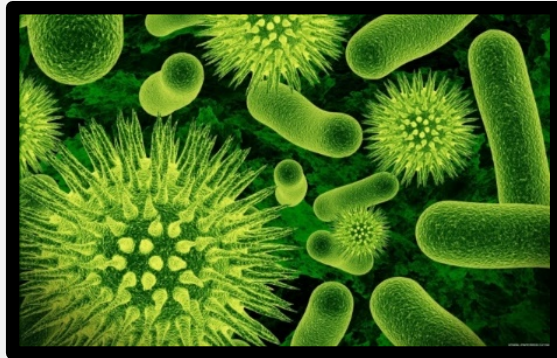




United States Department of Agriculture



USDA, ORGANISMS AND VECTORS PERMITTING: PROTECTING AMERICAN AGRICULTURE

TROY BIGELOW, DVM
STAFF OFFICER
U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
12/04/19



Overview

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



Where Are We

We are under the Agriculture Select Agents Services (AgSAS)

OV Director: Vacant

2 Staff VMO's

1 Veterinary Permit Examiner

1 Program Assistant

An AgSAS Support Staff

What do we do

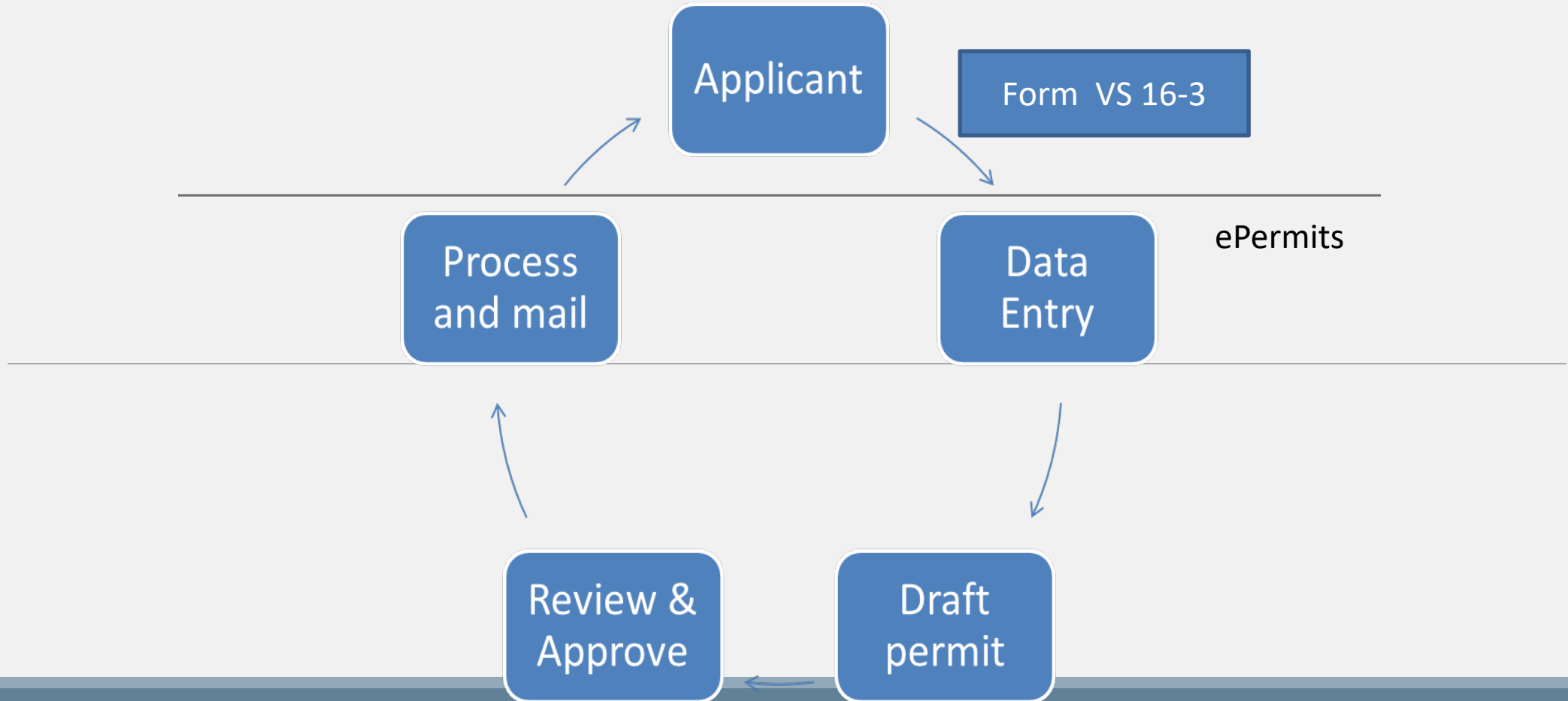
Regulate the importation and interstate transit of organisms and vectors of pathogenic diseases of livestock and poultry

“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**”

What do we do

- 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

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

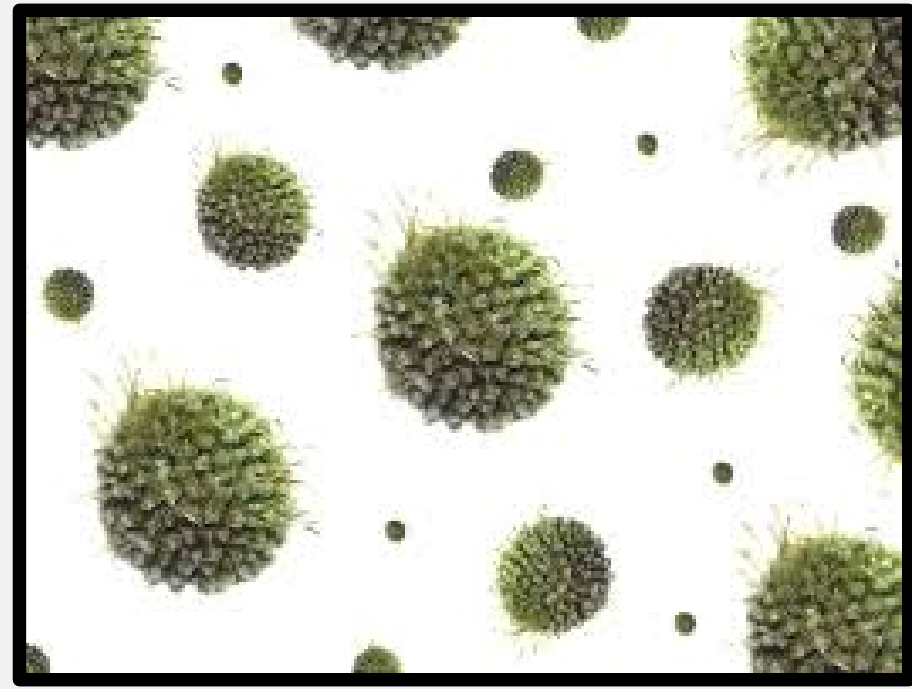
VS also controls
movement of any
potential vector of
pathogen of livestock or
poultry

Insect vector:
mosquito, ticks, etc.

Imported media vector:
FBS, trypsin, egg etc.



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



Antigens
Vaccine components
DNA/RNA



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

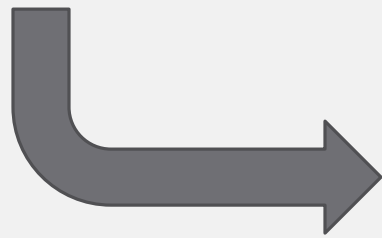
Vectors!



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



VS does not
regulate human
only pathogens or
Human Diagnostic
Samples





VS 16-3

How do I apply?

- Web page has info:

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

- ePermits

- Email: OV@aphis.usda.gov

- US Mail: USDA-APHIS-VS-NIES
 4700 River Road, Unit 2
 Riverdale, MD 20737

- Fax: 301-851-2239

Application Form

VS 16-3



Interstate Transport
or Import Permit for
Controlled Organisms
and Vectors

VS 16-6

VS permit is not required for in-state transport



Biocontainment

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

Safety testing/treatment (FADDL/DVL)

Biosafety levels – Veterinary pathogens do not necessarily have BSLs

- *Biosafety in Microbiological and Biomedical Laboratories, appendix D*

Lab inspection –Service Centers, SA inspectors



Is inspection required - organism

National/OIE Reportable Disease?

Endemic?

Importance to industry/economic impact

Level of pathogenicity

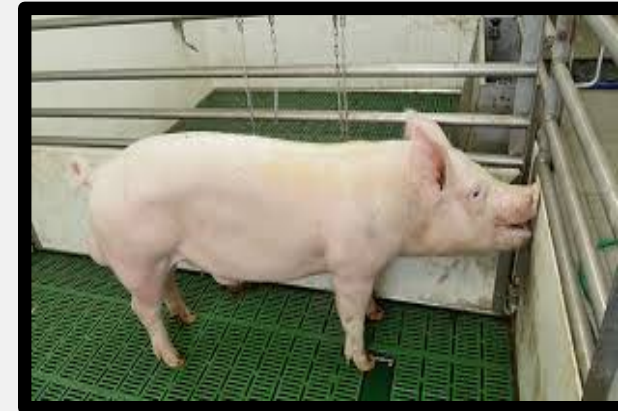
Risk of spread/infectivity/mode of transmission

Would VS respond to outbreak?

Emerging

Is inspection required - permit?

- Analytical
- Live culture





Inspection

BMBL is basis for inspection checklists

Inspected lab database in ePermits

Inspection valid for 3 years

Approval of labs – based on inspector recommendation

Deficiencies – addressed with applicant

CFR 9, section 130 covers inspection fees



Guidelines - no permit required

- 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*

NEWSFLASH!!!

Guideline 1125

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

1125: No permit for:

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.



Contact Info

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

OV@usda.gov

Phone: 301-851-3300, option **3**

Fax: 301-851-2239



Website

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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

Troy Bigelow, DVM

Staff Officer

U.S. Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

301-851-3464

Troy.t.bigelow@USDA.gov

OV@aphis.usda.gov – Recommended

incase we are out of office