

# Research Materials: Shipping, Import, & Export



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# Important Overview / General Awareness

1. Shipping & Transporting Dangerous Goods & Hazardous Materials
2. Material requiring special paperwork for transport, Import, & Export
3. UF Shipping-Related Requirements
4. Steps to send or receive materials



# Make Successful, Safe & Compliant Shipments!

## Helping you avoid or prevent:

- Refusal of package by the carrier
- Delays & potential spoilage of package contents
  - Exposure of personnel to hazards
  - Contamination of the environment
  - Damage to aircraft or other property
  - Seizure of the material by authorities
- Fines / potential criminal liability for you the shipper, or UF



# Hazardous Materials & Dangerous Goods are *Highly Regulated for Transport*

UF personnel must comply with the strict training, documentation, & packaging requirements specified in **Department of Transportation (DOT) & International Civil Aviation Organization (ICAO) laws**

Why it matters ....fines currently up to \$78,000 per violation (& up to \$183,000 per violation if damage, illness or injury/death occur as a result of violation)

UF, the PI, and/or the shipper can be fined

The screenshot shows the FAA website's press release page. The header includes the United States Department of Transportation logo and the Federal Aviation Administration logo. Navigation links for 'FAA Home', 'Jobs', 'News', and 'About FAA' are visible. A search bar is located in the top right. The main navigation bar lists categories: Aircraft, Airports, Air Traffic, Data & Research, Licenses & Certificates, and Regulations & Compliance. The breadcrumb trail reads 'FAA Home > News > Press Releases'. A left-hand menu lists various content types: Press Releases (selected), Fact Sheets, Speeches, Testimony, News & Updates, Media Advisories, Conferences & Events, FAA Safety Briefing, Public Affairs Contacts, and Stay Connected. The main content area features a press release titled 'Press Release – FAA Proposes \$70,050 Civil Penalty Against the University of Wisconsin-Madison for Alleged Hazardous Materials Violations'. Below the title is a 'For Immediate Release' section with the date 'May 29, 2015' and contact information for Tony Molinaro. The body of the release begins with 'CHICAGO—The U.S. Department of Transportation's Federal Aviation Administration (FAA) proposes a \$70,050 civil penalty against the University of Wisconsin-Madison for allegedly violating Hazardous Materials Regulations.' It details the FAA's allegations that on January 13, 2015, an official traveling on behalf of the university offered an undeclared hazardous material shipment to Delta Air Lines for transport on a passenger flight from Madison to Minneapolis. The shipment included 1.89 liters of ethyl alcohol and 120 milliliters of Epofix hardener. The release concludes by stating that the FAA alleges the shipment, which was in the passenger's checked baggage, should have been offered to Delta as cargo containing hazardous materials and that the university failed to ensure its employees had received required hazardous materials training and did not include emergency response information with the shipment.

# Hazardous Materials & Dangerous Goods defined as: capable of posing a risk to health, safety, property or the environment & which are listed in the regulations or classified according to the regulations



**Class 1** Explosives



**Class 2** Gases



**Class 3** Flammable Liquids



**Class 4** Flammable Solids; Liable to Spontaneous Combustion; Substances Which, in Contact with Water, Emit Flammable Gases



**Class 5** Oxidizing Substances and Organic Peroxides



**Class 6** Toxic and Infectious Substances



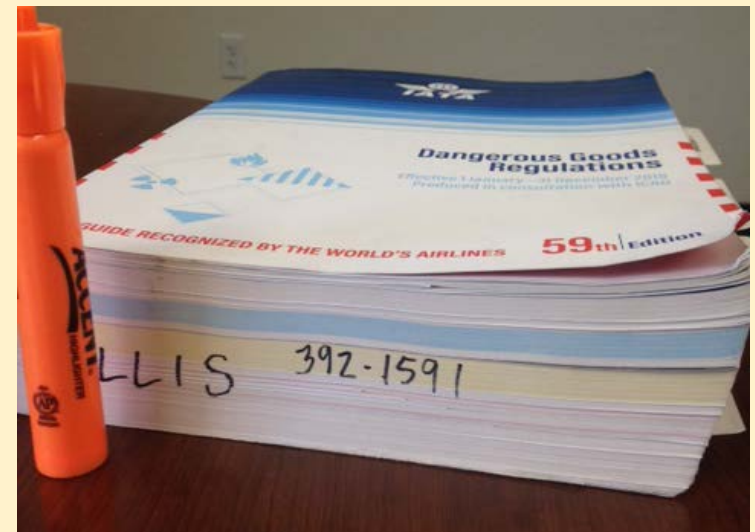
**Class 7** Radioactive Materials



**Class 8** Corrosives



**Class 9** Miscellaneous Dangerous Goods



# “Haz Mat” or Dangerous Goods Shipping

Federal & international regulations require certification training for individuals who:

Transport, prepare, classify, pack, label, or offer “Dangerous Goods” for transport

Re-certification is required every 2 years.

- **Biohazardous materials or their preservatives:** On-line **certification** class available (Shipping & Transport of Biological materials). To register, email [bsol@ehs.ufl.edu](mailto:bsol@ehs.ufl.edu).
  - Examples: **Human & animal pathogens, plasmids/viral vectors, genetically-modified microorganisms, fixative solutions, dry ice.**
  - See <http://www.ehs.ufl.edu/programs/bio/shipping/>
- **Chemicals & Toxins:** Contact UF Hazardous Material Management Program 352-392-8400 for training & assistance with **EVERY** shipment
- **Radioactive Materials:** Shipped **ONLY** by UF Radiation Control. Call 352-392-7359

# Import into the USA

Import Regulations: *permit needed* by the receiving Principal Investigator:

- **CDC**
  - materials infectious/potentially infectious to humans
  - vectors (mosquitoes, flies, bats, etc.) of human disease
- **USDA Veterinary Services**
  - materials infectious/potentially infectious to livestock
  - vectors of livestock disease
  - items containing animal products
- **USDA Plant Protection & Quarantine**
  - plant disease agents, plant pests
  - bees, biological control organisms, soil, noxious weeds
  - plants, plant products
- **USDA Biotechnology Regulatory Service**
  - genetically engineered organisms that may impact plant/crop health
- **FDA**
  - Human cells for implantation, biologics, drugs, medical devices, food
- **US Fish & Wildlife / CITES**
  - wildlife, endangered plant, insect & animal species, wildlife specimens



US Customs & Border Protection ensures federal import laws are followed. *Fines & civil penalties may be applied for violations*

**Critical website!** [https://help.cbp.gov/app/answers/detail/a\\_id/3681/~/importing-biological-materials-into-the-united-states](https://help.cbp.gov/app/answers/detail/a_id/3681/~/importing-biological-materials-into-the-united-states)

# Movement within USA



## Inter-state Movement Regulations – *permit needed by receiving* *Principal Investigator:*

- **USDA Veterinary Services** – “organisms & vectors”: materials known/suspected infectious to livestock
- **USDA Plant Protection & Quarantine** – plant disease agents, plant pests, bees, soil, biological control organisms, noxious weeds
- **USDA Biotechnology Regulatory Service** – genetically engineered organisms/microorganisms impacting crops
- **State of Fla Division of Agriculture** – Movement of material into (or in some cases around) Fla. that may harm our agriculture.

*Fines & civil penalties may be applied for violations by regulating agency*



# Permits – Some Comments...

1. UF & the Biosafety Office do not hold any “umbrella” permits. Permits are a legal contract between recipient of the material & the State /Federal government specifying how recipient will safeguard the material in transit & once here.
2. Once issued, the permit conditions specify exactly how the permit must be used. Read carefully.
3. Typically, permits cannot be shared with other investigators; they are issued to a person (PI) or small group of PIs. There are a few exceptions. Read the permit conditions.
4. When applying for a permit, plan ahead and think broadly so you don't need to keep amending your permit and re-applying. For example request to import worldwide vs. just from specified countries, or list additional persons in the department as recipients of the material instead of just yourself.
5. CDC permits are free but cannot be amended; USDA permits have an associated application fee (\$150), but can be amended or renewed for a (lower) fee.
6. Permits can take 2-8+ weeks to receive – plan ahead.
7. Before the permit is issued, the State or Federal agency may require an inspection of the area where the material is received, stored, & used. Contact the Biosafety Office for help (pre-inspection).
8. Once received, send EHS a copy of your permit so we can ensure the research space continues to meet the requirements.
9. Keep your permit up to date. Watch expiration dates & plan ahead for renewal. EHS does not track these dates.

# Don't need a Permit? You still need an Exemption Certification / Letter of Information

CDC <https://www.cdc.gov/cpr/ipp/index.htm>

- To facilitate customs clearance for materials that do not require a CDC import permit, each shipment must be accompanied by a *certification statement, on official letterhead, from the sender or the recipient* of this material.
- The certification statement must include:
  - A detailed description of the material &
  - Statements affirming:
    - The material is not known or suspected to contain an infectious agent, &
    - One of the following:
      - How the shipper or recipient knows that the material does not contain an infectious agent, or
      - Why there is no reason to suspect that the material contains an infectious agent, or
      - A detailed description of how the material was rendered noninfectious

- Clearly state that the material is for research purposes only. If the material is not dangerous goods, indicate that.
- The statement must be available as a separate document for review by the DHS, CBP Officers at the U.S. port of arrival; the producer/shipper should *not* place this document(s) inside the shipping container(s).

## USDA:

- Must have a written statement 1) explaining in detail what the material is, 2) what it will be used for, & 3) confirming that no permit is required & why.
- The written statement should be supplied on shipper/foreign producer's letterhead, with the letterhead containing the physical address of the foreign producer/shipper.

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req> (use drop down arrows)

## Guidelines: Animal Products That Do Not Require An Import Permit

Last Modified: Jul 26, 2018



These materials do not require a USDA import permit, but will be reviewed at the port of entry.

- ✓ Guideline 1100: Human And Veterinary Pharmaceuticals and Vaccines
- ✓ Guideline 1101: Non-Human Primate Material (excluding cell cultures)
- ✓ Guideline 1102: Feline and Canine Material
- ✓ Guideline 1103: Live Laboratory Mammals and Their Material (for research purposes)
- ✓ Guideline 1104: Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)
- ✓ Guideline 1105: Chemically Synthesized Materials
- ✓ Guideline 1107: Importation of Lactose and Lactose Derivatives
- ✓ Guideline 1110: Microbially Produced Materials
- ✓ Guideline 1114: Recombinant Microbes and Their Products
- ✓ Guideline 1116: Non-Pathogenic Microorganisms (and their extracts)
- ✓ Guideline 1119: Pet Chews and Treats Made of Antlers or Rawhide
- ✓ Guideline 1120: Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
- ✓ Guideline 1121: Self-Contained Test Kits Containing Animal-Derived Ingredients
- ✓ Guideline 1122: Vitamins and Minerals
- ✓ Guideline 1123: Histopathological Fixed Slides

# Export from the USA

- US Depts. of State, Commerce, & Treasury regulate the distribution of strategically important *commodities, services & information to foreign countries or persons.*
- Export license may be required
- *Many* types of research materials & equipment export controlled! (lab chemicals, assay kits, biologicals, etc.) See [http://www.ehs.ufl.edu/programs/bio/shipping/export\\_control/](http://www.ehs.ufl.edu/programs/bio/shipping/export_control/)
  - Biologicals include many Risk Group 2 , 3, & 4 pathogens of humans, animals, & plants
    - *No exclusions for attenuated strains. Extracted DNA/RNA may also require a license*
- If the commodity is not controlled, the recipient may be; have UF Export Control conduct a “Restricted Party Screening” check

Severe penalties for noncompliance (*finer up to \$1 million per occurrence and 20 yrs. jail time*)

# UF Paperwork/Requirements

- From the **Office of Research Compliance:**
  - Compliance with established federal, state and local rules, regulations, policies & procedures. See <http://research.ufl.edu/compliance.html>
- From the **Office of Research:**
  - You may need a [Material Transfer Agreement](#) or other research agreement (contract between the owner of a material & intended recipient that delineates transfer & subsequent use of the material) before receiving or sending
  - Contact UF Innovate <http://innovate.research.ufl.edu/> (352) 392- 8929
- From **Environmental Health & Safety:**
  - Receipt or shipment out may require new or updated
    - Biosafety/IBC project registration
    - Chemical inventory & Chemical hygiene plan/hazard assessment
    - Safety SOPs
    - Dangerous goods shipping training
    - See <http://www.ehs.ufl.edu/programs/lab-research/>
- From the **Institutional Review Board (IRB):**
  - Receiving, sending, using or storing human tissue/specimens *may* require IRB approval. See [http://research.ufl.edu/compliance/pdf/GuidanceforPI\\_HumanTissue\\_without%20IP.pdf](http://research.ufl.edu/compliance/pdf/GuidanceforPI_HumanTissue_without%20IP.pdf)

## Sending Materials Out of the USA

- Export check! Is material controlled for export? See [http://www.ehs.ufl.edu/programs/bio/shipping/export\\_control/](http://www.ehs.ufl.edu/programs/bio/shipping/export_control/)
- Is the end user or recipient institution controlled? Contact UF Export Control to conduct “restricted party screening”.
- If you need a license, UF (Office of Research or Biosafety) will apply on your behalf. Takes a minimum of 8 weeks.
- Stringent license conditions are placed on how material is to be *received, used, stored, destroyed* - record keeping is critical.
- Shipments under export license will 1<sup>st</sup> require an EEI (Electronic Export Information) filing through the AES. This is typically done by the shipping courier. The wording on the Commercial or Pro Forma invoice must reference the use of an export license.

- Do you need an MTA? Contact UF Innovate: <http://innovate.research.ufl.edu/> 352-392-8929

- Contact recipient. Do they need to send you any documentation for the package to get through their Customs?
- At a minimum, need a “letter of information” stating what the material is, where it’s going, & for what purpose – on letterhead, in document pouch on outside of box. Indicate why no permits are needed. If applicable, state the material is nonhazardous, & not dangerous goods.
- Recipient’s country may require a Certificate of Origin. Have the recipient send their form. If not, carrier may have a generic one (FedEx does).

Complete International Waybill. Highly recommend calling carrier for help 1<sup>st</sup> in case the carrier or country has special requirements. Example: <http://www.fedex.com/us/international-resource-center/internationalfaq.html>

Is the value of any single item on your commercial or Pro Forma invoice over \$2,500? If so, will also need to file an EEI (Electronic Export Information) filing through the AES. This is typically done through the courier.

Provide 3 copies of a Commercial or Pro Forma Invoice to establish need for taxes, tariffs, fees, etc. The value you assign to the contents determines these fees.

Best to use the on-line version from the carrier (e.g. FedEx, DHL, etc). Contact EHS for a template if they don’t have one.

Include 1 original and 2 copies in the shipping documents pouch.

May require input of a “Harmonized Tariff Schedule Code”; see <https://hts.usitc.gov/current>

Prepare a packing list and place inside the container. All other paperwork should be accessible on the outside of the container/box.

Is the material “dangerous goods”? If so, make sure you are certified to ship dangerous goods.

Make copies of all documentation & keep all paperwork at least 2 yrs. (5 years for international shipment of dangerous goods)

## Receiving Materials Into the USA

- Do you need an import permit?
  - Check CDC, APHIS Vet Services, APHIS PPQ, APHIS BRS, FDA, US Fish & Wildlife as appropriate.
- If you have one, send it in advance to the shipper to include with the package
- If it doesn't need one, prepare an exemption certification letter or letter of information explaining why no permit needed & send to the shipper or have shipper prepare one
- **Critical websites!** [https://help.cbp.gov/app/answers/detail/a\\_id/3681/~/importing-biological-materials-into-the-united-states](https://help.cbp.gov/app/answers/detail/a_id/3681/~/importing-biological-materials-into-the-united-states) & also <https://www.cbp.gov/travel/us-citizens/know-before-you-go/prohibited-and-restricted-items>
- Do you need an MTA? Contact UF Innovate: <http://innovate.research.ufl.edu/>
- Are you approved to have this material at UF?
  - Contact EH&S, IACUC or IRB as appropriate.
- Are you being asked to provide TSCA ("TOSCA") Certification? TSCA = [Toxic Substances Control Act](#)
  - There's an exemption for R&D materials. See <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/research-and-development-exemption>.
  - If the exemption applies, on the TSCA form: check "No", meaning not regulated & for the item description, write "R&D exemption"
- Keep all paperwork at least 2 yrs. (5 years for international shipment of dangerous goods)

# Research materials in Checked or Carry-on Baggage:

- Baggage is screened for prohibited, undeclared, or unusual items.
- This can result in confiscated items that will be held until questions are answered and/or forms are submitted.
- May result in *travel delays, spoilage of the items, fines, or other penalties.*



Dangerous goods, including biological materials classified as infectious and chemical preservatives are prohibited in both checked & carry-on baggage

But... it is **Strongly Recommended** that you **do not move any biological material in baggage.**





# Really Complicated Shipment Coming Up?



- Consider a *Freight Forwarder*...a “travel agent for cargo”  
Or....
- You may need a *Customs Broker*... an intermediary between the importer & the government’s customs department in the country of import
- Both charge fees
- Call EHS or UF Purchasing for assistance

Contact me with any questions!

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Thank You!

