

U.S. Customs and Border Protection

Agriculture Programs and Trade Liaison

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

Romelito Lapitan, *Ph.D.*
Director, Agro/Bio-Terrorism Countermeasures
DHS/CBP/OFO/APTL/
Email: romelito.lapitan@cbp.dhs.gov
Phone: (202) 344-2637



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Detroit Biological Workshop
May 7, 2019

Field Operations



Organization and Mission

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**



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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)**

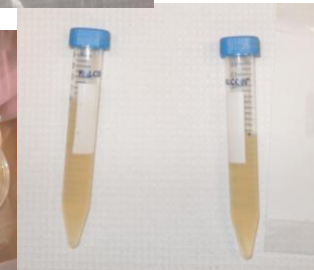


CBP's Agriculture Mission

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
 - 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



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



Regulated Biologicals – USDA:



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
 - Convention on International Trade in Endangered Species 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:

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.



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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>



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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.”)

[\(https://www.faa.gov/about/initiatives/hazmat_safety/\)](https://www.faa.gov/about/initiatives/hazmat_safety/)



National Marrow Donor Program

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

MARROW HARVEST REPORT		
PATIENT:		
Patient's name:	Transplant centre:	
Patient ID#:	Courier's name:	
DONOR:		
Donor ID#:	Sex:	Date of birth:
Weight (kg):	Blood group:	
MARROW HARVEST DETAILS:		
Date of collection:	Harvest physician:	
Collection centre:		
Address of collection centre:		
Phone no:		Fax no:
Time collection started:		Time collection finished:
Total number of bags:		Total volume collected:
Total number of nucleated cells collected:		
Anticoagulant used:		Tissue culture media used:
Any changes in marrow requirements? If yes, please specify:		Any changes in peripheral samples requested? If yes, please specify:
Name of person handing marrow to courier:		
Additional comments:		
Harvest physician's signature:		Date:



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:
https://help.cbp.gov/app/answers/detail/a_id/3681/~importing-biological-materials-into-the-united-states



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/



Case Example: Commingled Imports

Environment: Express Courier
Mode: Mail
Destination: National Laboratory
Documentations:
With shipment: PPQ Permit
CDC Permit

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**



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Questions?



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