

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, 1C360) (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

Key Questions to Determine if License is needed

- What is the ECCN?
 - EAR99
 - NLR
- What is the destination country (or countries)
- Who are the recipients
 - Ultimate Consignee
 - End User
- End use

Biological Agents

- 1C351,1C352,1C354 and 1C360
 - Human, Animal and Plant Pathogens Australia Group (AG) controlled -
 - Select Agent exempt strains & amounts controlled
- 1C353
 - Genetic Elements for controlled agents/toxins
- 1C991
 - Vaccines
 - Medical toxins

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
 - Member consensus
- Sample of AG non Select Agents
 - Yellow Fever virus
 - Chlamydophila psittaci
 - Rabies

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

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

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
- Protective Suits and Class III safety cabinet
- Aerosol Challenge Chambers
- Aircraft Spraying or Fogging Systems

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.

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)

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

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