CBP’s Role in Protecting American Agriculture and Public Health
In March 2003 –

- DHS was formed, integrating 22 different Federal agencies, including CBP.
- USDA-APHIS inspection duties at the ports of entry transferred to CBP.
- The office that later became Agriculture Programs & Trade Liaison (APTL) began to manage the agriculture mission at the ports of entry.

≈ 2,472 Agriculture Specialists in CBP
A Typical Day in Fiscal Year 2018:

- 1,133,914 passengers and pedestrians
  - 358,448 incoming international air passengers and crew
  - 78,912 passengers and crew on arriving ships/boats
  - 696,555 incoming land travelers
- $7.7 billion worth of imports
- 4,552 quarantine material interceptions (plant and animal products, and soil)
The ABTC Division serves to support CBP’s operational capacity and capability to prevent and mitigate the risk of biological threats to American agriculture, natural resources, and public health.

Biological threats are addressed by multiple regulations. To address bio-threat exclusion, ABTC works with multiple agencies.
### Title 7 Plant Protection Act

Live plant pests, disease agents, biological control agents, parasitic plants, Federal noxious weeds:  

### Title 9 Animal Health Protection Act

Genetically engineered organisms; organisms and vectors; semen, embryo; hatching eggs:  

### 7 CFR Part 331, 9 CFR Part 121

USDA Select Agents  
Veterinary biological products:
- Cytokine nucleotide sequence administered with vaccine
- Bacteria, viruses, bacterial and viral-derived products for treatment or cure of cancer animals
- Vaccines, viruses, bacterins, bacterial extracts, allergens, antiserums, antitoxins, toxoids, diagnostics and immunomodulators for the prevention/treatment of animal diseases
- Recombinant DNA cell culture, monoclonal antibodies, ascetic fluid, etiologic agents/vectors of diseases
- Immunoglobulins, serum, and plasma for passive transfer


Permit Office: https://www.aphis.usda.gov/aphis/resources/permits
### Regulated Biologicals – FWS & CDC

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<th>Regulation</th>
<th>Description</th>
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• CITES of Wild Fauna and Flora  
• Marine Mammal Protection Act  
• Migratory Bird Treaty Act  
([https://www.fws.gov/](https://www.fws.gov/)) |
| 42 CFR Part 71, Subpart F, 71.51-71.56 | Etiological agents, hosts, and vectors of infectious human diseases:  
([https://www.cdc.gov/](https://www.cdc.gov/)) |
| 42 CFR Part 73 | HHS Select Agents and Toxins  
([https://www.selectagents.gov/SelectAgentsaNdToxinsList.html](https://www.selectagents.gov/SelectAgentsaNdToxinsList.html)) |

**Permit Office:**
- FWS: [https://www.fws.gov/permits/](https://www.fws.gov/permits/)
- CDC: [https://www.cdc.gov/phpr/ipp/index.htm](https://www.cdc.gov/phpr/ipp/index.htm)
| Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 | Antibiotics, anti-inflammatories, Anthelmintic/antipROTOzoal, genetic constructs (excluding DNA and vaccines), stem cell therapies, gene and somatic cell therapies, hormones, growth factors and promotants, cytokines (human origin, affect blood cell formation, treat mastitis, use as systemic or anti-inflammatory effect), whole blood, transfusion, and clotting products, products administered to animals to reduce human exposure to pathogens. ([https://www.fda.gov/](https://www.fda.gov/)) |

Note: FDA posts Import Alerts on any company, product, or country from which goods can be detained at U.S. ports of entry without physical examination.
# Regulated Biologicals – EPA

| Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) | Intergeneric microorganisms, including bacteria, viruses, fungi, algae, protozoa etc., and their products used for TSCA purposes by application of genetic principles. ([http://www.epa.gov/oppt/biotech/pubs/biorule.htm](http://www.epa.gov/oppt/biotech/pubs/biorule.htm)) |
| 40 CFR 725.420 (TSCA Exemptions) | Acetobacter aceti, Aspergillus niger, Aspergillus oryzae, Bacillus licheniformis, Bacillus subtilis, Clostridium acetobutylicum, Escherichia coli K-12, Penicillium roqueforti, Saccharomyces cerevisiae, Saccharomyces uvarum |

Hazardous Materials Regulations: Transportation Requirements for Infectious Substances (49 CFR Parts 171-175)

- Proper shipping name and identification number:
  - Example for Category A infectious substances:
    - “Infectious substances, affecting animals, UN2900”
    - “Infectious substances, affecting humans, UN2814”
  - Example for Category B infectious substances:
    - “Biological substance, Category B, UN3373”
- Proper labeling/marking (e.g., “Infectious substance”, “Exempt human specimen”, “Exempt animal specimen”, “Toxins extracted from living sources, liquid, n.o.s.”, “Toxins extracted from living sources, solid, n.o.s.”)

(https://www.faa.gov/about/initiatives/hazmat_safety/)
Regulated Biologicals – CBP

- All import products are subject to inspection.
- The Importer/Shipper, or their agent, is responsible for complying with all applicable shipping regulations including permits, certificates, and meeting DOT packaging and labeling requirements.
- Biologicals do not qualify for Section 321 as they are regulated by OGAs.
Bio-Threat Exclusion Approach

- **Before Arrival:**
  - Target smuggling networks/known subject(s) of interest
  - Advanced screening of high risk imports

- **On Arrival:**
  - Non-intrusive inspection (x-ray)
  - Inspection of biological and agricultural imports
Carrier transmits manifest to CBP

Cargo is held in a bonded facility awaiting CBP inspection

Cargo Examined by CBP

Release

Field Operations

CBP Cargo Inspection Process
ABTC Shipment of Interest

- Express consignment shipment
- Cargo Description: “Harmless Biological Samples”
- Shipping documents included PPQ Form 526 declaring *Ralstonia solanacearum*
CBP Admissibility screening

CBP Secondary inspection

Carrier transmits manifest to CBP

OR

GO

OR

GO

Field Operations
Passenger declared “antibodies”
Passenger did not have an import permit or Form 2
Research supported passenger’s professional study of coronaviruses (e.g. MERS and SARS)
Lack of harmonization between agencies

- **APHIS/CDC Form 2 (Form 2)**
  - CDC – Brokers are *required* to submit documents using the Document Image System.
  - APHIS – paper format is *authorized*

- First right of refusal for investigation purposes
- Timeline for custody
- Secure storage location is not one size fits all
ABTC Outreach Initiatives

Expanded outreach initiatives include:

- Informational Tear Sheets and update to the passenger “Know Before You Go” guidance on cbp.gov

- Updated information available for Trade on CBP.gov

- Informational “Postcard” for outreach events

- Multi-agency collaboration for outreach events

- Locally, ports and field offices are including biologicals as a topic for Trade Days and other local events
ABTC Outreach Initiatives

What you need to know before importing Biological Materials into the United States

Federal, international, and state laws strictly regulate shipping, transport, and import of biological materials. Federal and international regulations pertaining to the shipment of dangerous goods or hazardous materials may also apply to biological materials. Import of biological materials must be clearly marked, labeled, packaged and/or placarded in accordance with the requirements of all applicable laws. Biological materials are categorized, permitted, and regulated based on the purpose of production or synthesis; packaging (bulk or final dosage form); species of animal, or plant disease; and status as an endangered species.

Examples of biological materials include (but are not limited to):

- Cell or tissue culture (includes primary cell/tissue cultures, recombinant cell/tissue culture products (includes monoclonal antibodies, nucleic acids (DNA/RNA)), histopathological slides (fixed in formalin), micro-organisms (includes recombinant or non-recombinant, products of micro-organisms (includes plasmids, nucleic acids), test kits, vaccines, bacteria, toxins, unused culture media.

For additional information or clarification on importing biological materials into the United States, please contact your local port of entry or CBP at webinfo@cbp.dhs.gov.
Agro/Bio-Terrorism Countermeasures Division

Questions for ABTC?

APTLABTC@cbp.dhs.gov