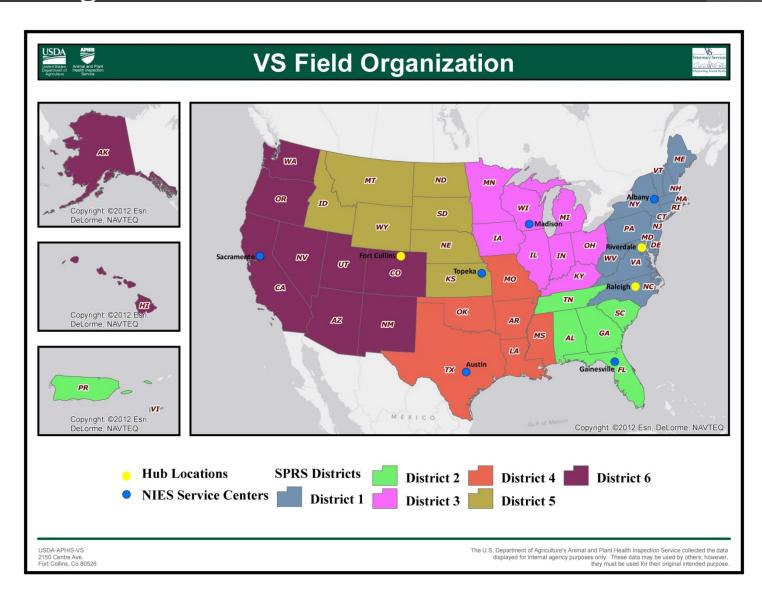
VETERINARY SERVICES REQUIREMENTS FOR ANIMAL RELATED MATERIALS, INCLUDING PATHOGENS

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



Veterinary Services

Reorganization of Infrastructure 2014

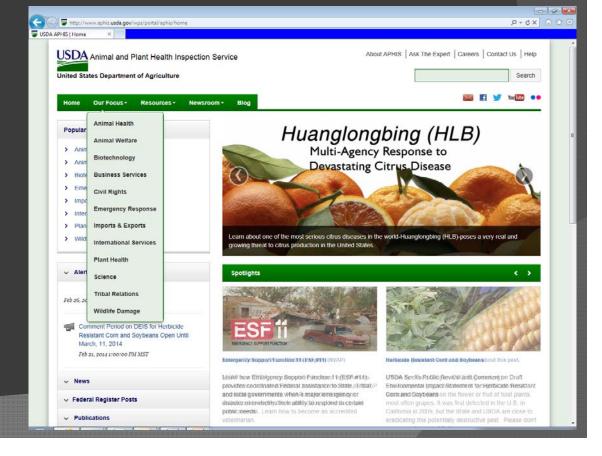






Complete Redesign of Website for APHIS

Work in progress









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 <u>specimens</u> 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 (<u>VECTORS</u>).



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

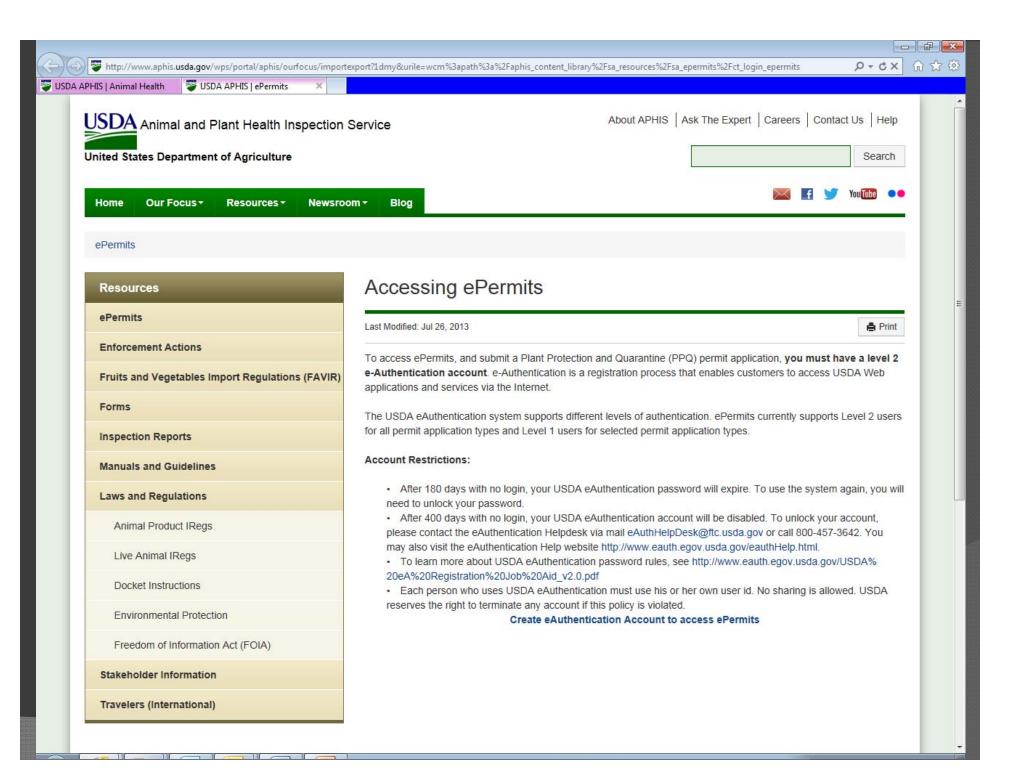
- Case by case requests
- Documentation needed
- Similar process for Select Agents and Non-Select agents
- Biosafety <u>facility inspection</u> may be needed
- prior to permit -
- Select Agent Inspection
- User Fee cost associated with application

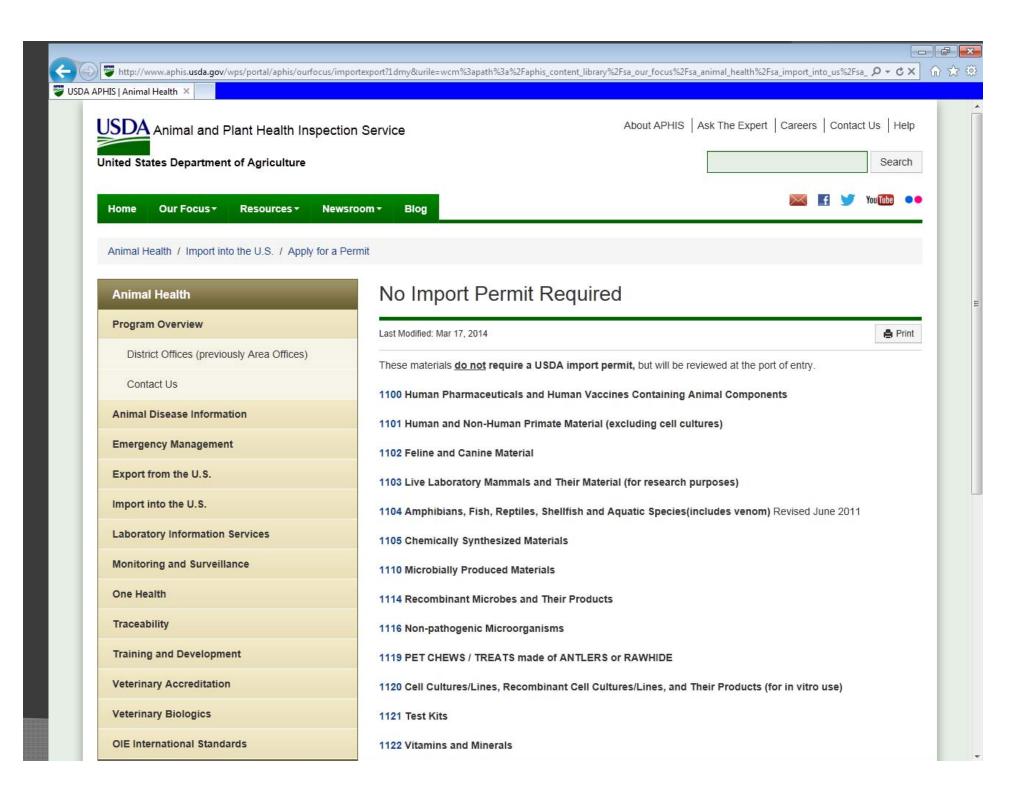


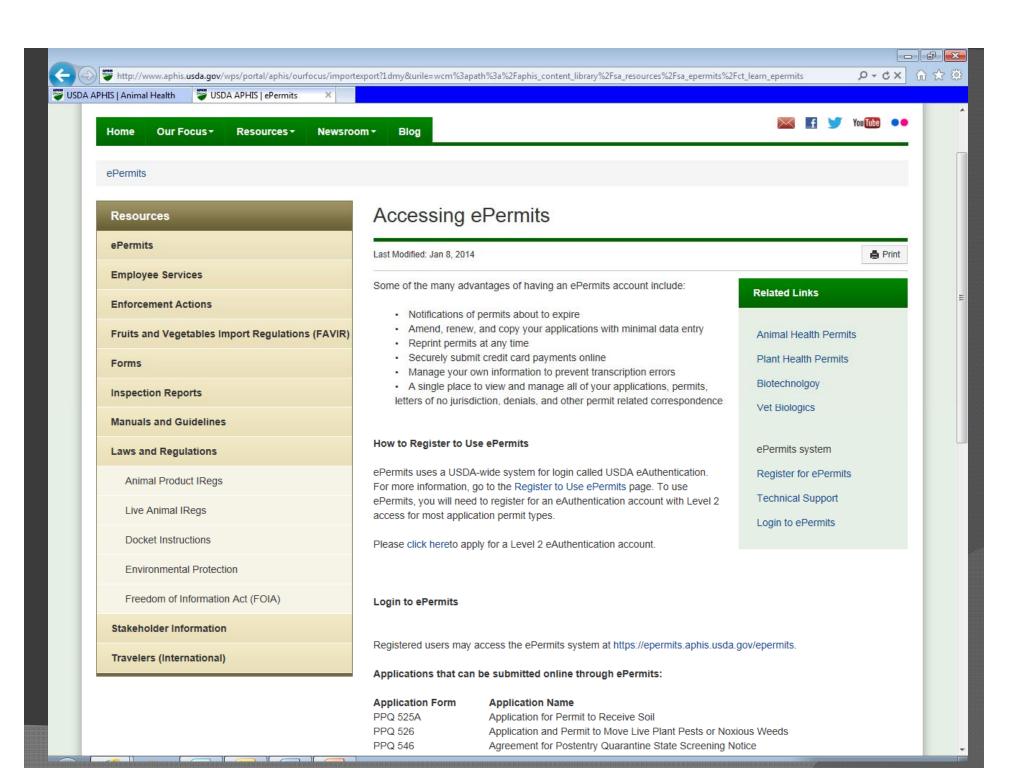
EXCLUSION OR EXEMPTION FOR ORGANISMS

ePermits

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







U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737

UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS

NAME AND ADDRESS OF SHIPPER(S)

Various shippers within the
UNITED STATES

SAMPL 1
Research

DATE EXPIRES

09/06/2005

DATELSSLIED

09/06/2006

CC:

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

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

THIS PERMIT IS ISSUED UNDER AUTHORITY CONTAINED IN 9 CFR CHAPTER 1, PARTS 94, 95 AND 122. THE AUTHORIZED MATERIALS OR THEIR DERIVATIVES SHALL BE USED ONLY IN ACCORDANCE WITH THE RESTRICTIONS AND PRECAUTIONS SPECIFIED BELOW (ALTERATIONS OF RESTRICTIONS CAN BE MADE ONLY WHEN AUTHORIZED BY USDA, APHISVS).

- o Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease.

o *** *** signe

signed: _____."

- $_{
 m O}$ All studies must be conducted in Biosafety Level 3 facilities inspected and approved by the USDA. This facility shall be reinspected every 3 years.
- o 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)].
- O 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.
- O Select Agent Program registration application number AGR00000.
- $_{\rm O}\,\rm Work$ 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

NO. LABELS

Senior Staff Veterinarian National Center - Import-Export

Copy of Permit

VS FORM 16-6A (MAR 95)

Replaces VS Form 16-3A and 16-28 which are obsolete

Page 1 of 2





U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737

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AVIC, VS, Annapolis, MD

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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





U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737

UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS

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

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o 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,

o *** *** signed: . " ***

- o All studies must be conducted in Biosafety Level 3 facilities inspected and approved by the USDA. This facility shall be reinspected every 3 years.
- o 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)].
- O 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.
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SIGNATURE Max Yeh

Senior Staff Veterinarian
National Center - Import-Export

Copy of Permit

VS FORM 16-6A (MAR 95)

Replaces VS Form 16-3A and 16-28 which are obsolete.

Page 1 of 2









UNITED STATES DEPARTMENT OF AGRICULTURE APHIS/ VETERINARY SERVICES, RIVERDALE, MD 20737.

ATTACH TO U.S. VETERINARY PERMIT - SAMPL 1

RESTRICTIONS AND PRECAUTIONS:

(continued from Permit Form VS 16-6)

- O Importer is responsible for obtaining any required authorization (letter or permit) from the U.S. Public Health Service. Importer to contact [(404) 498-2260].
- o This permit does not exempt the permittee from responsibility for compliance with any other applicable federal, state, or local laws and regulations.
- o This permit DOES NOT authorize direct or indirect exposure of domestic animals, including poultry, cattle, sheep, swine, horses, etc.
- O All laboratory animals which are to be exposed to the material must be held only in isolated insect & rodent-proof facilities.
- o Packaging, containers, and all equipment in contact with these materials shall be sterilized or considered a biohazard and be disposed of accordingly.
- o Pens, cages, bedding, waste, and dead animals in contact with these materials shall be sterilized or considered a biohazard and be disposed of accordingly.
- O 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.)
- $_{
 m O}$ On completion of your work, all permitted materials and all derivatives therefrom shall be destroyed.
- $_{
 m O}$ The restrictions on this permit remain in force as long as the material is in the United States.
- $_{
 m O}$ 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



Safeguarding Animal Health

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

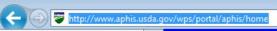
(National Import-Export Services - District Service

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











USDA Animal and Plant Health Inspection Service

United States Department of Agriculture

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public needs.



Herbicide-Resistant Corn and Soybeans

USDA Seeks Public Review and Comment on Draft Environmental Impact Statement for Herbicide-Resistant Corn and Sovbeans



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Imports & Exports



Import Export

Last Modified: Feb 25, 2014

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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.

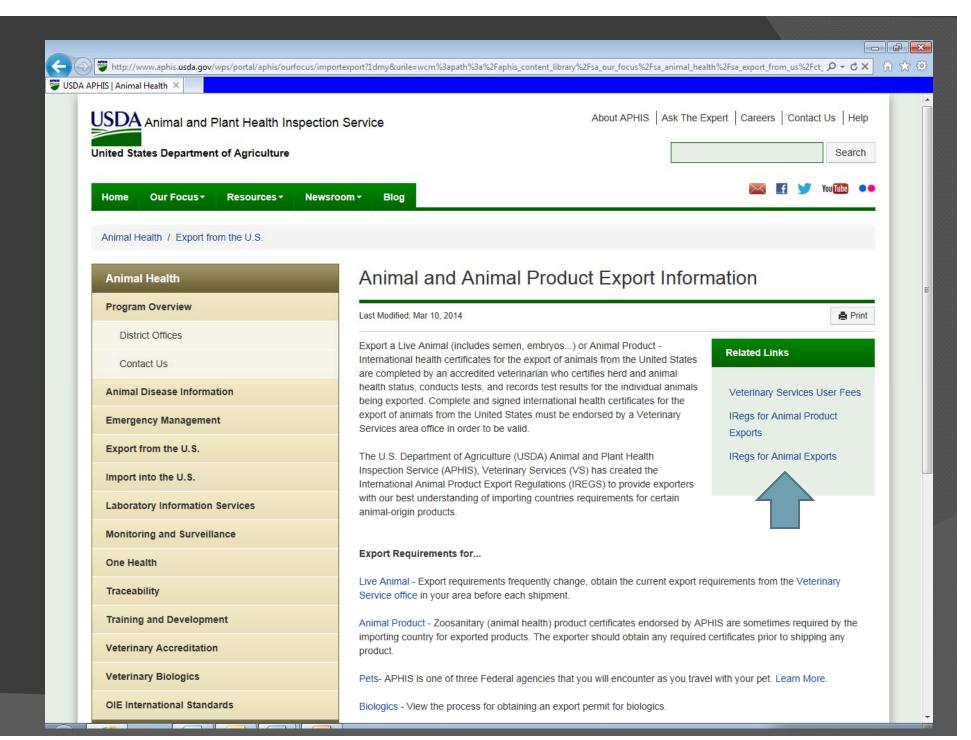
APHIS also keeps export markets open for American agricultural products by working to eliminate unjustified sanitary or phytosanitary (SPS) barriers - that is, concerns involving plant and animal health - raised by U.S. trading partners. APHIS' team of technical experts, based in the United States and 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 (Factsheet)
- This factsheet is available in Amharic, 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 web site contains an alphabetized list of Plant Protection and Quarantine manuals in electronic format

Veterinary Service Forms





Website for APHIS

http://www.aphis.usda.gov/wps/portal/aphis/home

