# Compliance with U.S. Export Controls as a Life Science Researcher

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# Export Controls

- Dual-use items
  - subject to BIS regulatory jurisdiction
  - predominantly commercial/academic uses
  - could also be used in military applications
  - Listed in Export Administration Regulations (EAR) by Export Control Classification Number (ECCN)
  - Commerce Control List (CCL)
- May require export license
- Other Controls - USML, OFAC

# Reasons for Control

- Multilateral controls (international regimes)
  - Australia Group (AG) for chemical and biological items and equipment
  - Wassenaar Arrangement (WA) for certain detection equipment associated with chemical and biological weapons
- Unilateral controls (US only)
  - Implemented independent of regimes to countries of concern

# What Might Need a License?

- Biological agents and genetic elements (1C351-4) (AG list plus Select Agents)
- Vaccines (ECCN 1C991) (unilateral)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use)
  - ECCN 1E001, 2E001, 2E002, 2E301
- Foreign worker in US facility (deemed export)
- Re-exports

# Reexports

- A U.S. item that is shipped from the original end user to another end user
- Reexports may also require a license
- *Reexport of U.S.-origin items* from a foreign country see 732.3(b)

# Key Questions to Determine if License is needed

- What is the ECCN of the item to be exported?
  - EAR99 okay to most destinations
  - Listed on Commerce Control List – might be
    - License required
    - No License Required (NLR)
    - License exception eligible
  - What is the destination country (or countries)
- Who are the recipients and are they reliable
    - Ultimate Consignee
    - End User
- End use – is it reasonable

# License Exceptions

- GOV (Government) EAR 740.11
  - Agencies of Cooperating Governments
  - Country Group A:1 (see Supplement No. 1 to 740) and the national governments of Argentina, Austria, Finland, Hong Kong, Ireland, Korea (Republic of), New Zealand, Singapore, Sweden, Switzerland and Taiwan
- STA (Strategic Trade Authority) EAR 740.20
  - Certain Toxins from ECCN 1C351
- RPL EAR 740.12
  - Identical item
  - Original must be destroyed or returned
- Read regulations carefully before use

# Biological Agents

- 1C351,1C352, and 1C354
  - Human, Animal and Plant Pathogens Australia Group (AG) controlled -
  - Select Agent
  - Select Agent (SA) exempt controlled for export
  - 1C353
    - Genetic Elements for controlled agents/toxins
  - 1C991
    - Vaccines
    - Medical toxins

# EBOLA and HPAI

- EBOLA
  - License required for all Ebola viruses
  - License exception GOV may apply – ask first
  - Emergency licenses may be requested if needed
- HPAI
  - Has to  be a highly pathogenic avian influenza virus as defined in ECCN 1C352a
  - Consider Dual use of Concern and Gain of Function issues

# CCL more than Select Agents

- Check Category 1 of the CCL
- Agents/Toxins with
  - History of attempted use in biowarfare
  - Serious economic/public health potential
  - Australia Group Member consensus
- Sample of AG controlled non Select Agents
  - Yellow Fever virus
  - Chlamydophila psittaci
  - Lyssaviruses

# Genomic Material

- Controlled under 1C353 ***if agent*** on CCL
- What is controlled ?
- Genetic elements  or GMOs that contain
  - nucleic acid sequences associated with the pathogenicity of controlled microorganisms
  - nucleic acid sequences coding for any controlled toxin or toxin sub-unit
  - for a virus, most sequences will be assumed associated with pathogenicity

# Genomic Material – Genetic Elements

- Genetic elements include and not limited to
  - Chromosomes
  - Genomes
  - Plasmids
  - Transposons
  - Vectors
- May be genetically modified or unmodified
- May be synthesized

# Genomic Material

- What is not controlled?
  - Pathogen or toxin not on CCL
  - Gene fragments (must be whole gene with ORF)
  - Chromosome fragments
  - *E. coli* Nucleic acid sequences
    - Unless sequence code for verotoxin

# Biological Processing Equipment

ECCN 2B352 – License required to Non Australia Group Countries

# 2B352 Equipment capable of use in handling biological materials

- Complete P3 or P4 facilities
- Fermenters – Including single use or disposable systems
- Centrifugal Separators
- Cross-flow Filtration Equipment & Components
- Freeze-drying equipment
- Spray drying equipment
- Protective Suits and Class III safety cabinet
- Aerosol Challenge Chambers
- Aircraft Spraying or Fogging Systems

# 2B352.a - Complete containment facilities at P3 or P4 containment level

- Technical Note:  P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual 3rd edition(Geneva, 2004).

# 2B252.b -Fermenters

- Capable of cultivation of pathogenic microorganisms or of live cells for the production of pathogenic viruses or toxins without the propagation of aerosols having a capacity equal to or greater than 20 liters
- Components for such fermenters, as follows:
  - Cultivation chambers designed to be sterilized or disinfected in situ;
  - Cultivation Chamber holding devices; or
  - Process control units capable of simultaneously monitoring and controlling two or more parameters
- Technical Note: Fermenters include bioreactors (including single-use (disposable) bioreactors, chemostats, and continuous-flow systems

# 2B352.c - Centrifugal separators

- Capable of the continuous separation of pathogenic microorganisms without the propagation of aerosols
- Having all of the following characteristics
  - c.1. One or more sealing joints within the steam containment area;
  - c.2. A flow rate greater than 100 liters per hour;
  - c.3. “Parts” or “Components “ of polished stainless steel or titanium; and
  - c.4. Capable of in-situ steam sterilization in a closed state.

- Technical Note: Centrifugal separators include decanters.

# 2B352.d.1- Cross flow filtration equipment

- Capable of separation of pathogenic microorganisms, viruses, toxins or cell cultures without the propagation of aerosols
- Having all of the following characteristics:
  - Total filtration area equal to or greater than 1 square meter (1 $m^2$); *and*
  - Capable of being sterilized or disinfected in-situ *or*
  - Using disposable or single use filtration “parts” or “components”
- Does not control reverse osmosis equipment

# 2B352.d.2 - Cross flow filtration accessories

- “parts or “components” (e.g., Modules, elements, cassettes, cartridges, units or plates)
  - Filtration area equal to or greater than 0.2 square meters (0.2 $m^2$) for each component and
  - Designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

# 2B352.e Freeze-Dryers/Lyophilizers

- Freeze drying equipment that is:
  - Steam sterilizable
  - Condenser capacity of 10 kgs of ice (10 liters of water) or greater in 24 hours, but less than
  - 1,000 kgs of ice (1000 liters of water) in 24 hours

# 2B352.f Spray-drying equipment

- Capable of drying toxins or pathogenic microorganisms having all of the following characteristics:
  - Water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h;
  - Able to generate as is or with minimal modification product mean particle size ≤ 10 μ
  - Capable of being sterilized or disinfected in situ

# 2B352.g - Protective and containment equipment

- Protective full or half suits, or hoods
  - Dependant upon a tethered external air supply
  - Operating under positive pressure
  - Technical Note: Does not control suits designed to be worn with self-contained breathing apparatus.
- Class III biological safety cabinets or isolators with similar performance standards
  - Flexible isolators, dry boxes, anaerobic chambers, glove boxes or laminar flow hoods (closed with vertical flow)

# 2B352.h – Aerosol Challenge Chambers

- Designed for testing with microorganisms, viruses, or toxins AND
  - Capacity of 1 $m^3$ or greater

# 2B352.i – Spraying or Fogging Systems

- Designed for fitting to aircraft , lighter than air vehicles or UAVs, capable of delivering from liquid suspension:
  - Initial droplet “VMD” of <50 microns and
  - Flow rate >2 liters/min
- Spray booms, arrays or aerosol generating units
- Technical Note: Does not control spraying or fogging systems and components that are not capable or delivering Biological Agents in the form of infectious aerosols

# Not Controlled

- Electrophoresis apparatus
- Protein Sequencing apparatus
- Peptide synthesis apparatus
- DNA sequencing apparatus
- Oligonucleotide synthesis apparatus
- Consumer or Medical protective gear
  - latex gloves,  surgical masks, etc

# Technology for controlled items

- “Technology” takes the form of “technical data” or “technical assistance”.
  - Tangible or intangible
  - Deemed Exports
- Types of Technology controlled:
  - “Production“, “Development”, “Use”
  - Specific definitions found in Part 772

# Technology for biological items

- “Development” is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts.

# Technology for biological items

- “Production” means all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance.

# Technology for controlled items

- “Use” includes all of the following
- Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing
- Definition of “Use” differs for 600 series items

# Technology NOT Subject to the EAR (734.3)

- “Publicly Available Technology and Software
- Already published or will be published (734.7)
- Arise during fundamental research (734.8)
- Educational (734.9)
- Included in certain patent applications (734.10)

# Fundamental Research §734.8 §734.11

- “Fundamental research” is basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community.
- “Fundamental research” does not include government sponsored or proprietary research the results of which ordinarily are restricted for proprietary reasons or specific national security reasons as defined in §734.11(b)

# Deemed Exports

- Export of controlled technology or source code
  - To a foreign national
    - Except for green card holders, permanent residents, or protected persons
  - Inside the United States
  - See EAR 734.2(b)(3)
  - http://www.bis.doc.gov/index.php/policy-guidance/deemed-exports

# Help with Classifications

- Commodity Classification request (Part 748.3 of the EAR)
- Provides ECCN
- SNAP-R is electronic online system
- Commodity Jurisdiction Determinations
  - USML vs EAR

# Contact Info

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