U.S. Customs and Border Protection (CBP) Role in Protecting American Agriculture and Public Health

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Field Operations
In March 2003 –

- DHS was formed, integrated 22 different Federal agencies, including U.S. Customs and Border Protection (CBP).

- USDA Plant Protection Quarantine inspection at POE transferred to CBP

- Agriculture Programs & Trade Liaison (APTL) – manages the agriculture mission at the POE.

328 Ports of Entry (POE)

- Land Crossings:
  - southern
  - northern

- Int’l Airports
  - ECO
  - Int’l Mail

- Seaports
  - Container ports
  - Cruise terminals

- Pre-Clearance

- POE staffed by Agriculture Specialists - 186
- Total CBPAS ~ 2,486
On a Typical Day in Fiscal Year 2017, CBP Processed:

- 1,088,300 passengers and pedestrians
  - 340,444 incoming international air passengers and crew
  - 55,709 passengers and crew on arriving ship/boat
  - 691,549 incoming land travelers
- 950,000 Inbound Mail (JFK)
CBP’s Agriculture Mission

Protect the border by preventing the entry of threats to American agriculture and natural resources

Threat exclusion approaches:

• Inspection of agricultural and biological imports
• Advanced screening of high risk imports
  o Targeting smuggling networks
• Non-intrusive inspection (x-ray)
Importing Biologicals

• All import products are subject to inspection.

• The Importer/Shipper is responsible for complying with all applicable shipping regulations including permits, certificates, proper labeling, packaging, and shipping.
# Regulated Biologicals – USDA

|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
Regulated Biologicals – USDA:

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


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

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

50 CFR – Wildlife & Fisheries
• Endangered Species Act of 1973
• Convention on International Trade in Endangered Species of Wild Fauna and Flora
• Marine Mammal Protection Act
• Migratory Bird Treaty Act
(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/)

42 CFR Part 73
HHS Select Agents and Toxins
(https://www.selectagents.gov/SelectAgentsandToxinsList.html)

Permit Office: https://www.fws.gov/permits/
Permit Office: https://www.cdc.gov/phpr/ipp/index.htm
Regulated Biologicals – FDA


Antibiotics, anti-inflammatories, Anthelmintic/antiparasitic, 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:
Be constantly aware of Import Alerts issued by FDA which contain information on company, products, or country of which goods can be detained at U.S. ports of entry without physical examination. For more information, contact (305)-794-1043 or sgarg@strtrade.com.
# 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.

(https://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:

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/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/)
Imports covered by the National Marrow Donor Program and Organ Donor Program:

- Must be declared in CBP Customs form
- The marrow bags (or the transport container) must be clearly labelled with:
  - Name and address of the transplant physician
  - Name of the harvesting physician; and,
  - Identity of the donor’s national registry.
- Signed “non-infectious” letter from harvest center
- Comply with DOT packaging and labeling regulations
CBP Entry Requirements
Cargo (Air, Sea, Land Border)

• 19CFR §143.22, formal entry may be required for “any merchandise if deemed necessary for import admissibility enforcement purposes, revenue protection or the efficient conduct of Customs business.

• The biological materials, imported for research purposes despite having no monetary value, may be deemed subject to formal entry.
Helpful Tips in Importation

- No legal requirement to hire a CBP Licensed Customs Broker *albeit* many importers opt to do so for convenience:
  - can conduct CBP business on behalf of importer
  - well versed in CBP requirements and filing entries into CBP systems
  - ensure compliance to all Federal rules and regulations

List of CBP Licensed Customs Broker by State:
https://www.cbp.gov/contact/find-broker-by-port

- For additional information on importing biological materials, you may also contact the port of intended arrival. To locate port of entry by State, see: https://www.cbp.gov/contact/ports.

- Other reference:
Key Import Requirements

- **Know exactly what you’re bringing into the USA**
  - Secure proper permit to accompany package
    - If permit not required, import requires either:
      - USDA Letter of No Jurisdiction; or,
      - Informational Letter for Non-Infectious Material

- **Proper shipping label, marking, and packaging**
  [https://www.faa.gov/about/initiatives/hazmat_safety/](https://www.faa.gov/about/initiatives/hazmat_safety/)
### Case Example: Commingled Imports

<table>
<thead>
<tr>
<th>Environment:</th>
<th>Express Courier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode:</td>
<td>Mail</td>
</tr>
<tr>
<td>Destination:</td>
<td>National Laboratory</td>
</tr>
<tr>
<td>Documentations:</td>
<td>With shipment: PPQ Permit CDC Permit</td>
</tr>
</tbody>
</table>
| Violation:         | • CDC permit – *S. aureus* not *S. simiae*  
|                    | • PPQ requires *Paraburkholderia spp.* shipped to USDA/PIS |
| Action:            | • Denied entry  
|                    | • Re-exported  

*Paraburkholderia spp.*  
*S. simiae*
Impact on Research

Failure to follow import/shipping regulations may result in the following:

• Package delays during transport
• Mishandling during transport
• Inadvertent release of the contents
• Delays release by CBP
• Compromise integrity and viability of live materials
• Destruction of the import materials
• Criminal or civil penalties

Key Takeaways:

• Know what you’re importing and import compliance requirements
• Contact your Department of Environmental Health and Safety or equivalent for information on importing/shipping requirements for biologicals
• Contact the port of intended arrival for further assistance
Questions?