Biologicals and Export Controls

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Department of Commerce
Export Controls

• Dual-use biological material
  • 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
  • Based on multilateral regimes (Australia Group)
  • Unilateral (Select Agents not on the AG list, vaccines)

• Other Controls to consider – USML (CAT XIV), OFAC
Department of Commerce
Export Controls

• Part 732 of the EAR – Steps for using the EAR
  • What is the item
  • Where is it going (what country)
  • Who will use it (ultimate consignee, end users)
  • What will they do with it (end use)
  • What else do the recipients do (red flags)

• Supplements 1 -3 of Part 732 of the EAR
  • Decision Tree for need for export license
  • Decision Tree for subject to the EAR
  • Know your Customer Guidance
Export Checklist

• Is it under Commerce Control?
  • Commodity Jurisdiction if unsure (DDTC - STATE)
• What is the ECCN of the item to be exported?
  • Commodity Classification if unsure (DOC)
  • EAR99 usually No License Required (NLR)
• Specific ECCN – may result in
  • License required
  • No License Required
  • License exception eligible
What May Require a License?

- Biological agents and genetic elements (1C351, 1C353, 1C354) (Australia Group list plus Select Agents) (worldwide)
- Vaccines (ECCN 1C991) (limited destinations)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use)
  - ECCN 1E001, 2E001, 2E002, 2E301
- Foreign worker in US facility (deemed export)
- Re-exports
Technology Considerations

- Is the technology for controlled biological processing equipment?
  - “Development”
  - “Production”
  - “Use”
- Is the technology related to manipulation of controlled biologicals that is not public domain or fundamental research?
- Where is the transfer taking place?
  - Deemed export vs. tech transfer
Relevant 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 Hong Kong, Singapore, and Taiwan

• **STA (Strategic Trade Authority) EAR 740.20**
  - Certain Toxins from ECCN 1C351
  - Has reporting requirements
  - Less than 100 mg, six or fewer shipments per CY

• Read regulations carefully before use
Biological Agents and Toxins

- **1C351 and 1C354**
  - Human, Animal and Plant Pathogens Australia Group (AG) controlled
  - Select Agents not on the AG list
  - Select Agent (SA) exempt strains ARE controlled for export

- **1C353**
  - Genetic Elements for controlled agents/toxins

- **1C991**
  - Vaccines
  - Medical toxins
Genomic Material

Genetic elements include and not limited to
  Chromosomes
  Genomes
  Plasmids
  Transposons
  Vectors
May be genetically modified or unmodified
May be synthesized
Current Control Language for Genetic Elements and Genetically-Modified Organisms:

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list.
- Genetic elements that contain nucleic acid sequences coding for any of the toxins in the list, or for their sub-units.
- Genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list.
- Genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units.
Technical note:

Nucleic acid sequences associated with the pathogenicity of any of the micro-organisms in the list means any sequence specific to the relevant listed micro-organism:

• that in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; or;

• that is known to enhance the ability of a listed micro-organism, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.
Genetic Elements

• Whole Nucleic acids – not controlled if
  • Certified non-infective and chemically treated to be non-recoverable

• Chimeric Viruses- controlled if
  • Based on a controlled virus
  • Has controlled virus element in non-controlled virus

• Plasmids - controlled if
  • Promoter present
  • Complete gene or Viral Particle
  • Replication competent
Example: Chimeric Viruses

Genetically modified Vesicular stomatitis virus (controlled as genetically modified VSV)

If the ebolavirus GP were incorporated into a non-controlled virus, this would be still controlled as a genetic element.
Example: Plasmids

Expression plasmid + promoter – Controlled

Expression plasmid – Not Controlled

pXX-hpai-HA

HA from High-path Influenza

HA + promoter = complete gene (viral particle replication competent)

HA from High-path Influenza

Without the promoter, the element is not replication competent

Export Controls
License Application Review

SNAP-R → CB Workflow Manager

Licensing Officer Review
- Item/Technology (ECCN)
- Reason(s) for Control
- Destination (Country Chart)
- Transaction Parties
- Available License Exceptions
- End use
- Documentation

Referral →
- Dept. of State
- Dept. of Energy
- Dept. of Defense

Recommendation

Return without Action (RWA) at any point

Validated License (or denial)

Export Controls
Guide to Success

• Don’t forget Select Agent exempt material may need license (List specific strain, serotype, BSL, and quantity)
• ECCNS (1C351,1C353,1C354) agents/toxins need license worldwide including Canada
• Recipient laboratory is ultimate consignee/end user
• Provide info on researcher, end use and biosafety level capability in additional information
• Provide shipment amounts in mg, ml, etc. and cost (≥$1)
• Highlight any DURC or GOF activity
• Vaccine seed stock is not considered vaccine
• If technology transfer
  • List all ECCNS
  • Clarify deemed versus regular export
  • Cost ≥$1
Technology for Dual Use

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

“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
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  - “Use”

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- Consider Fundamental Research, Public Domain

Export Controls
Technology NOT Subject to the EAR

- Publicly Available Technology and Software
- Already published or will be published (734.7)
- Arise during fundamental research (734.8)
- Included in certain patent applications (734.10)
- Review 734 for recent changes September 2016

Export Controls
Fundamental Research (EAR 734.8)

University based research
Research based at federal agencies
Corporate Research

“Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons “
Deemed Export (734.13)

Export or Re-Export of Technology or Software release in the U.S. of technology or software to a foreign national

Release

“Release” of technology or source code, subject to the EAR to foreign persons in the U.S., or in a third country, through:

- Visual inspection of U.S. origin equipment and facilities
- Oral exchanges of information in the U.S. or abroad
- Application of personal knowledge or technical experience acquired in the U.S. to situations that will benefit

Export Controls
Deemed Key Points

- Two Triggers must be met
- Technology must require a license
  - Rule in/out fundamental research and public domain
  - First identify the ECCN of the technology
  - See where a license would be required
  - If license is needed evaluate foreign national background
- Foreign National background
  - No license needed
    - Green card, protected person
    - Export to home country would not require a license
- Apply for a deemed export license when
  - Technology license needed to FN home country

Export Controls
Scenarios

• Researcher working with Suid Herpesvirus 1 (Pseudorabies)
• Is this a Select Agent? No
• CCL listed pathogen? Yes (Australia Group)
• Export License for virus shipment required? Yes (all countries)
• Deemed export? Only if FN is learning controlled technology
Scenarios

- Researcher working with Rift Valley Fever Virus
- Is this a Select Agent? Yes
- CCL listed pathogen? Yes

- Exports strain to colleague in Kenya for use in vaccine production ?? License Required

- Foreign student in lab on different project
  - not working with pathogens ??? No
  - working with pathogen?? Maybe

- Research generates an attenuated strain
- no approval or IND # so License required for export
Scenarios

• Research generates an attenuated strain of RVFV
  • no approval or IND # yet
  • Still ECCN 1C351 and export license required

• FN growing virus using published methods
  • Public domain tech, no deemed export

• FN Research shifts to novel methods of growing virus
  • Deemed export license and/or
  • Commodity Classification to rule on fundamental research exception
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https://www.export.gov/welcome
Website Shortcuts

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Select from the list below:
Speak to an Export Counselor

Export Control Reform
Export Control Reform -- Upcoming Weekly Teleconferences and Webinars

Consolidated Screening List
The following list may be relevant to your export or reexport transaction.

Exporter Portal
Everything you need to know about exporting

In The News
BIS Newsroom

Report Violations
Reporting Possible Violations

Export Controls