

# USDA, ORGANISMS AND VECTORS PERMITTING: PROTECTING AMERICAN AGRICULTURE

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ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
VETERINARY SERVICES  
11/18/20



# Overview

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- Who we are
- What do we do
- The application process
- Guidelines for no permit required
- Questions



# Where Are We

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We moved!! We are no longer part of Select Agents

Now part of the Animal Products Import Export team.

APIE Director: Dr. Keith Wiggins

Import Director: Dr. Lisa Dixon

New STAFF OFFICER:

Dr. Scott Epperson- Please welcome him

# What do we do

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Regulate the importation and interstate transit of organisms and vectors of pathogenic diseases of livestock and poultry

“No **organisms or vectors** shall be **imported** into the United States or **transported** from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a **permit**”

# Definitions

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## 9 CFR 122.1

Organism- All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry).

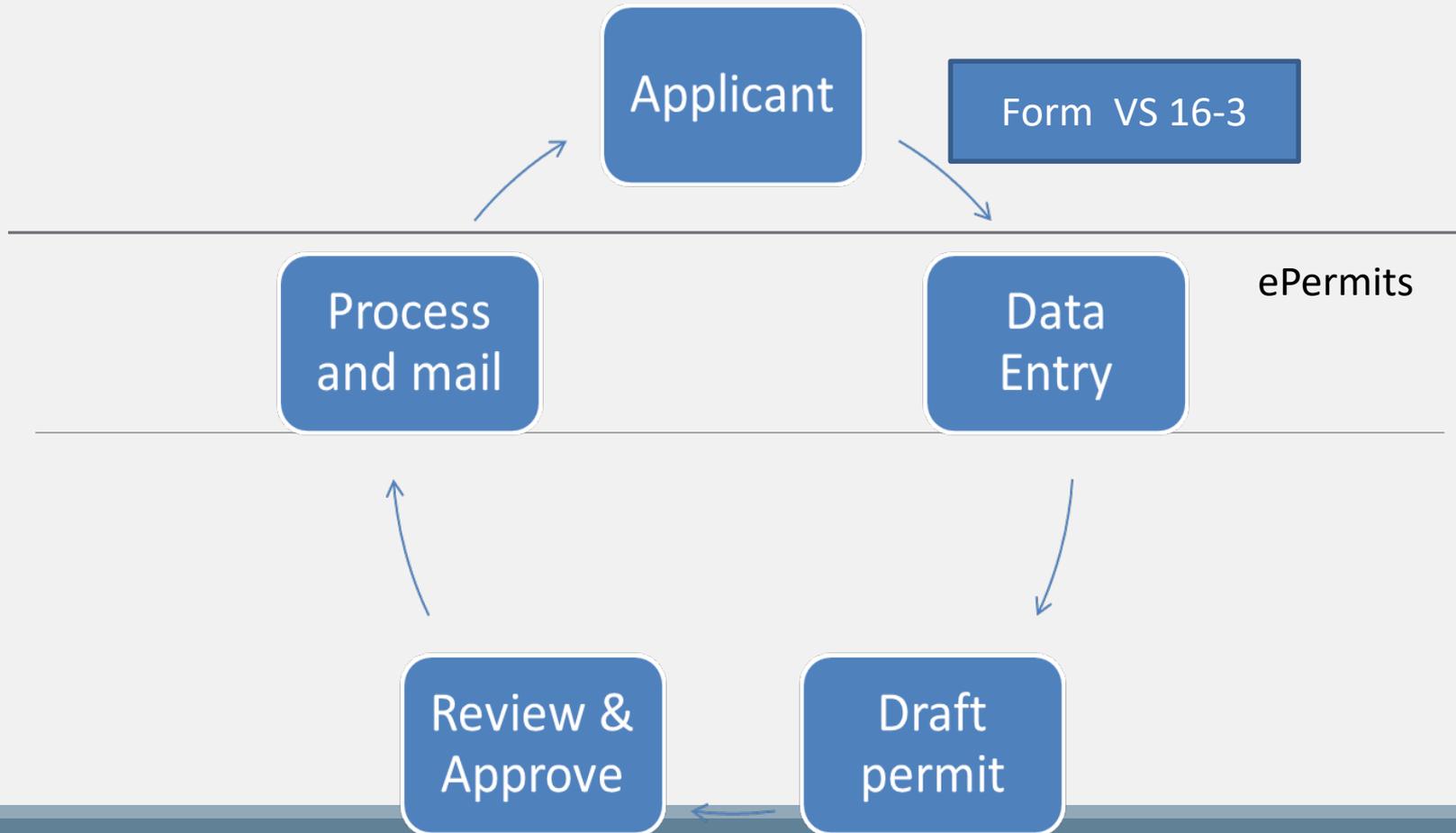
Vector -All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

# What do we do

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- On average we issue around 3,000 permits annually
- We review applications to verify they need a permit
- We perform outreach to stakeholders
- We assign laboratory inspections for those agents with higher risk to US livestock and poultry industries
- We verify inspection results and issue permits

# OV Application process



# The application process

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What needs a permit

What do we review



VS permit is required  
to receive livestock and  
poultry pathogens  
from outside of the  
state or the country

bacteria

virus

fungi

parasite



VS does not control  
transportation within  
a state

Intrastate transport:  
Contact state and local  
authorities

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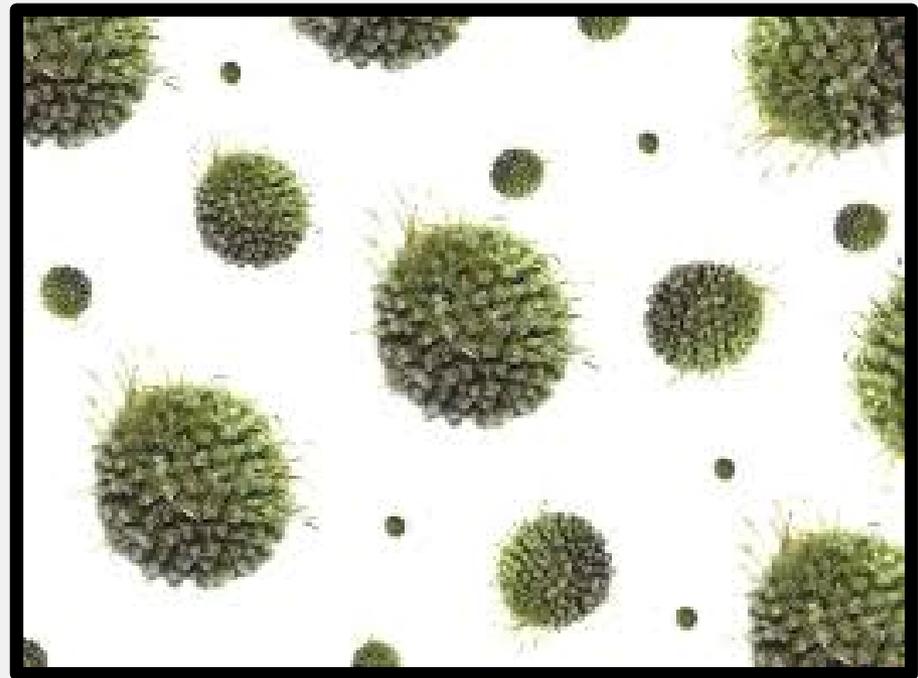
VS also controls  
movement of any  
potential vector of  
pathogen of livestock or  
poultry

*Insect vector:*  
mosquito, ticks, etc.

*Imported media vector:*  
FBS, trypsin, egg etc.



For **import**, a Permit is required for movement of **killed** pathogens and vectors and their derivatives



Antigens  
Vaccine components  
DNA/RNA



## Vectors!

VS permit is required  
for **importation** into  
U.S. of any organism  
(including **non-**  
**pathogens**) if  
exposed to medium  
of animal origin

(example: Childhood MMR vaccine with  
FBS exposure)



VS does not  
control  
movement of  
non-  
pathogens  
e.g., yeast,  
mold,  
lactobacillus



VS does not  
regulate human  
only pathogens or  
Human Diagnostic  
Samples





# If I need a permit: How do I apply?

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- Web page has info:

<http://www.aphis.usda.gov/animal-health/organisms-vectors>

- Email: [APIE@usda.gov](mailto:APIE@usda.gov)
- US Mail:           USDA-APHIS-VS-APIE  
                          4700 River Road, Unit 2  
                          Riverdale, MD 20737
- Fax: 301-851-2239

# e-FILE

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## Coming soon in 2021

Be on the look out for official announcements from APHIS

eFile is a new APHIS permitting system replacing ePermits

<https://efile.aphis.usda.gov/s/>

eFile includes permitting as well as the VS Permitting Assistant (VSPA).

- VSPA is a self-service online tool to assist with understanding permit requirements as well as streamlining the permitting process

Permits will not transfer from ePermits to eFile

- Will have ability to “renew” your ePermits permit in eFile

Application Form

Interstate Transport  
or Import Permit for  
Controlled Organisms  
and Vectors

VS 16-3



VS 16-6

**VS permit is not required for in-state transport**



# Import Safety Testing

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Materials containing products from countries with non-negative disease status are scrutinized to **protect animal agriculture!!!**

\*\*\*\*\*Review our website for “Animal Health Status of Regions” a country disease status does change\*\*\*\*\*

Safety testing/treatment (FADDL/DVL) sometimes required.

Permit restrictions prevent importation of CSF, ASF, SVD, FMD, HPAI, NDV, AHS

Remember FMD RNA is a select agent!!!



# Is Inspection Required?

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Depends On the Organism or Risks

- National/OIE Reportable Disease?
- What country or region is the material from?
- Endemic?
- Importance to industry/economic impact
- Level of pathogenicity
- Risk of spread/infectivity/mode of transmission
- Would VS respond to outbreak?
- Emerging



# Inspection

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Inspection when required, are for permit issuance.

- Inspections are not certifying labs, they are only for permit issuance
- Inspections are a tool we use to protect animal agriculture
- Inspections

BMBL is basis for inspection checklists

Inspection valid for 3 years

Approval of labs – based on inspector recommendation

Deficiencies – addressed with applicant

CFR 9, section 130 covers inspection fees

**\*\*\*COVID Delays\*\*\***

- **Due to COVID we are exploring new opportunities virtual inspections (previously inspected entities only)**

# BSL Levels

Biosafety levels – Veterinary pathogens do not necessarily have BSLs

We use the *Biosafety in Microbiological and Biomedical Laboratories Manual as a guideline*

*Appendix D Contains veterinary pathogens that are BSL 3*





# Guidelines – no import permit required

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- 1100 Human Pharmaceuticals and Human Vaccines Containing Animal*
- 1101 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)*
- 1105 Chemically Synthesized Materials*
- 1110 Microbially Produced Materials*
- 1114 Recombinant Microbes and Their Products*
- 1116 Non-Pathogenic Microorganisms (and their extracts)*
- 1119 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*
- 1123 Histopathological fixed slides*

# Interstate Movement

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## Guideline 1125

- INTERSTATE Movement Only
- GL 1125 is VS permission to move non-infectious materials Interstate
- GL 1125 is VS permission to move previously imported materials that meet the requirements

# GL 1125:

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Non-pathogenic microorganisms not able to spread communicable disease to livestock, poultry, or aquatic animals.

Biological agents (not capable of introducing or disseminating infectious diseases to livestock, poultry, or aquatic animals.

Toxins or toxoids that are not infectious (able to multiply) or able to spread communicable disease

Samples from animals or aquaculture systems not confirmed as infected by laboratory testing, not exposed to or suspected of illness caused by an infectious pathogen, and not experimentally infected with organisms or vectors.

Inactivated forms of pathogens.

Viable or dead insect vectors – excluding screwworms and other arthropods such as ticks – of livestock, poultry, or aquatic animal pathogens reared in a U.S. laboratory colony, not known to have been exposed to or to carry pathogens on the VS Pathogen List.

# COVID

## 2019 Novel Coronavirus (COVID-19) – Effective February 21, 2020

USDA **REGULATES** the *importation into the United States* of COVID-19 isolates exposed to livestock or poultry products (such as eggs, fetal bovine serum, etc). The application is [VS form 16-3](#), available on this web page.

- Please also obtain permitting information from [CDC Import Permit Program](#).
- Additionally, [US Fish and Wildlife Service](#) regulates the importation of Vero cells under The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).
- Permits for COVID-19 exposed to fetal bovine serum from countries considered as affected with Foot and Mouth Disease will require BSL3 handling (see "Country Animal Disease Status")

USDA **DOES NOT REGULATE** the *interstate movement* of COVID-19 isolates. Use Guideline for No Interstate Transport Permit Required, #1125 for movement of organism between US states and territories.

USDA **DOES NOT REGULATE** the importation or interstate transport of **HUMAN DIAGNOSTIC SAMPLES** (tissues, blood, etc. suspected to contain organisms). Please obtain permitting information from [CDC Import Permit Program](#).



# Contact Info

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<http://www.aphis.usda.gov/animal-health/organisms-vectors>

[APIE@usda.gov](mailto:APIE@usda.gov)

Phone: 301-851-3300, option **4**

Fax: 301-851-2239



# Website

**USDA United States Department of Agriculture**  
Animal and Plant Health Inspection Service

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## Organisms and Vectors Guidance & Permitting

Last Modified: Nov 1, 2019 Print

The Veterinary Services, Organisms and Vectors (OV) Permitting Unit regulates the importation into the United States, and interstate transportation, of organisms and vectors of pathogenic diseases of livestock and poultry.

The Code of Federal Regulations, in [9 CFR, §122.2](#), mandates that “no organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit”.

**NEW** **VS Issues Guideline 1125 – Effective April 15, 2019**

Veterinary Services will implement changes to permitting requirements based on Guideline 1125, effective April 15, 2019. The guideline describes allowances for non-regulated interstate movement of

CDC presentation on new guidelines June 2016 - PowerPoint



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**Troy Bigelow, DVM and Scott  
Epperson, DVM**

Staff Officers

U.S. Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

301-851-3464

APIE@usda.gov – Recommended incase we  
are out of office