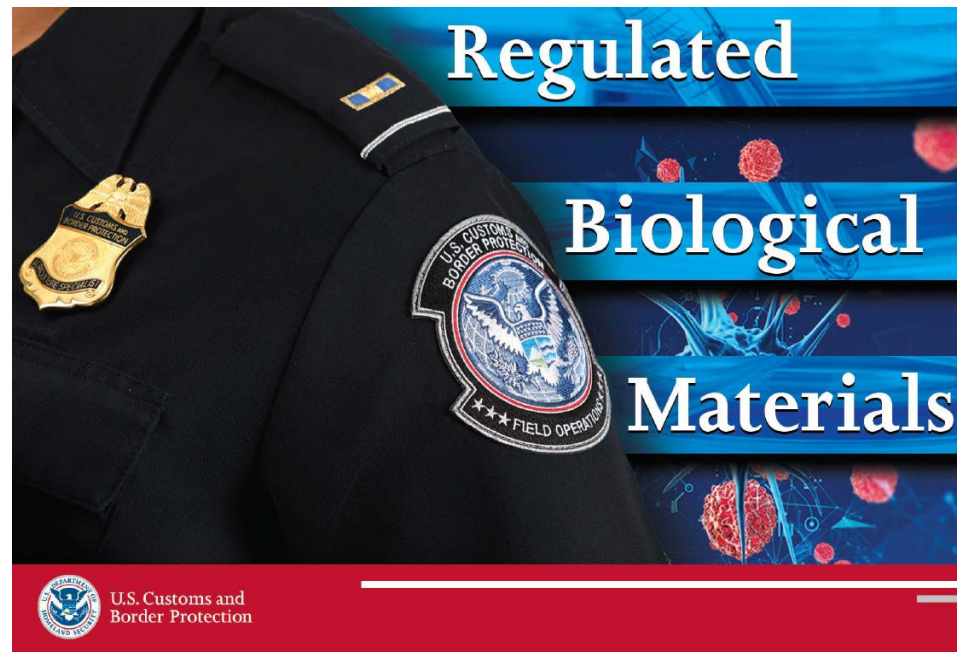


U.S. Customs and Border Protection

Agriculture Programs and Trade Liaison

**CBP's Role in
Protecting American
Agriculture and
Public Health**



**U.S. Customs and
Border Protection**

Field Operations



Organization & Mission

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.**

Northern and Southern Land Borders, including rail.

Express Consignment Int'l Mail Facilities Int'l Airports



Seaports
- Container ports
- Cruise terminals

**Pre-Clearance
Container Security Initiative**

≈ 2,472 Agriculture Specialists in CBP



U.S. Customs and Border Protection

Field Operations



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)**



U.S. Customs and
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Agro/Bio-Terrorism Countermeasures Division

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.



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Field Operations



Regulated Biologicals – APHIS

Title 7 Plant Protection Act

Live plant pests, disease agents, biological control agents, parasitic plants, Federal noxious weeds:
(https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/ct_plant_import_information)

Title 9 Animal Health Protection Act

Genetically engineered organisms; organisms and vectors; semen, embryo; hatching eggs:
(https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_organisms_and_vectors)

7 CFR Part 331, 9 CFR Part 121

USDA Select Agents
(https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/sa_ag_select_agent/ct_agricultural_select_agent_program)



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Regulated Biologicals - APHIS



Virus-Serum-Toxin Act; 9 CFR Part 101- 118

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

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/ct_veterinary_biologics



Permit Office:

<https://www.aphis.usda.gov/aphis/resources/permits>



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Regulated Biologicals – FWS & CDC



50 CFR – Wildlife & Fisheries

- Endangered Species Act of 1973
 - CITES of Wild Fauna and Flora
 - Marine Mammal Protection Act
 - Migratory Bird Treaty Act
- (<https://www.fws.gov/>)

✓ Permit Office: <https://www.fws.gov/permits/>



42 CFR Part 71,
Subpart F, 71.51-
71.56

Etiological agents, hosts, and vectors of infectious human diseases:
(<https://www.cdc.gov/>)

42 CFR Part 73

HHS Select Agents and Toxins
(<https://www.selectagents.gov/SelectAgentsandToxinsList.html>)

✓ Permit Office: <https://www.cdc.gov/phpr/ipp/index.htm>



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Regulated Biologicals – FDA



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/>)



Permit Office: <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/default.htm>

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.



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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>)

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



Filing PMN to EPA:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>



U.S. Customs and Border Protection



Regulated Biologicals – DOT/FAA



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/marketing (*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/)



U.S. Customs and Border Protection



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.



Regulated Biologicals – CBP

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



CBP Cargo Inspection Process



**Carrier transmits
manifest to CBP**



**Cargo is held in a
bonded facility awaiting
CBP inspection**



**Cargo Examined
by CBP**



**U.S. Customs and
Border Protection**

Field Operations



ABTC Shipment of Interest



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



CBP Passenger Inspection Process



Carrier transmits manifest to CBP



CBP Admissibility screening



CBP Secondary inspection

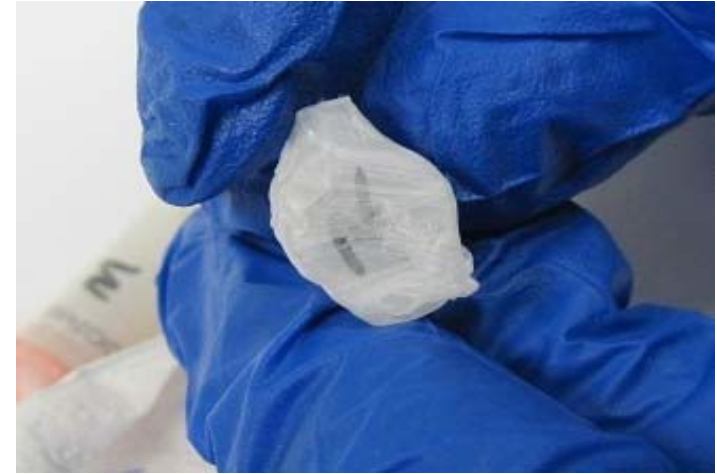


U.S. Customs and Border Protection

Field Operations



ABTC Biological Encounter in Passenger 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)**



CBP Inspectional Challenges

- 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](https://www.cbp.gov)
- Updated information available for Trade on [CBP.gov](https://www.cbp.gov/trade/basic-import-export/what-you-need-know-importing-biological-materials-united-states)
<https://www.cbp.gov/trade/basic-import-export/what-you-need-know-importing-biological-materials-united-states>
- 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



U.S. Customs and Border Protection

[About CBP](#)
[Newsroom](#)
[Travel](#)
[Trade](#)
[Border Security](#)
[Careers](#)

HOME >> TRADE >> BASIC IMPORT EXPORT

Trade

- Basic Import and Export
 - ACE and Automated Systems
 - Programs and Administration
 - Priority Trade Issues
 - Rulings and Legal Decisions
 - Stakeholder Engagement
 - Trade Facilitation and Trade Enforcement Act

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 in

Biological materials are categorized, permitted, and regulated of production or synthesis; packaging (bulk or final dosage for 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, re
- Cell/tissue culture product (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 acid
- Test kits
- Vaccines
- Bacterins
- Toxoids
- Unused culture media

Partner Government Agency permitting websites:

 United States Department of Agriculture (USDA) Permits	 United States Fish & Wildlife Service (USFWS) Permits	 Environmental Protection Agency Requirements for Importers and Exporters
 Centers for Disease Control & Prevention (CDC) Permits	 Food & Drug Administration (FDA) Prior Notice & Review	 U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration
 Joint CDC and USDA Federal Select Agent Program (FSAP)	 U.S. Department of Transportation Federal Aviation Administration (FAA) Specific Packaging & Shipping Requirements	
		

For additional information or clarification on importing biological materials into the United States, please contact your intended port of arrival or CBP at apttabc@cbp.dhs.gov



Agro/Bio-Terrorism Countermeasures Division

Questions for ABTC?



APTLABTC@cbp.dhs.gov



U.S. Customs and
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Field Operations

