

# Biological and Chemical Export Controls That Impact University Research: What You Need to Know

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# Agenda

- Biological Export Controls
- Chemical Export Controls
- Impact to Universities
- UCSD's Approach to Address These Export Controls



# Why Does This Matter?

- These items could be detrimental to human, animal and plant health
- Universities are leading discoveries for treatment and require access to these materials and may need to export them to collaborators
- Licensing takes time- minimum 6 weeks
- The US not only controls these items, but other countries do too
  - US export license and foreign government import license
- US CDC, APHIS or ITAR import license may be required
- Fines \$250k per violation; possible prison time

# Recent Biological & Chemical Examples

- April 2014, Ricin Oklahoma Murder for Hire Pizza Delivery
- August 2013 , Syria sarin chemical weapons Ghouta Attack
- 2001 Anthrax letters



# Export Control Basics

- Reasons for control: national security & foreign policy
- Export licenses required when:
  1. The country involved is a trade sanctioned or **embargoed country** under the Dept. of Treasury Office of Foreign Asset Control (OFAC)
    - Imports and Exports regulated
  2. The recipient or end user is a **restricted party** listed on a US government list
  3. The **end use is prohibited** (ex. chem/bio weapons, nuclear, military end use)
  4. Item is specifically listed in the US export regulations and indicates that country requires a license
    - Includes equipment, materials, software or technology
    - Could trigger foreign national license requirements in the US (deemed exports)

# US Export Regulations

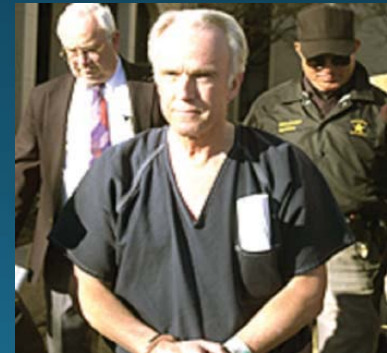
- Export Administration Regulations (EAR)
  - Listed items ECCNs Category 1 materials, chemicals, microorganisms and toxins and Category 2 materials processing
    - Other chemicals could be listed in other categories
  - Unlisted items EAR99
- International Traffic in Arms Regulations (ITAR)
  - Toxicological agents: chemical, biological agents & equipment
    - Specifically developed to produce casualties in humans or livestock, degrade equipment or damage crops
  - Explosives and Energetic Materials- Propellants
- Office of Foreign Asset Controls (OFAC)
  - Licensing for any item import or export with embargoed countries: Cuba, Iran, North Korea, Syria or Sudan and others
- Nuclear Regulatory Commission (NRC) Regulations for Export & Import

# Chem Bio Export Enforcement

- 2009 FMC Technologies \$610k penalty for unlicensed exports of valves controlled equipment
  - Voluntary Disclosure
- 2008 Buehler Limited \$200k penalty for unlicensed exports of a mixture of triethanolamine (TEA) schedule 3 chemical precursor
  - Voluntary Disclosure
- 1999 ALCOA \$750k penalty for unlicensed exports of potassium fluoride & sodium fluoride

# University Researcher Example

- Dr. Thomas Campbell Butler, M.D., a professor at Texas Tech University in Lubbock, Texas, had illegally exported *Yersinia pestis* to Tanzania
- Convicted of 47 counts; sentenced to 2 years prison and agreed to pay \$37,400 penalty and denied export privileges for 10 years





# Researcher Comments & Concerns

- This is naturally occurring in the environment or can be easily synthesized in a lab, how can it be controlled?
- This is an attenuated strain
- This is a minimal quantity and doesn't trigger select agent regulations
- My international collaborator doesn't have access to this material
- This is for medical research to help eradicate infectious disease or to provide treatment
- NIH already knows about this research why do I need permission from another US government agency?
- This is fundamental research, how could it be controlled?

# Export Classification of Restricted Biologicals

- Export Control Classification Number (ECCN)
- Listed items are part of biological weapons treaties
- Export license required to ALL countries for specifically listed items (CB1)
  - 1C351 Human and zoonotic pathogens and "toxins"
  - 1C352 Animal pathogens
  - 1C353 Genetic elements and genetically modified organisms
  - 1C354 Plant pathogens
  - 1E001 "Technology" for the "Development" or "Production" of items controlled by 1C
  - 1E351 "Technology" for the disposal of chemicals or microbiological materials controlled by 1C350, 1C351, 1C352, 1C353, 1C354, or 1C360.

# Export Restricted Biological Materials

- See Export Controlled Biologicals Handout (ECCN 1C351-1C354)
- Examples of Export Restricted Items
  - Bacillus anthracis
  - Brucella Abortus
  - Dengue
  - Escherichia Coli (pathogenic)
  - Lymphocytic Choriomeningitis Virus (LCV)
  - Salmonella typhi
  - Shigella dysenteriae
  - Staph aureaus toxins
  - Tetrodotoxin (TTX)
  - Vesicular Stomatitis Virus (VSV)
  - Vibrio cholerae



# Is there an exemption for small amounts or attenuated biological items?

- **No.** Any amount of a biological agent (attenuated or not) controlled under the Export Administration Regulations (EAR) will require an export license to any country.
- This is different from other regulations like Select Agents and HazMat transportation (DOT, FAA, IATA).



# Does genomic material require an export license?

- Yes, *if the agent* is export restricted, then the genomic material also requires an export license if it includes genetic elements or GMOs that contain:
  - Nucleic acid sequences associated with the pathogenicity of controlled microorganisms. Any sequence that represents a significant hazard to human, animal or plant health.
  - Nucleic acid sequences coding for any controlled toxin or toxin sub-unit.
- Genetic elements include & not limited to:
  - Chromosomes
  - Genomes
  - Plasmids
  - Transposons
  - Vectors
  - And may be genetically modified or unmodified or may be synthesized.



# ITAR Controls on Biologicals

- Category XIV Toxicological agents, including chemical agents, biological agents, and associated equipment
  - (b) Biological agents specifically designed for increasing their capability to produce causalities in humans or livestock, degrade equipment or damage crops
  - (g) antibodies, polynucleotides, biopolymers or biocatalysts specifically designed for use in ITAR articles in this category
  - (h) medical countermeasures, pre- and post treatment, vaccines, antidotes and medical diagnostics, specially designed or modified for use with chemical agents in this category and vaccines with sole purpose of protecting against biological agents in this category
    - Ex. Barrier creams, atropine auto injectors specially designed to counter nerve agent poisoning
- No foreign national access to ITAR controlled items without an export license or exception. Certain nationals will never be issued licenses by USG-Chinese, Iranians
- Export Reform has not yet reviewed this category and it will likely change

# Medical Products Containing Restricted Biologicals

- 1C991 Vaccines, immunotoxins, medical products, diagnostic & food testing kits
  - Medical products containing ricin D and ricin E, saxitoxin (CB1)
  - Medical products containing the following (CB3)
    - Abrin; Aflatoxins; Cholera toxin; Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins; Diacetoxyscirpenol toxin; HT-2 toxin; Microcystin (Cyanginosin); Modeccin toxin; Shiga toxin; Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F); T-2 toxin; Tetrodotoxin (TTX); Verotoxin and other Shiga-like ribosome inactivating proteins; Viscum Album Lectin 1 (Viscumin); or Volkensin toxin.

# Other Items Triggering Export Licensing

- Items with listed export restricted biologicals:
  - Infected Blood
  - Infected Tissue
  - Pathogenic genetic elements
  - Infected Animals
  - Infected Insects
- Listed Equipment





# What Does Not Require a Biological Export License?

- Agents that are not listed in the Export Administration Regulations (EAR99)- except to restricted parties or terrorist supporting countries
- Gene fragments (must be whole gene with ORF)
- Chromosome fragments
- *E. coli* Nucleic acid sequences
  - Unless sequence code for verotoxin
- Haz Mat shipping requirements may still apply
- US Fish and Wildlife controls wildlife exports- a declaration or permit may be required

# Biosensor Export Controls

- **Regional stability (RS<sub>1</sub>) export controls-licenses required for every country except Canada**
- **oA521** - Biosensor systems & dedicated detecting components capable of detecting aerosolized bioagents (anthrax, ricin, Botulinum toxin, Francisella tularensis, orthopoxvirus and Yersinia pestis) and having all of the following:
  - showing results in 3 minutes or less; containing an integrated bioaerosol collector & identifier; containing Antibodies to the bioagents listed in the entry; & utilizing bioluminescence as a process.
- **oD521** – “*Software*” for the function of biosensor systems controlled by ECCN oA521.
- **oE521** – “*Technology*” for the “development” or “production” of biosensor systems controlled by ECCNoA521.

# Export Controls on Protective & Detection Equipment

- Licenses required to most countries- check commerce country chart
- 1A004-Protective and detection equipment
  - Gas masks, filter canisters and decontamination equipment, protective suits, gloves & shoes, detection systems, to protect against biological, chemical and nuclear items adapted for use in war
    - This does not apply to personal radiation monitoring dosimeters or lab safety gear for OSHA requirements
  - Electronic equipment designed for automatically detecting or identifying the presence of “explosives”
    - This doesn't apply to specially designed equipment for lab use

# 2B352 Equipment Capable of Use in Handling Biological Materials

- Complete containment facilities at P<sub>3</sub> or P<sub>4</sub> containment level (BL<sub>3</sub>, BL<sub>4</sub>, L<sub>3</sub>, L<sub>4</sub>)
- Fermenters capacity of 20 liters or greater & specified components
- Centrifugal separators (flow rate greater than 100 liters per hour) & components
- Cross (tangential) flow filtration equipment
- Steam sterilizable freeze-drying (lyophilization) equipment
- Spray-drying equipment capable of drying toxins or pathogenic microorganisms
- Protective and containment equipment
  - Class III biological safety cabinets
- Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 m<sup>3</sup> or greater
- UAV fogging and aerosolizing equipment
- **If this equipment needs to be returned to a manufacturer overseas, or otherwise exported an export license could be required**

# Technology Controls

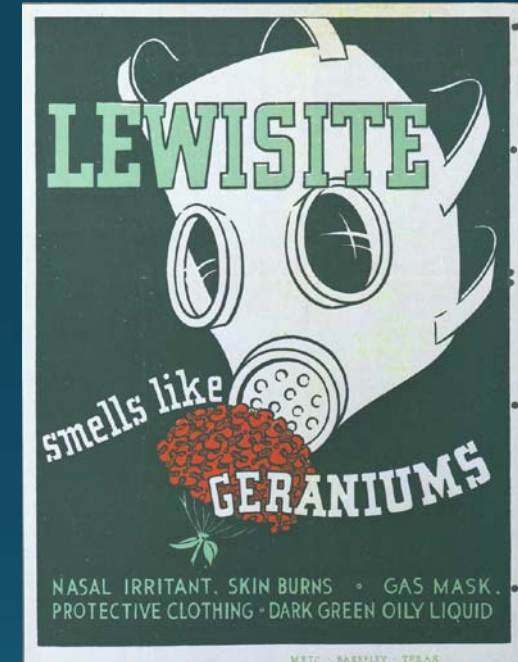
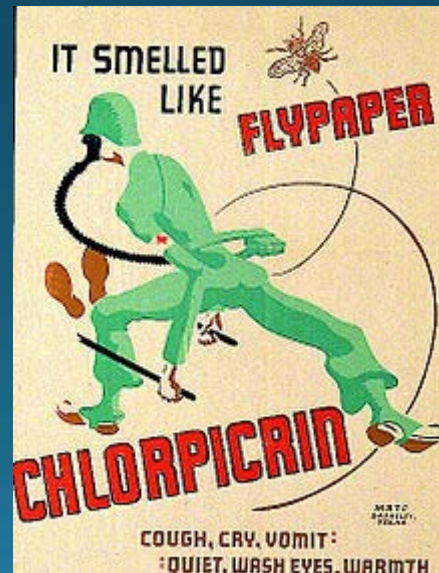
- 1E001: “development” or “production” technology for listed restricted biologicals or chemicals
  - If the technology being shared with the foreign national on how to grow, maintain, quality check a pathogen is in the public domain & the research is going to be published, then this research is not subject to the EAR & no foreign national (deemed) export license is required. International collaborations require further review.
  - Alternatively, if the researcher was working on a sensitive project involving biodefense or some other type of research that would not be allowed to be published or delayed review & involved proprietary or non-standards technology regarding the pathogen (not in the scientific literature), then 1E001 might apply and trigger a foreign national license review requirement.
- 1E351: disposal technology for listed restricted biologicals or chemicals
  - Most biological agents are destroyed through autoclave, chemicals, & other publically available techniques and therefore it is not subject to the EAR.
  - Unpublished or proprietary disposal techniques could trigger foreign national license requirements.

# Technology Controls on Equipment, SW and Use of Equipment

- 2E001, 2E002, 2E201, 2E301: technology for development of equipment and software, production of equipment or use of equipment
  - “Use” -Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing
    - All six elements of use must be met to trigger foreign national license requirements.
  - These would only apply if the researcher was developing export restricted chemical & biological equipment. They would be producing or developing controlled equipment. The same exclusion applies, that if the research will be broadly published, then it would be considered fundamental research & not subject to the EAR.
  - International collaborations and physical exports would require export reviews.

# Chemical Export Controls

- Chemical Weapons Convention
- Precursors
- Chemicals used in production of other export restricted items
- Rather than exporting restricted chemicals, recommend that chemicals be sourced locally in country
- HazMat transportation considerations



# ITAR Classification of Chemical Agents

- Category XIV Toxicological agents, including chemical agents, biological agents, and associated equipment
- Category V - Explosives and Energetic Materials- Propellants- Incendiary Agents and Their Constituents
- No foreign national access to ITAR controlled items without an export license or exception. Certain nationals will never be issued licenses by USG-Chinese, Iranians
- **Recent Examples of ITAR controlled items**
  - USMLXIV(m) Tool to predict the placement of Chemical and/or Biological detectors
  - USMLXIV (f)(5) Chemical agent resistant coatings ("CARC") paint (2013)
  - USMLV(c )(10) Lead 2-Ethyl Hexoate (2014)
  - ([http://www.pmdtdc.state.gov/commodity\\_jurisdiction/determination.html](http://www.pmdtdc.state.gov/commodity_jurisdiction/determination.html) )



# Examples of Restricted Chemicals

- See Export Restricted Chemical List Handout
- 1C350 Chemicals that may be used as precursors for toxic chemical agents (CB2)
  - Sodium fluoride
- 1C395 Mixtures and medical, analytical, diagnostic, and food testing kits not controlled by 1C350
  - Mixtures of controlled chemicals are not restricted when they are normal ingredients in consumer goods packaged for retail sale for personal use.

# Chemical Equipment Controls CB2

- 1C350 Chemicals that may be used as precursors for toxic chemical agents
- 2A226 Valves
- 2A292 Piping, fittings and valves made of, or lined with, stainless steel, copper-nickel alloy or other alloy steel containing 10% or more nickel and/or chromium
- 2B350 Chemical manufacturing facilities and equipment
- 2B351 Listed Toxic gas monitoring systems and their dedicated detecting “parts” and “components” (i.e., detectors, sensor devices, and replaceable sensor cartridges)

# Chemical Software & Technology Controls

- 2D351 Dedicated “software” for toxic gas monitoring systems and their dedicated detecting “parts” and “components” controlled by ECCN 2B351.
- 2E001, 2E002, 2E201, 2E290, 2E301
- Technology for the development, production or use of equipment or software controlled by the ECCNs

# Export License Process

- Discuss with researcher the entire scope of research and how item will be used by collaborator
- An import license may be required by the collaborator
- Prepare license and letter of explanation & submit
- Processing time takes 6-8 weeks for Commerce and longer for ITAR licenses
- License issued with conditions (rules)- need to be reviewed to determine how they impact the research
- Collaborate with HazMat shipping (EHS) and freight forwarder to meet terms of the export license
- File AES export declaration, Ship Item, maintain records for 5 years

# Filing for an Export License

- SNAP-R Access <http://www.bis.doc.gov/snap/index.htm>
- **END USERS:** List all end users. Provide a detailed explanation of the transaction in the Additional Information Section or attach a Letter of explanation
- **END USE:** Provide exact description of the end-use. For example, “for research purposes” is not sufficient. Explain the nature of the research. Provide information about the appropriateness of the item for the end-use.
- **Microorganisms and Toxins (1C351, 1C352, 1C353, 1C354, 1C360, 1C991)**
  - Any alternative names for the organism: For example, Variola virus is the same as smallpox, Lyssa virus is the same as rabies.
  - A summary of current research activities of the institution when the organism is intended for use in research.
  - For individual researchers, place the name of the institution or university where the product is to be delivered in the Ultimate Consignee or end user block. Provide the researcher’s name, date & place of birth, academic background, work experience, summary of research history, and recent publications in the Additional Information section – do not place an individual’s name in the Consignee or End user block.
  - Identify the specific department in which the item will be used, i.e., biology, pathology, radiology, etc. in the End Use block.
  - <http://beta-www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls?id=128>

# University Export Controls

- Departments: biology, chemistry, engineering, medicine, marine biology, pathology, pediatrics, pharmacology
- International Biological or Chemical Shipments
- Equipment Shipments
- Return/Repair
- Material transfer agreements (MTAs)
- Service agreements
- Shipping issues-timing, specimens, live animals/insects, hazmat/dangerous goods

# Fundamental Research & Export Controls

- US Government Funded Research- without publication restrictions
- DURC concerns= self imposed publication restrictions
- Exports of restricted material developed under fundamental research still require export licenses

# Limits of the FRE

Fundamental  
Research does **NOT**  
cover --

**Exports** of Biological  
Material, Chemicals,  
Hardware, Software,  
or Technology

Dealings with  
**Restricted Parties** or  
Entities

Export Restricted  
**Activities** – “defense  
services”

Other Transactions  
Involving **Embargoed**  
or **Sanctioned**  
**Parties/Countries**



# Examples of items not protected under Fundamental Research

- Proprietary research, industrial development, design, production, & product utilization the results of which are restricted & government funded research that specifically restricts the outcome for national security reasons are not considered fundamental research.
  - Example: University based research on bacillus anthracis that has restrictions on publications of scientific & technical information resulting from the research
  - Example: A university has a collaborative research agreement with a private company. The company releases its proprietary technology to the university to conduct the research with the condition that it not be released to the public. The university agrees to a non-disclosure statement as part of the collaborative agreement. The company proprietary information, if subject to the Export Regulations, may require foreign national (deemed) export licensing authorization if released to a foreign national.

# Examples for Universities

- Aerosolized research DITRA, NIH –prophylactics, vaccines, countermeasures
  - Depending on the item, it may be Dual Use Research of Concern (DURC), ITAR or EAR controlled
  - Foreign national access controls
  - International collaboration considerations
  - Publishing considerations
- Netherlands researcher had to obtain export license from the NL government to publish pathogenicity increases to flu

# Security Concerns with Export Restricted Items

- Theft of materials from labs
  - Homeland security concerns
- Economic Espionage- trade secrets theft
- Targeting of researchers
  - at conferences or during foreign travel
  - Social networks

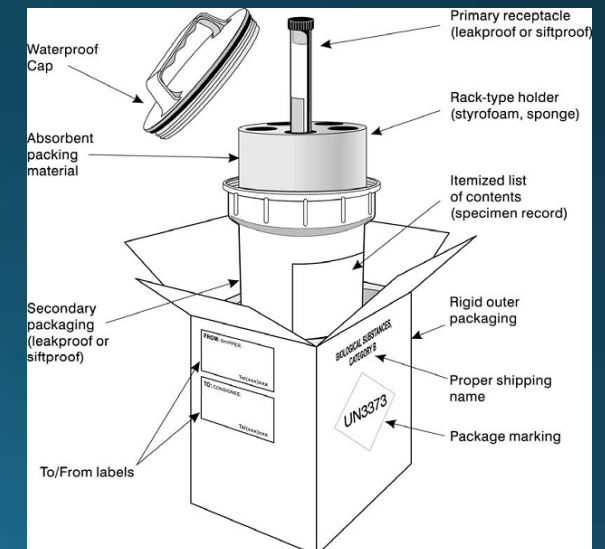
# UCSD Export Controls

# Review Intl Shipping Process

- Decentralized
- Dangerous Goods Shipping was a natural fit for export control reviews
- Reviewed 300 shipments in 2013; 4 required more in depth biological & chemical export licenses reviews
  - Researchers were informed of export review, licensing process & fines
    1. Plasmids with export restricted listed biological but the genetic material was not associated with pathogenicity; no export license required
    2. Beryllium; no export license required
    3. Chemical compound review; no export license required
    4. Biological material required export license; they chose not to ship items and had collaborators source materials in country

# Dangerous Goods or HazMat

- Some export restricted biologicals that are category B may require export licenses
- Work closely with shippers and hazmat team
- Many dangerous goods are also export restricted
  - Red flag for further review



# Assess Export Restricted Biologicals on Campus

- Gather Data-Who, What, Why, Where
- Review Export Restricted List & work with EHS Biosafety for list of items and PIs
- Review those Biological Use Authorizations (BUAs) on BIO <https://ehs.ucop.edu/bio/> to understand how and why the items are being used
  - Activities in increasing pathogenicity could trigger foreign national licensing requirements
  - Will the items be shipped?

# Proactive Outreach to PIs & Lab Mgr

- Email sent indicating they are working with export restricted material & export licenses will be required for intl shipments
- Requested meeting to discuss intl shipping needs
- Import permits are likely required by their collaborators in other countries
- These items are likely dangerous goods and will require appropriate packaging and documentation (DGD)



# Training

- In person briefing on export restricted biologicals as part of Haz Mat Dry Ice and Category B Biological Shipping Training
- Online biological export controls video for UC system
  - On demand
  - will be available to all faculty, staff and students
  - Other videos on export controls will also be available

# Review Considerations

- Life cycle approach
- Inventory existing items
- Authorization (BUA or other)
- Funding (proposals & awards)
- Purchasing & acquisition of restricted materials
- MTA and Tech Transfer license process
- Service agreements/ recharge facilities (non-research)
- Shipment reviews
- Destruction

# Next Steps

- UCSD
  - Tools, SOPs, Policy review & enhancement
- UC System wide Working Groups
  - Export Control
    - Openness in Research and Export Control Policy Working Group
  - International Shipping
  - Hazardous Materials
  - TSCA

# Partners in Export Control



# Questions?

- Brittany Whiting
- UC San Diego Export Control Officer
- 858-534-4175
- [brwhiting@ucsd.edu](mailto:brwhiting@ucsd.edu)
- <http://export.ucsd.edu>

# UC Systemwide Export Control Contact Information

- LBNL: Nancy M Ware [NMWare@lbl.gov](mailto:NMWare@lbl.gov)
- UARC NASA Ames: Scott Fong [scott.fong@uarc.ucsc.edu](mailto:scott.fong@uarc.ucsc.edu)
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# Homeland Security Concerns or Questions

- Contact your local FBI WMD coordinator
- <http://www.fbi.gov/contact-us>
- Homeland Security
  - <http://www.dhs.gov/contact-us>
  - CFATS Chemical Facility Security Tip Line: **877-394-4347** (877-FYI 4 DHS)
  - You may report concerns on voicemail anonymously. If you want a return call, leave your name and number. Calls to this tip line involve the Chemical Facility Anti-Terrorism Standards (CFATS) regulation at your facility or another facility.
  - National Infrastructure Coordination Center: **202-282-9201**
  - If a potential security incident that has already occurred, call this number to report it. Call 911 or contact your [local FBI field office](#) instead if this is a security emergency or terrorist incident.