

Overview of the Federal Select Agent Program and Import Permit Programs

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Importation of Biologicals Workshop
U.S Customs and Border Protection
Michigan State University
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U.S. Federal Biosafety & Biosecurity Oversight

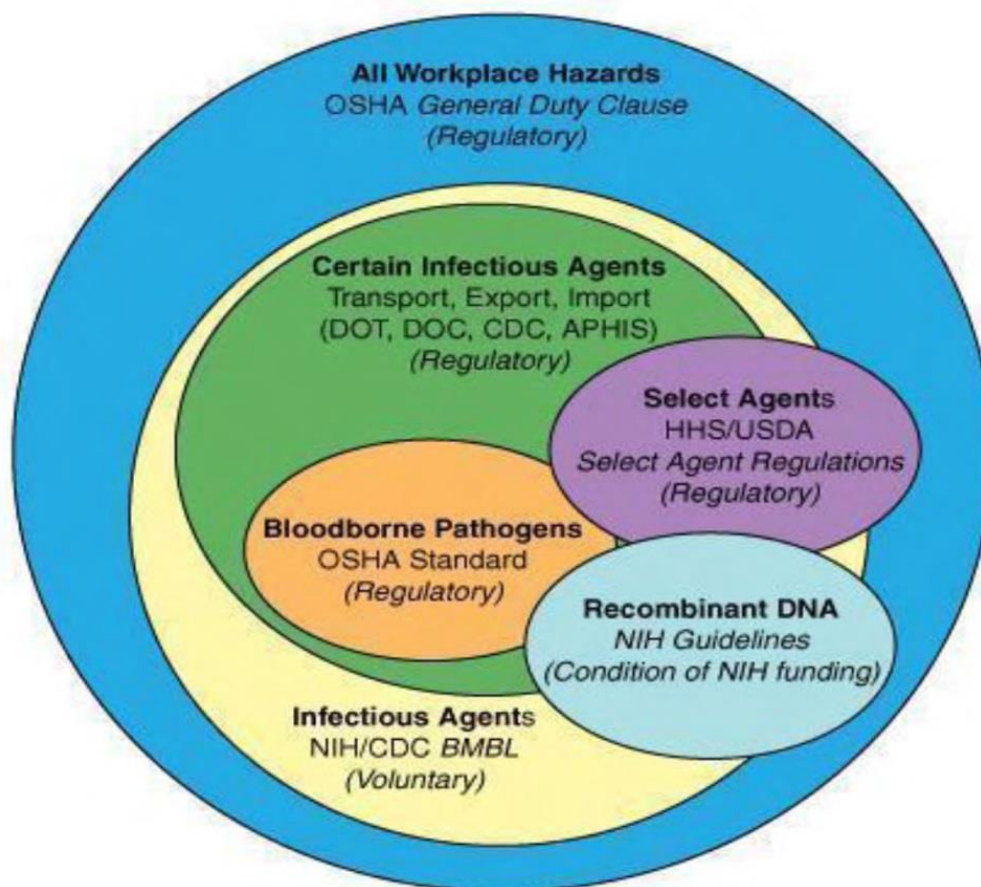


OSHA

Occupational Safety & Health Administration



BIOHAZARD



CDC • NIH

5th Edition

Biosafety in Microbiological
and Biomedical Laboratories



CDC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE



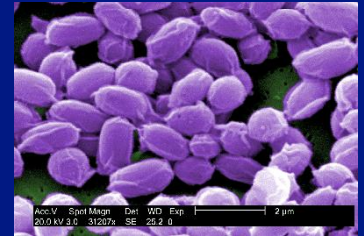
NIH Guidelines for
Research Involving
Recombinant or Synthetic
Nucleic Acid Molecules
(NIH Guidelines)

March 2013

FEDERAL SELECT AGENT PROGRAM

Federal Select Agent Program (FSAP)

- ❑ FSAP regulates the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products



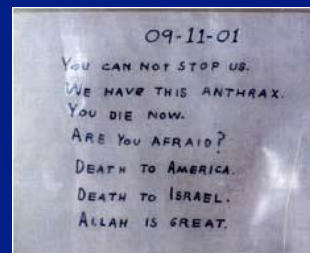
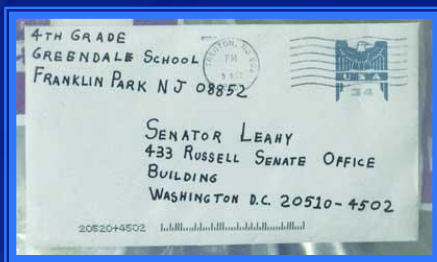
- ❑ Managed jointly by:

- The Division of Select Agents and Toxins (DSAT) at the Centers for Disease Control and Prevention (CDC), part of the U.S. Department of Health and Human Services (HHS)
- The Agriculture Select Agent Services (AgSAS) at the Animal and Plant Health Inspection Service (APHIS), part of the U.S. Department of Agriculture (USDA)



Overview & History

- ❑ 2001 anthrax attacks led to strengthening of program
- ❑ Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
 - Legal authority for the current Federal Select Agent Program
 - Required security measures in addition to biosafety measures
 - Strengthened the regulatory authorities of HHS
 - Granted comparable regulatory authorities to USDA



Title II of The Act: Enhanced Control of Dangerous Biological Select Agents and Toxins

- ❑ Establish a list of biological select agents and toxins**
 1. Effect of exposure
 2. Degree of contagiousness and method of transmission
 3. Availability of effective pharmacotherapies and immunizations
 4. Other criteria determined to be appropriate by the Secretary
- ❑ Consult with other federal departments and agencies, as well as scientific experts representing appropriate professional groups**
- ❑ Review/republish the list biennially, or revise as often as needed**

Types of Select Agents and Toxins

- ❑ **HHS-only agents** (HHS has sole authority and responsibility to regulate)
 - Potential to affect public health and safety
 - Botulinum neurotoxins, *Yersinia pestis*, Smallpox virus
- ❑ **USDA-only agents** (USDA has sole authority and responsibility to regulate)
 - Potential to affect animal & plant health; animal & plant products
 - Foot-and-mouth disease virus, Rinderpest virus
- ❑ **“Overlap” agents**
 - Subject to regulation by both agencies because they have potential to affect both humans and animals (requires interagency coordination)
 - *Bacillus anthracis*, *Brucella abortus*, Rift Valley fever virus

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

1. Abrin
 2. *Bacillus cereus* Biovar *anthracis**
 3. Botulinum neurotoxins*
 4. Botulinum neurotoxin producing species of *Clostridium**
 5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)¹
 6. *Coxiella burnetii*
 7. Crimean-Congo haemorrhagic fever virus
 8. Diacetoxyscirpenol
 9. Eastern Equine Encephalitis virus³
 10. Ebola virus*
 11. *Francisella tularensis**
 12. Lassa fever virus
 13. Lujo virus
 14. Marburg virus*
 15. Monkeypox virus³
 16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
 17. Ricin
 18. *Rickettsia prowazekii*
 19. SARS-associated coronavirus (SARS-CoV)
 20. Saxitoxin
- South American Haemorrhagic Fever viruses:
21. Chapare
 22. Guanarito
 23. Junin
 24. Machupo
 25. Sabia
26. Staphylococcal enterotoxins A,B,C,D,E subtypes
 27. T-2 toxin
 28. Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses:
29. Far Eastern subtype
 30. Siberian subtype
31. Kyasanur Forest disease virus
 32. Omsk hemorrhagic fever virus
 33. Variola major virus (Smallpox virus)*
 34. Variola minor virus (Alastrim)*
 35. *Yersinia pestis**

*Denotes Tier 1 Agent

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus³

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus³
50. Classical swine fever virus
51. Foot-and-mouth disease virus*
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*³
55. *Mycoplasma mycoides*³
56. Newcastle disease virus^{2,3}
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ)
SELECT AGENTS AND TOXINS

61. *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
62. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
63. *Ralstonia solanacearum*
64. *Rathayibacter toxicus*
65. *Sclerophthora rayssiae*
66. *Synchytrium endobioticum*
67. *Xanthomonas oryzae*

67 agents and toxins on the HHS and USDA list:

- 35 HHS-only
- 21 USDA-only
- 11 Overlap (HHS/USDA)

-
- 14 Tier 1 agents

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Tier 1 Select Agents and Toxins

- Tier 1 is a subset of the select agents and toxins list that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence

HHS select agents and toxins

- (1) *Bacillus cereus* Biovar *anthracis*
- (2) Botulinum neurotoxin
- (3) Botulinum neurotoxin producing species of *Clostridium*
- (4) Ebola virus
- (5) *Francisella tularensis*
- (6) Marburg virus
- (7) Variola major virus
- (8) Variola minor virus
- (9) *Yersinia pestis*

USDA select agents

- (1) Foot-and-Mouth Disease virus
- (2) Rinderpest virus

Overlap select agents

- (1) *Bacillus anthracis* (excluding Pasteur strain)
- (2) *Burkholderia mallei*
- (3) *Burkholderia pseudomallei*

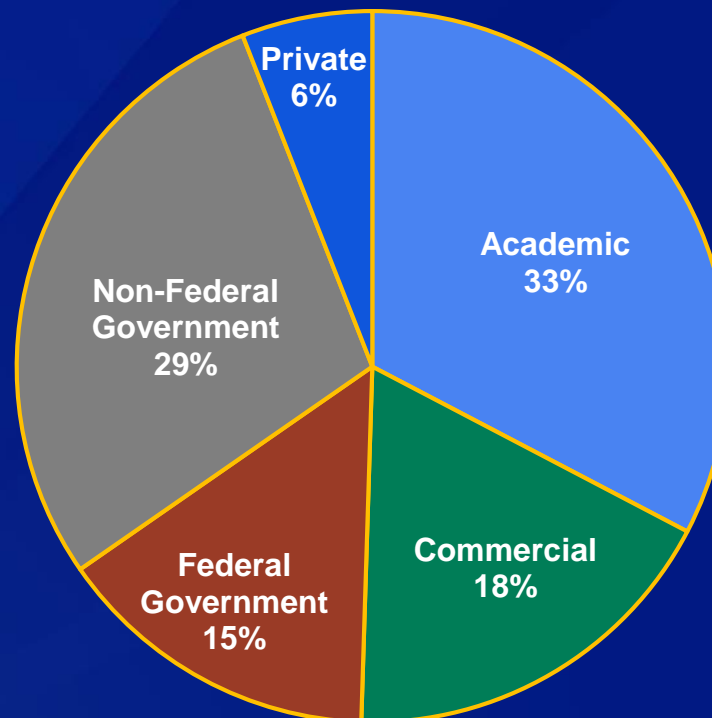
Key Regulatory Functions & Activities

- ❑ Promulgate the select agent regulations
- ❑ Provide oversight of possession, use, and transfer
- ❑ Conduct inspections and approve registrations
- ❑ Approve individual access to select agents & toxins
- ❑ Receive reports of a theft, loss, or release
- ❑ Take appropriate enforcement actions
- ❑ Serve as a resource on compliance with the regulations



Types of Entities Registered with FSAP, 2017

Total: 263



Source: 2017 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2017.html>

Inspection Types

- ❑ Compliance
- ❑ Maximum containment
- ❑ New entity
- ❑ New space
- ❑ Renewal
- ❑ Verification

FSAP Inspection Basics

❑ Biosafety

- Entity-specific biosafety plan
- Standards described in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th edition) or equivalent
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Notification of release
- Select agent inactivation

Training; drills or exercises

❑ Biosecurity

- Entity-specific security plan
- Security risk assessments of individuals
- Access controls
- Inventory and accountability
- Notification of theft or loss
- Tier 1 agents and toxins, 3 security barriers, and suitability assessment for individuals

Select Agent Enforcement

❑ Voluntary action

- Corrective Action Plan (CAP)

❑ Administrative actions

- Denial of application
- Revocation or suspension of registration

❑ Civil money penalties

- Up to \$250k for an individual for each violation
- Up to \$500k for an entity for each violation

❑ Criminal

- Imprisonment for up to 5 years, a fine, or both



FEDERAL SELECT AGENT PROGRAM

2017 Annual Report | Key Statistics

263

ENTITIES WERE
REGISTERED
WITH FSAP

33% ACADEMIC
18% COMMERCIAL
15% FEDERAL GOVERNMENT
29% NON-FEDERAL GOVERNMENT
6% PRIVATE
50% of entities are registered
for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

31% have BSL-2 and/or ABSL-2 labs
79% have BSL-3 and/or ABSL-3 labs
3% have BSL-4 and/or ABSL-4 labs

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

1. *Brucella melitensis*
2. *Brucella suis*
3. *Brucella abortus*
4. *Bacillus anthracis*
(Pasteur strain)
5. *Francisella tularensis**

APHIS's Agriculture Select Agent Services

1. Newcastle disease virus
2. Avian influenza virus
3. *Bacillus anthracis**
Brucella abortus
Ralstonia solanacearum

The 2017 Annual Report of the Federal Select Agent Program continues to provide insight into the regulatory activities of the Federal Select Agent Program (FSAP). The report includes a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation. This annual report is FSAP's third report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding of the program.

- FSAP is managed jointly by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services
- FSAP regulates the possession, use, and transfer of biological select agents and toxins (BSAT) so that important work with potentially dangerous and deadly pathogens is conducted as safely and securely as possible
- BSAT are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

COMPLIANCE & ENFORCEMENT

- 8** total entities participated in a corrective action plan
(including **1** entity that newly agreed to participate in 2017)
- 4** total entities had suspended registrations
(including **2** entities newly put under suspension in 2017)
- 18** matters were shared with the Federal Bureau of Investigation for potential investigation (no action was needed in **17** of those cases, with one pending)
- 7** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- 0** thefts reported
- 199** incidents reported involving potential occupational exposure of 1,152 laboratory workers
- 9** reports of losses determined to be records management errors
- 0** potential exposures resulting in illness, death, or transmission

TRANSFER APPROVALS: 177 DSAT | 79 AgSAS

- 29%** of the transfers were from unregistered entities to registered entities, mostly as a result of identification of BSAT in a diagnostic specimen

169

TOTAL
INSPECTIONS
CONDUCTED BY FSAP

106 by DSAT
31 by AgSAS
32 joint DSAT & AgSAS

2.6

AVERAGE
DURATION (IN DAYS)
FOR INSPECTION

Range of
1 to **9** days

9,916

ACTIVE INDIVIDUAL
SECURITY RISK
ASSESSMENTS

Denied access
for **17** individuals

KEY ABBREVIATIONS:

FSAP: Federal Select Agent Program **DSAT:** Division of Select Agents and Toxins **BSAT:** Biological select agents and toxins **ABSL:** Animal biosafety level
CDC: Centers for Disease Control and Prevention **APHIS:** Animal and Plant Health Inspection Service **AgSAS:** Agriculture Select Agent Services

Program Metrics

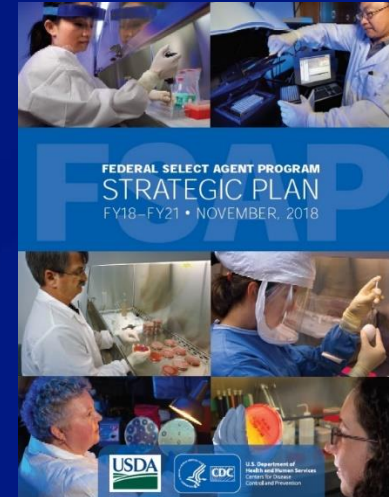
Since 2003, there have been:

- ❑ **No reported thefts of a select agent or toxin from a registered entity**
- ❑ **No deaths among laboratory workers**
- ❑ **No reported cases of illness or death in the general public due to work with these agents in regulated laboratories**

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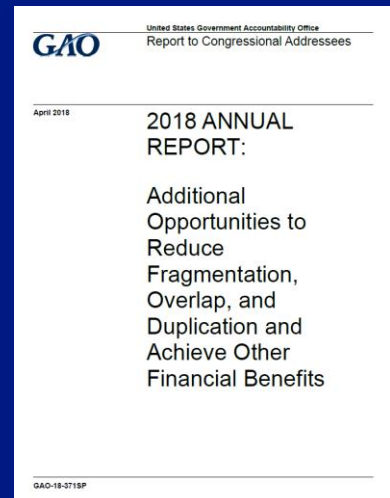
Needs for Transformational Change

- ❑ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requirement to maintain database
- ❑ GAO's recommendation to improve coordination and oversight
- ❑ National Biodefense Strategy – 2018
- ❑ FSAP Strategic Plan developed covering multiple aspects of the program – focus on system as force multiplier making it possible



FSAP Strategic Plan

1. Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce
2. Harmonize FSAP organizational processes and inspections
3. Leverage data-driven, risk-based approaches to guide FSAP operations
4. Engage, increase transparency, and highlight program benefits, with FSAP's diverse stakeholders



Electronic FSAP (eFSAP) Information System

- ❑ Secure, web-based user interface (portal)
- ❑ Searchable; will provide immediate, real-time information on who has what select agents, how they are being used in the work, and where they are located
- ❑ Increased efficiency; FSAP can be more timely and effective
- ❑ FSAP and regulated entities will both use the set of data
- ❑ Reduced paper
- ❑ New method of releasing inspection findings can help entities work towards resolution in days vs. weeks or months

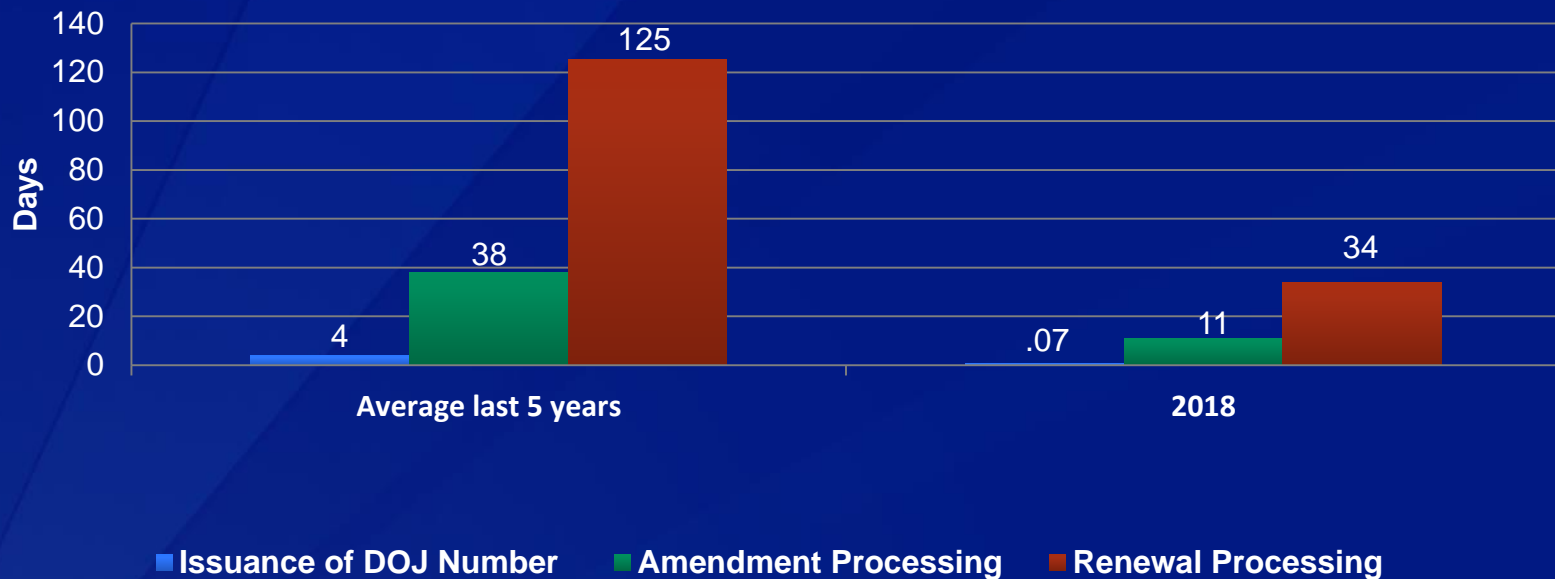
The screenshot displays the 'Federal Select Agent Program Portal' for the 'eFSAP Test Entity'. At the top, logos for CDC and USDA are visible. The page includes a navigation bar with 'Home' and 'Notifications'. Below the title, there are tabs for 'Forms' (Form 1, Form 2, Form 3, Form 4). The main content area shows the following details:

- Entity: eFSAP Test Entity
- LEAD AGENCY: CDC
- REGISTRATION STATUS: Approved
- REGISTRATION EXPIRES: 10/10/2019
- Facility Address: 1020 Valley Drive, Atlanta, GA 303291234
- Responsible Official Name: Stevenson Steve
- Responsible Official Title: Director of Science
- Responsible Official Address: 1020 Valley Drive, Atlanta, GA 30329
- Registration #: 20161010-1852
- Application #: c0c7e336-f01e-e711-80cf-001dd8003fe2
- Type Status: Commercial - Profit

Burden Reduction and Customer Satisfaction

- ❑ **Many aspects of entity registration maintenance have been revamped to be self-service**
 - Reduces administrative burden for both program and entity
 - Significantly speeds up processing
- ❑ **Increased ease of validating and submitting information**
- ❑ **Entities have immediate visibility of where their submissions are in life cycle**
- ❑ **Direct interaction between SMEs and entity representatives**
- ❑ **Informal and anecdotal commendations for the enhancements**
 - Looking forward to formalized surveys next spring

eFSAP Information System: Accelerated Processing Times



Processing times for adding individuals, amendment & renewal processing

For More Information

www.selectagents.gov

CDC: lsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or
301-851-3300 option 3 (voice only)

IMPORT PERMIT PROGRAMS

Permitting Programs

- ❑ Both APHIS and CDC have import permitting units, for non-select biological materials that could cause or introduce agricultural or human disease (respectively)
- ❑ These programs help ensure that the importation (CDC + APHIS) and/or interstate transport (APHIS) of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the permitted agents

CDC Import Permit Program (IPP)

Thomas Cremer, PhD & Glen DeGruy, MS.

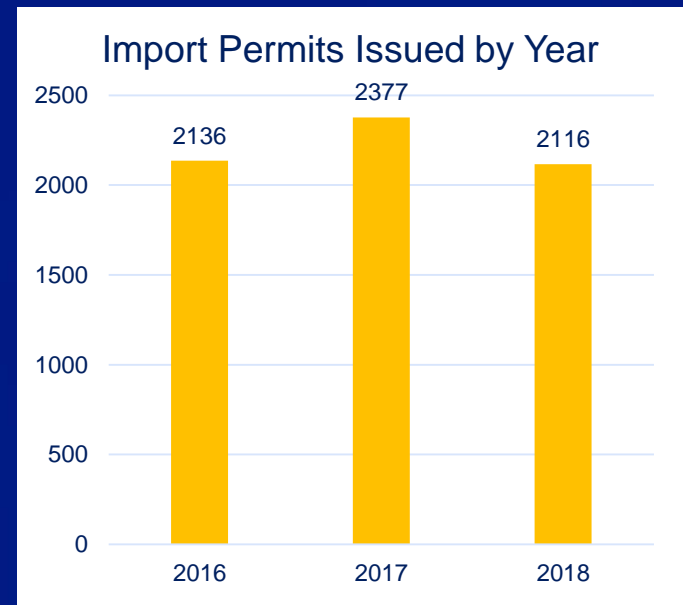


IPP: Background

- ❑ Regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.**
- ❑ The regulations require that anyone wishing to import infectious biological agents, infectious substances, or vectors associated with communicable disease in humans must first obtain a permit issued by CDC**

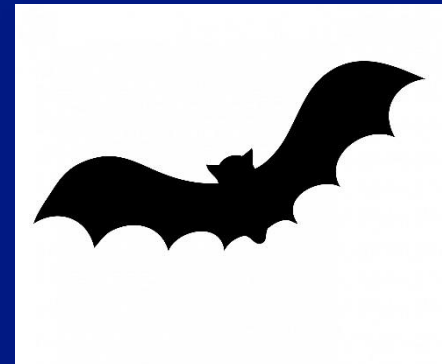
IPP: Background (cont.)

- ❑ Ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents
- ❑ More than 2,000 import permits issued annually
- ❑ Most issued to laboratory facilities at government agencies and universities, or to private and commercial laboratories conducting research studies or diagnostic activities
- ❑ No fee



Materials Requiring Permits

- ❑ Infectious biological agents capable of causing illness in humans
- ❑ Materials known or reasonably expected to contain an infectious biological agent
- ❑ Vectors of human disease (e.g., insects, bats)

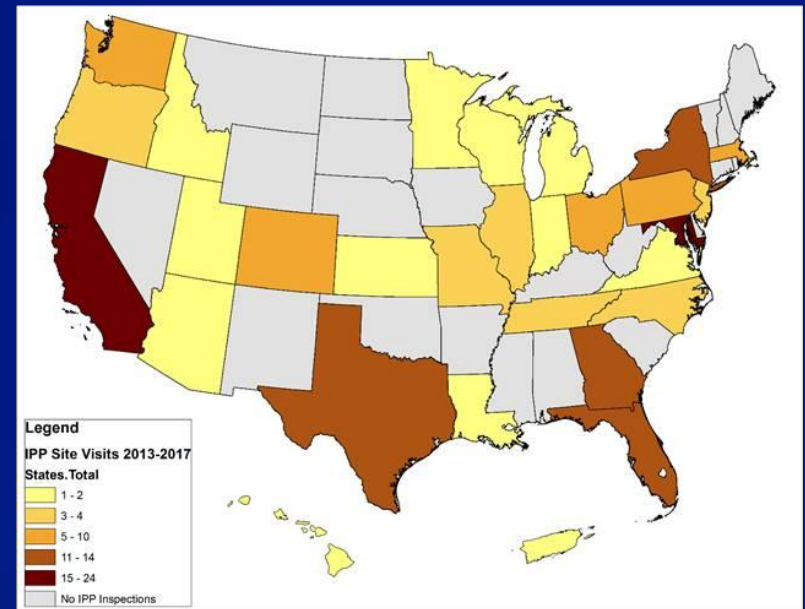


Most commonly imported agents (2017):

1) Human Immunodeficiency Virus	11) Adenovirus
2) <i>Escherichia coli</i>	12) <i>Klebsiella</i> species
3) Zika virus	13) <i>Plasmodium</i> species
4) Hepatitis c virus	14) <i>Shigella</i> species
5) Hepatitis b virus	15) <i>Enterobacter</i> species
6) Dengue virus	16) <i>Mycobacterium tuberculosis</i>
7) Cytomegalovirus	17) <i>Campylobacter</i> species
8) <i>Streptococcus</i> species	18) Epstein-barr virus
9) <i>Salmonella</i> species	19) <i>Proteus</i> species
10) <i>Staphylococcus</i> species	20) <i>Enterococcus</i> species

Key Regulatory Functions & Activities of IPP

- ❑ Issues permits
- ❑ Conducts inspections to ensure appropriate biosafety measures are in place
- ❑ Provides outreach and training
- ❑ Collaborates with federal partners



**CDC Import Permit
Inspections, 2013-2017**

eIPP Information System

- ❑ Two-way portal for submitting and sharing information; accessible by both the program and those seeking import permits
- ❑ System is electronic-based, user-friendly and allows for real-time updates on the status of pending applications
- ❑ Use of this system is mandatory for anyone applying for a CDC import permit



eIPP: Benefits

- ❑ Faster processing time for permits
- ❑ Provides a centralized location where applicants can get status updates
- ❑ Saves user time when applying for future permits
- ❑ Provides applicants with a historical record of permits
- ❑ Improved communication between applicants and IPP



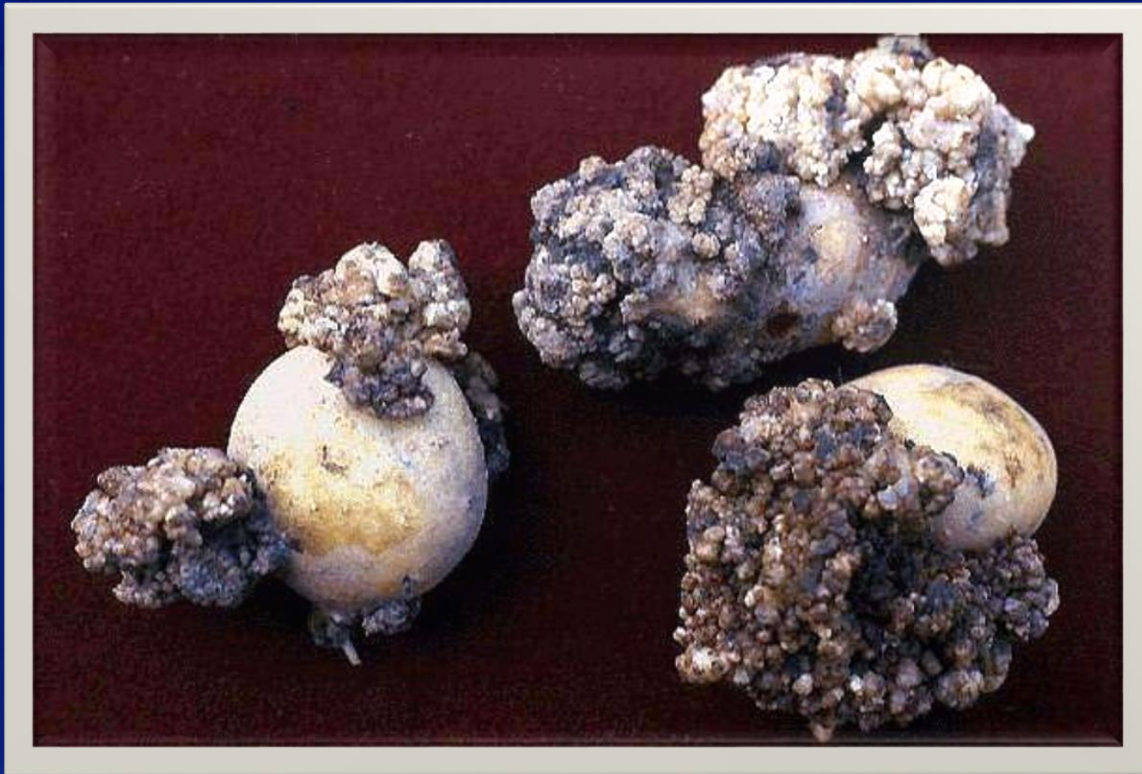
For More Information

❑ CDC Import Permit Program

- Phone: (404) 718-2077
- Fax: (404) 718-2093
- Email: importpermit@cdc.gov

<https://www.cdc.gov/cpr/ipp/index.htm>

USDA Plant Protection and Quarantine Select Agent Permitting



Regulation

❑ All plant pathogen permits are under the Plant Protection Act

- Regulation 7 CFR § 330.200

“No person shall knowingly move any plant pest into or through the United States from any place outside thereof, or interstate, or knowingly accept delivery of any plant pest...unless such movement is authorized under permit under this part and is made in accordance with the conditions therein and the provisions in this part.”



ePermits

- ❑ All permits are processed through the ePermits system
- ❑ Applicants must be eAuthenticated to submit a permit application
- ❑ Applicants applying for select agents must go through the select agent pathway
 - All applications can only be seen by AgSAS
 - Applicants must be registered with the FSAP
 - Exclusions from SA conditions for applicants applying for *Ralstonia solanacearum* non Race 3 Biovar 2
- ❑ All permittees must abide by the conditions in the permit and all facilities will be inspected

Movement of Select Agents

Select Agent Movement Types

- ❑ **Importation**
- ❑ **Interstate Movement**
- ❑ **Intrastate Movement**
- ❑ **Continued Curation**



Hand Carry

- ❑ **Permit must have “hand-carry” listed as an option for transport**
- ❑ **Importation- applicant needs to request a letter from AgSAS to show Customs Officer when entering the country along with the permit**
 - The package can be sent to CPHST 580 in Beltsville if Customs deems it needs to be assessed

APHIS Organisms and Vectors Import Permitting



9 CFR Part 122

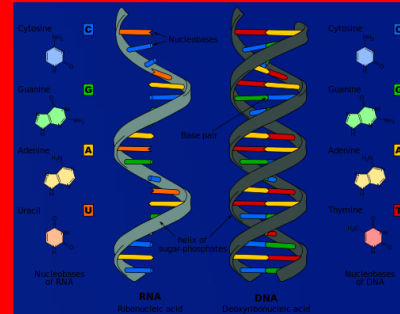
“No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit”

Materials Requiring Permits: ORGANISMS

- ❑ Livestock and poultry pathogens
- ❑ DNA, RNA, killed pathogens
- ❑ Any organism exposed to livestock or poultry materials

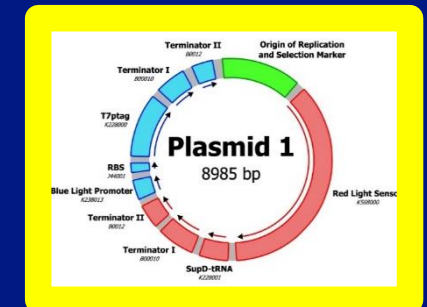
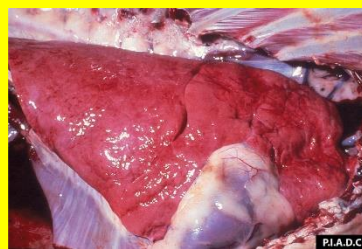
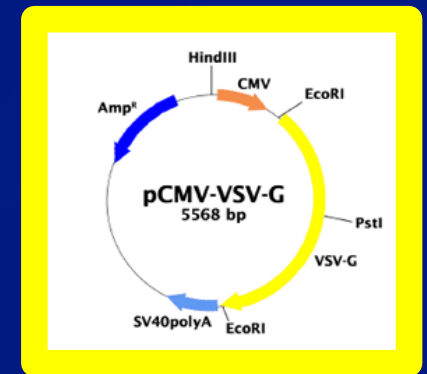



Killed
Pathogen



Materials Requiring Permits: VECTORS

- ❑ Arthropods, parasites
- ❑ Animal samples
- ❑ Animal products
- ❑ Vectors, plasmids with pathogen genes




United States Department of Agriculture
 Animal and Plant Health Inspection Service

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Import into the U.S.

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Laboratory Information Services

Monitoring and Surveillance

Veterinary Services IT Applications

One Health

OIE International Standards

Traceability


Training and Development

Veterinary Accreditation


Veterinary Accreditation

Veterinary Biologics

Site Map



Equine Import/Export




Importing Dogs into the United States for Resale (including Adoption)

Organisms and Vectors Permitting

Last Modified: Apr 2, 2019

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 (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".



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 certain materials such as non-infectious materials and materials that have not been exposed to infectious agents. To view Guideline 1125 in its entirety, please click [here](#).

Types of Permits


How to Apply for a VS Form 16-3 Permit

Additional Resources

Additional Information

- Animal and Animal Product Import Information
- Agriculture Select Agent Services
- Organisms and Vectors Guidance
- On Hold Shipment
- Veterinary Biologics
- Plant Pest and Disease Programs
- Biotechnology Regulatory Services
- Center for Disease Control and Prevention's (CDC) Import Permit Program (IPP) [↗](#)
- U.S. Fish and Wildlife Service permits [↗](#)

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



United States Department of Agriculture
 Animal and Plant Health Inspection Service

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Equine Import/Export



Importing Dogs Into the United States for Resale (Including Adoption)

Organisms and Vectors Guidance

Last Modified: Apr 2, 2019

- Do I Need an OV Permit?
- VS-Regulated Livestock and Poultry Pathogens
- Excluded and/or Killed Select Agent Pathogens that May Need an OV Permit
- Guideline 1125: Conditions Under Which Veterinary Services (VS) Does Not Require an Interstate Transportation Permit for Organisms and Vectors
- Frequently Asked Questions For Importation and Transportation Of Organisms and Vectors (OV)

Additional Information

- Animal and Animal Product Import Information
- Agriculture Select Agent Services
- Organisms and Vectors Permitting
- On Hold Shipment
- Veterinary Biologics
- Plant Pest and Disease Programs
- Biotechnology Regulatory Services
- Center for Disease Control and Prevention's (CDC) Import Permit Program (IPP)
- U.S. Fish and Wildlife Service permits

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

VS-regulated livestock and poultry pathogens (partial list, Revised 3/21/2019)

Absidia corymbifera

Acremonium strictum

Acinetobacter spp. **

Actinobacillus pleuropneumoniae

Actinomyces bovis

Aedes mosquito

Aedes mosquito eggs

Aeromonas hydrophila

Aeromonas spp. **

African horse sickness (only the excluded select agent*)

African swine fever (only the excluded select agent*)

Akabane virus

Alcaligenes faecalis

Amblyomma spp. - tick

Amidostomum anseri

Amycolaptosis spp. **

Anaplasma centrale

Anaplasma marginale

Anaplasma phagocytophilum

Anopheles mosquito eggs

Anopheles mosquitos

Guidelines: Animal Products That Do Not Require An Import Permit

Last Modified: Jul 26, 2018

 Print

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

- ✓ Guideline 1100: Human And Veterinary Pharmaceuticals and Vaccines
- ✓ Guideline 1101: Non-Human Primate Material (excluding cell cultures)
- ✓ Guideline 1102: Feline and Canine Material
- ✓ Guideline 1103: Live Laboratory Mammals and Their Material (for research purposes)
- ✓ Guideline 1104: Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)
- ✓ Guideline 1105: Chemically Synthesized Materials
- ✓ Guideline 1107: Importation of Lactose and Lactose Derivatives
- ✓ Guideline 1110: Microbially Produced Materials
- ✓ Guideline 1114: Recombinant Microbes and Their Products
- ✓ Guideline 1116: Non-Pathogenic Microorganisms (and their extracts)
- ✓ Guideline 1119: Pet Chews and Treats Made of Antlers or Rawhide
- ✓ 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
- ✓ Guideline 1122: Vitamins and Minerals
- ✓ Guideline 1123: Histopathological Fixed Slides

For More Information

□ APHIS Organisms and Vector Permitting

- Email: OV@usda.gov
- Phone: 301-851-3300, option 3
- Web page:
<http://www.aphis.usda.gov/animal-health/organisms-vectors>
- Staff Officers: Deb Dufficy, Troy Bigelow

Discussion

