

IMPORTATION OF BIOLOGICAL SUBSTANCES

Michigan State University

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Border Protection

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What are Biologicals?

- A WIDE range of materials used in research and the commercial biotechnology industry
- Derived from plants, animals, or microbes
- Can include Synthetics



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Okay, so what does that mean?

primary cell culture
Bovine serum Albumin (BSA)
proteins
fungi
hybridomas
prions
antisera
Histopathological Slides
Blood
toxins
Anti-venom
tissue culture supernatants
monoclonal antibodies
peptides
bacterins
urine
saliva
test kits
viruses
ascitic fluid
toxoids
DNA
Fetal bovine serum
Tissue and organ samples
antitoxins
RNA
vaccines
yeasts
plasmids
plasma
feces
protozoa
Unused culture media
biopsies
vectors
fomites
used/conditioned culture media
bacteria
Polyclonal antibodies
extracts
recombinant cell lines
Clotting factors
enzymes
hormones
primary tissue culture



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Why does CBP Regulate Biologicals?

- Public Safety
 - The Public
 - Federal Agents
- Safeguarding the U.S. Economy
- International Biosecurity



AP Photo/Abbas Dulleh



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Challenges and Need for Public Partnership

We Need You!

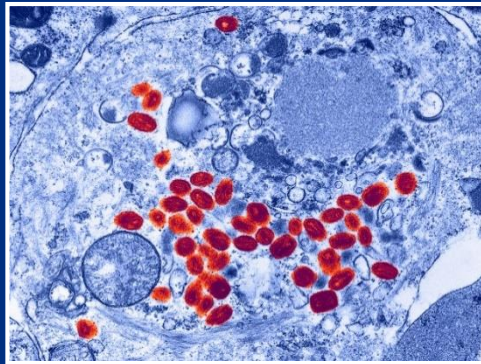
- Biological threats are Dynamic
- Future of Synthetic Biology is unknown
- Global traffic and trade are increasing
- **Public partnership is critical to:**
 - Facilitate legitimate imports
 - Allow CBP to focus its manpower and resources to inspecting high risk, illegal agricultural and biological entries.



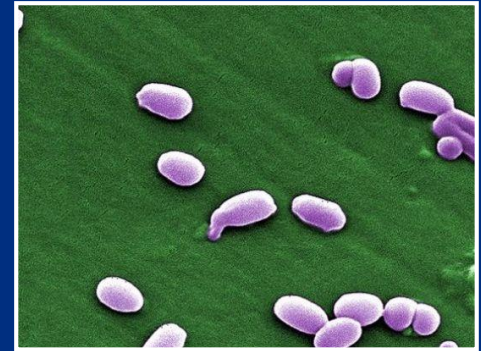
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Biosafety Complacency

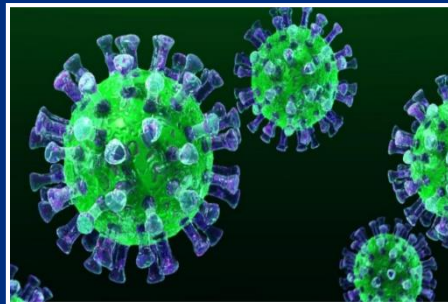
“Smallpox Virus Found In Unsecured NIH Lab” (Nature, Jul 9, 2014)



“Pentagon: Live anthrax inadvertently distributed by Army laboratory” (Washington Post, May 27, 2015)



“Pasteur Institutes Acknowledge Unauthorized Import of MERS Samples on a Flight from Seoul to Paris” (Nature, Oct 24, 2016)



“Deadly bacteria (*Burkholderia pseudomallei*) release sparks concern at Louisiana lab” (USA Today, Mar 5, 2015)



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Importation of Biologicals in Passenger Baggage



- Who brings biologicals into the U.S. in passenger baggage?
 - Researchers
 - Grad Students & Post Docs
 - Visiting Scholars/Students
 - Medical doctors
 - Veterinarians
 - Corporations
 - Medical patients
 - Couriers



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Importation of Biological Substances: Requirements for CBP Release

Requirements for hand-carried shipments arriving on passenger aircraft.



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Importation of Biologicals in Passenger Baggage

- Determining Admissibility of a Biological Substance
 - 1) Was it declared?
 - 2) Are valid permits present and being followed?
 - 3) Is it properly labeled and packaged?
 - 4) Has a formal entry been completed?



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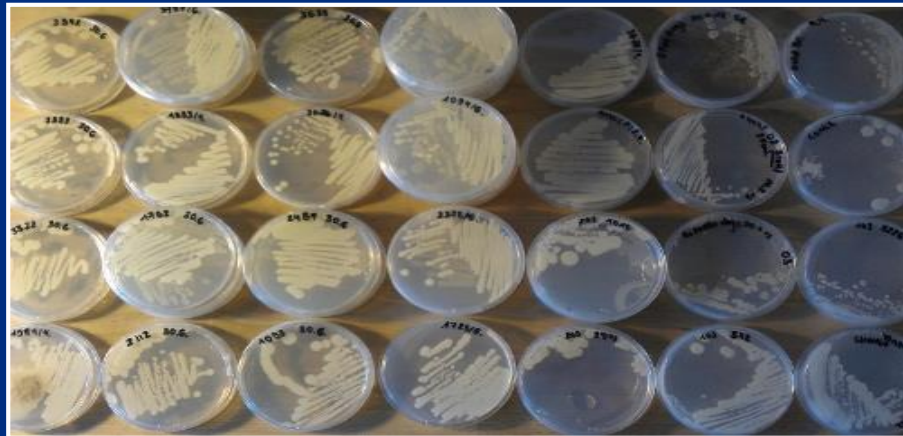
Importation of Biologicals in Passenger Baggage

- How should biologicals be transported into the U.S. in passenger baggage?
- **Follow your Permit!**
 - Checked or hand-carry bags
 - 100% in accordance with proper importation guidelines, including:
 - Properly labeled and packaged
 - Prior Notice (if applicable) and Proper Port
 - Notice given to airline if the material is potentially hazardous



Don't think you need a permit?

- You need lots of documentation and MUST declare
 - Letters of non-regulation suggested
- Still needs a formal entry
- If it turns out to be regulated, it could be much harder to get permits after-the-fact (Is your material perishable?)



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What is a Formal Entry?

A Formal Entry is the process of importing a commodity that is covered by an entry bond.

- Can be done **Prior** to travel
- How do I file a Formal Entry?
 - Consider a Customs Broker
 - CBP.gov
- The shipment must have:
 - Invoice / Packing list
 - Documentation
 - Required Permits / Letters

DEPARTMENT OF HOMELAND SECURITY U.S. Customs and Border Protection				1. Filer Code/Entry No.	2. Entry Type	3. Summary Date
ENTRY SUMMARY				4. Surety No.	5. Bond Type	6. Port Code
				7. Entry Date		
8. Importing Carrier		9. Mode of Transport		10. Country of Origin		11. Import Date
12. B/L or AWB No.		13. Manufacturer ID		14. Exporting Country		15. Export Date
16. I.T. No.	17. I.T. Date	18. Missing Docs	19. Foreign Port of Lading		20. U.S. Port of Unlading	
21. Location of Goods/G.O. No.		22. Consignee No.		23. Importer No.		24. Reference No.
25. Ultimate Consignee Name and Address				26. Importer of Record Name and Address		
City State Zip			City State Zip			
27.	28. Description of Merchandise			32.	33.	
Line No.	29. A. HTSUS No. B. ADA/CVD No.	30. A. Grossweight B. Manifest Qty.	31. Net Quantity in HTSUS Units	A. Entered Value B. CHGS C. Relationship	A. HTSUS Rate B. ADA/CVD Rate C. IRC Rate D. Visa No.	34. Duty and I.R. Tax Dollars Cents



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Importation of Biologicals in Passenger Baggage

- Final outcome of the biological importation after inspection:
 - If PERFECT:
 - Passenger is allowed to exit the Federal inspection area with the biologicals.
 - If NOT:
 - Post-Entry awaiting permits and documentation.
 - Expect delays
 - If remediation is needed, will occur at YOUR COST.



Do you want to ship your Biologicals instead?

Great!

All Regulations Still Apply.

The FedEx logo, featuring the word "FedEx" in a bold, sans-serif font. "Fed" is in purple and "Ex" is in orange.

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Importation of Biological Substances: Requirements for CBP Release

Cargo and Express Courier Facilities (ECF) requirements.

- Must be properly manifested
 - Accurate!
- Must be accompanied with EXTENSIVE import documents:
 - You are not there to answer questions!
 - Permission letters or permits
 - Statement of non-infectiousness on official letterhead, if applicable
- Formal Entry Requires to meet CBP entry requirements



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Using High-Quality Descriptors

Sample Descriptions

- “Live Influenza Virus, H1N1”. **Good!**
- “Biopsies for Research” **Okay**
- “Sample” **Poor!**
- Additional Statements:
 - MSDS Toxic Substances Control Act (TSCA) Certification,
 - USDA Statement of non-hazardous/non-infectious exempt human specimens – human cell lines. Material is not recombinant and not derived from livestock. Material is being sent for in lab testing (in vitro) only.



QUESTIONS?

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