

RESEARCH MATERIALS: SHIPPING, EXPORT, IMPORT & TRANSPORT

Karen Gillis, MS, CBSP
Associate Director/Research Services
UF Division of Environmental Health & Safety
916 Newell Drive, UF

352-392-1591

kgillis@ehs.ufl.edu

<http://www.ehs.ufl.edu/>

QUICK OVERVIEW / GENERAL

AWARENESS USE LINKS/CONTACTS PROVIDED FOR MORE INFO

- **“Haz Mat” Shipping** - e.g. *chemicals, biohazards*
- **Permits & Licenses**
 - Export Control & Export Licenses
 - Import Permits
- **UF Requirements**
 - Material Transfer Agreements (MTAs)
 - EH&S Registration
 - Human Tissues, Specimens & Clinical Materials
- **Review: Steps to send or receive**

“HAZ MAT” SHIPPING

- Hazardous materials (“dangerous goods”) in commerce: *highly* regulated by Department of Transportation (DOT) & International Civil Aviation Organization (ICAO).
 - UF personnel must comply with strict training, documentation, & packaging requirements these entities require.
- **Biohazardous materials:** You can ship these provided you are certified. On-line certification class available. To register, email bs@ehs.ufl.edu. Re-certification is required every 2 years.
 - Examples: Human & animal pathogens, genetically-modified microorganisms
 - Dry ice & specimen preservative solutions: regulated as Dangerous Goods.
- **Chemicals:** Contact UF Hazardous Material Management Program for assistance with EVERY shipment at 352-392-8400.
- **Radioactives:** Shipped ONLY by UF Radiation Control. Call 352-392-7359
- **Why it matters** Up to \$75,000 per violation (up to \$175,000 per violation if damage/illness/injury/death occur as a result of violation)
https://www.faa.gov/news/press_releases/news_story.cfm?newsId=18954

EXPORT CONTROL/EXPORT LICENSES

- Who is your shipment going to & What institution?
 - UF Export Control will conduct Restricted Party Screening
- What are you sending? Does it need a license?
 - Many items controlled!
 - Biologicals for example:
 - http://www.ehs.ufl.edu/programs/bio/shipping/export_control/
 - Includes pathogens, DNA/RNA from listed agents, & “lower risk” (BSL2 or attenuated versions) agents
- Contact the Division of Research Compliance at (352) 392-9174 or compliance@research.ufl.edu

IMPORT/EXPORT - USDA

<https://www.aphis.usda.gov/aphis/ourfocus/importexport>

- ◉ **What are you IMPORTING into the United States?**
- ◉ **Food and Agricultural Products**
- ◉ **Animal or Animal Product**
 - **State Regulations and Import Requirements**
- ◉ **Organism and Vectors**
- ◉ **Organism and Soil**
- ◉ **Plants or Plant Products**

What are you EXPORTING from the United States?

- ◉ **Animal or Animal Products**
 - **International Animal Export Regulations (IREGs)**
 - **International Products Export Regulations (IREGs)**
- ◉ **Plants or Plant Products**

IMPORT PERMITS - USDA VS

○ USDA/APHIS Veterinary Services

- Materials derived from agricultural animals or exposed to animal products https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_imports_home
- Livestock/poultry disease agents (even inactivated or DNA/RNA from them) https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_organisms_and_vectors
- List of agents requiring permit(13 pgs !)
https://www.aphis.usda.gov/animal_health/downloads/organisms_and_vectors/vsregulatedlivestockpoultrypathogens_partial%20list.pdf
- Flow Chart (note even inactivated material or DNA/RNA requires permit !)
https://www.aphis.usda.gov/animal_health/downloads/organisms_and_vectors/ov_flowchart.pdf
- Exemptions ??? **No permit required** - Must provide declaration statement *as directed* on letterhead
https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits/ct_animal_imports_nopermit
- If you get a permit, read the conditions carefully

IMPORT PERMITS - USDA PPQ

○ USDA/APHIS Plant Protection & Quarantine

- Soil, plant material, plant pests and plant pathogens.

<https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information>

- If you get a permit, read the conditions carefully
- PPQ permits are for possession, not just import

IMPORT PERMITS - USDA BRS

○ USDA/APHIS Biotechnology Regulatory Service

- Genetically-engineered organisms or microorganisms associated with plants
- https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_permits_notifications_and_petitions/ct_submissions_home

○ Read all permit conditions

- (1) The mosquitoes are to be shipped in containers as specified in 7 CFR Part 340.8(4), for insects, mites, and related organisms or as stated in the permit
- (2) This authorization is strictly for rearing and research in a controlled laboratory environment.
- (3) All laboratories and growth chambers where this genetically engineered insect is employed will be locked with limited access by authorized personnel. If where a regulated genetically engineered organism is used, at least one sign must be posted on the door or wall stating that a regulated genetically eng organism is being used.
- (4) Upon completion of research all engineered insects (except those retained for future research), will be disposed of by freezing at -20 for 24 hours/or aut minimum of 20 minutes.
- (5) This authorization for movement under permit, is valid for execution, for a period of 1 year.
- (6) There is to be no further distribution of these genetically engineered insects under this permit without prior approval from State (intrastate movement) ar regulatory officials (interstate movement).
- (7) THIS AUTHORIZATION IS NOT VALID FOR THE RELEASE INTO THE ENVIRONMENT OF THIS GENETICALLY ENGINEERED INSECT.

All necessary precautions must be taken to prevent escape of these genetically engineered insects.
- (8) Without prior notice and during reasonable hours authorized Plant Protection and Quarantine and State regulatory officials shall be allowed to inspect th under which this genetically engineered insect is being kept.
- (9) Reporting an Unauthorized or Accidental Release

1. According to the regulation in 7 CFR § 340.4(f)(10)(i), APHIS shall be notified orally immediately upon discovery and notified in writing within 24 hour: any accidental or unauthorized release of the regulated article.

- For immediate verbal notification, contact APHIS BRS Compliance Staff at (301) 851-3935 and ask to speak to a Compliance and Inspection staff mer verbal report on voicemail if the phone is not answered by a Compliance Officer.
- In addition, in the event of an emergency in which you need to speak immediately to APHIS personnel regarding the situation, you may call:

The APHIS/BRS Regional Biotechnologist assigned in the region where the field test occurs:
For Western Region, contact the Western Region Biotechnologist at (970) 494-7513
or e-mail: BRSWRRT@aphis.usda.gov

IMPORT PERMITS - CDC

- **CDC: Import of materials infectious to humans**
 - “Etiologic Agents” (infectious substances, non-human primate material, vectors of human diseases)
 - Even exempt materials will need a certification statement on letterhead stating material is not known or suspected to contain an infectious biological agent & why you know that
 - If you get a permit, read the conditions carefully
 - <http://www.cdc.gov/od/eaipp/>
 - <http://www.selectagents.gov/resources/IPPetool/>

IMPORT PERMITS - USFWS & CITES

○ By US Fish & Wildlife Service:

- Specimens or materials from wild plants or animals
- <http://www.fws.gov/permits/overview/overview.html>
- * Tom Webber at the FMNH has good experience with these permits, especially for bird specimens. Contact me for his info if needed.

○ CITES (Convention on International Trade in Endangered Species)

- <https://www.cites.org/eng/prog/e/e-permitting-toolkit.php>

UF REQUIREMENTS - MTA

- Do you need a Material Transfer Agreement or other research agreement?
 - contract between the owner of a material and the intended recipient
 - delineates the transfer and subsequent use of the material
- UF's Office of Technology Licensing executes MTAs for materials coming into & leaving UF when intellectual property rights or collaborative research agreements need to be defined and documented. <http://research.ufl.edu/otl/for-uf-inventors/transfer-materials.html>

UF REQUIREMENTS - EHS

- Receipt or shipment of research materials to or from the lab will require update of
 - Any project registrations/protocols,
 - Chemical inventory & chemical hygiene plan
 - Or any SOPs

- See <http://www.ehs.ufl.edu/>

UF REQUIREMENTS - HUMAN SOURCE MATERIALS

- UF Office of Research tools to assist with compliance:
 - <http://research.ufl.edu/faculty-and-staff/research-compliance/human-subjects.html>
- IRB Requirements and MTAs may apply

STEPS TO SEND OR RECEIVE

Sending Out	Receiving In
<p>What is it ? & Where & to whom is it going? Contact UF Export Control for Restricted Party Screening & need for license or not.</p>	<p>Are you approved to have this material at UF? Contact EH&S or IRB as appropriate.</p>
<p>Contact recipient. Do they need to send you any documentation for the package to get through their Customs? At a minimum, a “courtesy letter” stating what the material is, where it’s going, & for what purpose is needed - on letterhead, in document pouch outside box. Indicate why no permits are needed. If applicable, state the material is nonhazardous.</p>	<p>Do you need an import permit? Check CDC, APHIS Vet Services, APHIS PPQ, APHIS BRS, US Fish & Wildlife as appropriate. Give the sender a copy of your permit so they can include it in the shipping papers.</p>
<p>Do you need to establish an MTA? Contact UF OTL</p>	<p>Do you need an MTA to receive it? Contact UF OTL</p>
<p>Is the material “dangerous goods”? Are you certified to ship the material or have you asked for help?</p>	<p>Keep all paperwork at least 3 yrs.</p>
<p>Provide a 3 copies of a Commercial Invoice to establish need for taxes, tariffs, fees, etc. See http://www.export.gov/logistics/eg_main_018121.asp https://smallbusiness.fedex.com/international/documents.html https://smallbusiness.fedex.com/international/faqs.html For blank forms/more info. Other forms may be needed depending on destination country</p>	
<p>Keep all paperwork at least 3 yrs.</p>	