

BIS Licensing for Biological Commodities and Technologies



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Important Disclaimer

This presentation is intended for discussion purposes only and does NOT constitute official U.S. Government regulatory guidance.

This is a snapshot of current export control regulations and activities as of May 2, 2023 and does not necessarily represent the actual export licensing requirements for your specific situation.

It is the exporter's responsibility to be familiar with all aspects of and the most recent changes to the Export Administration Regulations.

www.ecfr.gov



Outline

- Fundamentals of U.S. export controls
- Controlled biological commodities
- Controlled biological technologies
- Some examples and Q&A
- General guidance





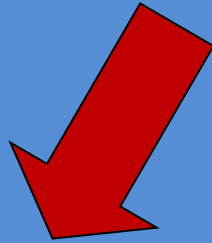
U.S. Export Controls

- Department of State: Munitions
- Nuclear Regulatory Commission: Trigger list
- Department of Energy: Technology for special nuclear material
- Department of the Treasury: Financial transactions and special sanctions
- Department of Commerce: Dual-use, small-caliber firearms (and ammunition), and “600” series military items



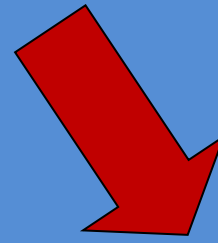
U.S. Export Controls

Why do we control exports?



Internal Considerations

National Security Concerns
Foreign Policy Initiatives
Economic Concerns



External Considerations

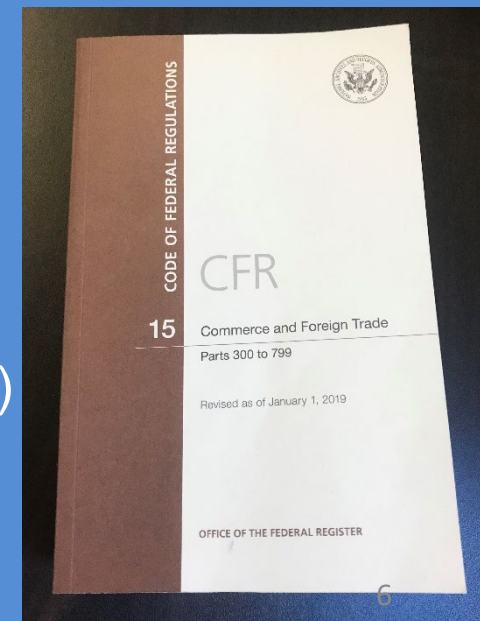
Wassenaar Arrangement
Missile Technology Control Regime
Nuclear Suppliers Group
Australia Group



Bureau of Industry and Security
U.S. Department of Commerce

Department of Commerce Export Controls

- Dual-use commodities and technologies
 - BIS jurisdiction
 - Predominantly commercial or academic application
 - Potential use in nuclear, biological, or chemical weapons (WMD).
- Authorized by The Export Control Reform Act of 2018 (ECRA)
- Codified in the Export Administration Regulations (EAR)
 - List-based controls – Commerce Control List (CCL)
 - Catch-all controls – End User/End Use based





What is Subject to the EAR?

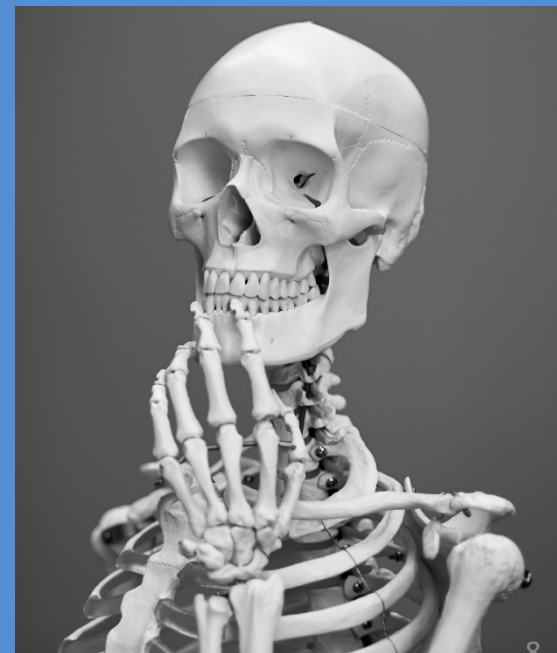
Everything in the United States except...

- Commodities and technology under other agencies' jurisdiction
- "Publicly Available" technology and software
- Information already published or will be published (734.7)
- Technology that arises from fundamental research (734.8)
- Information included in patent applications (734.10)



Fundamental Research and Publication

- Fundamental Research
 - “research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the scientific community, and for which the researchers have not accepted restrictions for proprietary or national security reasons”
 - Unpublished/proprietary technology used in conducting fundamental research IS subject to the EAR.
 - Technical data and software resulting from fundamental research IS NOT subject to the EAR.





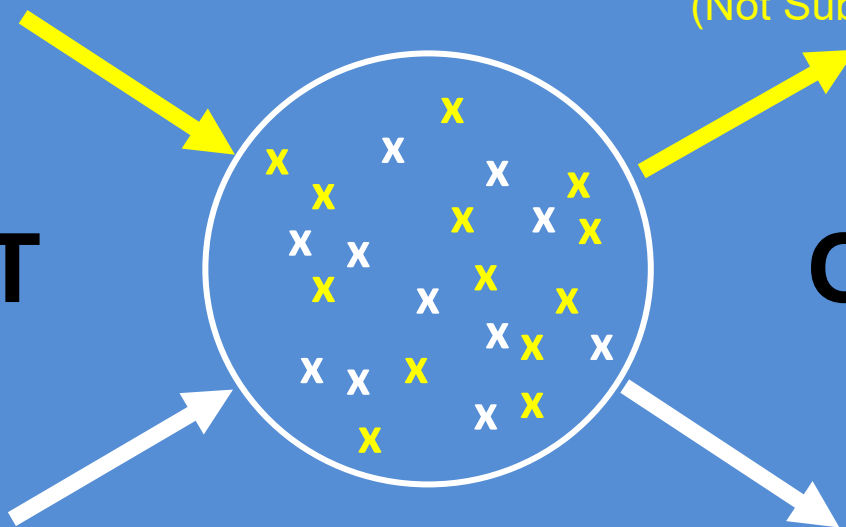
Fundamental Research and Publication

Publicly available technologies
(Not Subject to the EAR)

**Results of research published: (e.g.,
Fundamental Research)**
(Not Subject to the EAR)

INPUT

OUTPUT



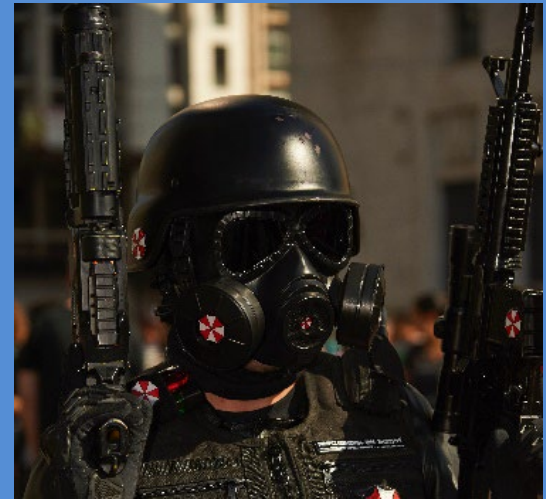
**Preexisting Export Controlled
Technologies**
(Subject to the EAR)

**Results of research withheld from
publication or specific publication
restrictions**
(Subject to the EAR)



The Commerce Control List

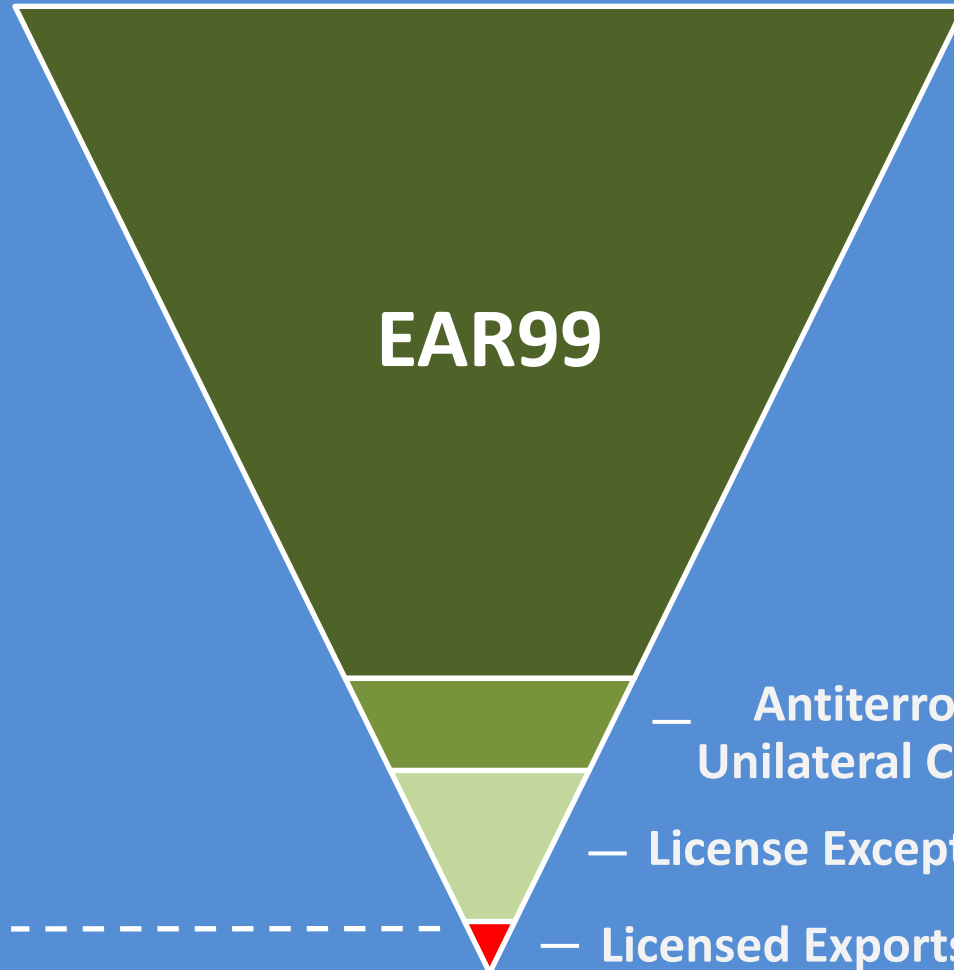
- Chemical and Biological Weapons
 - Australia Group
 - Chemical Weapons Convention
 - Biological Weapons Convention
- Missiles - Missile Technology Control Regime
- Conventional Arms
 - Wassenaar Arrangement
- Nuclear
 - Nuclear Suppliers Group
 - Nuclear Nonproliferation Treaty





Licensing Pyramid

>99% of exports
do not require
a BIS license



EAR99

— Antiterrorism
Unilateral Controls

— License Exceptions

— Licensed Exports



Export Authorizations

- No License Required
 - Not Subject to the EAR
 - EAR99 (mostly)
 - Licensing policy to destination country
- License Exception
 - Limited for biological items
 - Record-keeping and reporting requirements
- Individually Validated License



What Might Require an Export License?

- Biological agents and genetic elements
 - ECCNs 1C351, 1C353, and 1C354
 - CB1 (worldwide license requirement)
 - Live agents and toxins are eligible for license exception GOV to certain destinations and end users
 - Some toxins are eligible for license exception STA
- Vaccines, immunotoxins, medical products, diagnostic and food testing kits
 - ECCN 1C991
 - CB3 and AT control (license required for limited countries of concern)



CCL is More than Select Agents

- Check Category 1 of the CCL
- Agents/Toxins with
 - History of attempted use in biowarfare
 - Serious economic, public health, or food security risks
 - Australia Group Member consensus
- Examples of non-Select Agents controlled on the CCL
 - Yellow Fever virus
 - Chlamydophila psittaci
 - Lyssaviruses
 - Vesicular stomatitis virus
- Select Agent *Bacillus cereus* biovar anthracis not controlled on the CCL



Genetic Elements and Genetically Modified Organisms

- Any genetically-modified organism which contains, or genetic element that codes for:
 - any gene or genes specific to any listed virus; or
 - any gene or genes specific to any listed bacterium or fungus, and which
 - in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health, or
 - could endow or enhance pathogenicity; or
 - any listed toxins or their sub-units.
- Controlled under 1C353 *if agent* is on CCL





What Might Require an Export License?

- Equipment capable of use in handling biological materials – ECCN 2B352
 - Complete P3 or P4 facilities and components
 - Fermenters and components (includes single use and disposable systems)
 - Centrifugal separators
 - Cross-flow filtration equipment and components
 - Freeze-drying equipment
 - Spray drying equipment
 - Protective suits and Class III safety cabinets
 - Aerosol challenge chambers
 - Aircraft spraying or fogging systems
 - Automated nucleic acid synthesizers (and software)





What Might Require an Export License?

- Technology associated with “development” or “production” of biological agents or genetic elements
 - ECCN 1E001
 - CB1 (worldwide license requirement)
- Technology associated with “development”, “production”, or “use” of biological equipment
 - ECCNs 2E001, 2E002, and 2E301
 - CB2 (all but AG members)
- Foreign nationals in US facility (deemed export)
- Re-exports (as well as deemed re-exports)
- Available license exceptions: GOV, STA, TSU, RPL



“Catch-All” Licensing

- Listed End User
 - Entity List
 - Specially Designated National List
 - Unverified List
 - Denied Persons List
- Prohibited End User Activities
 - Weapons of Mass Destruction programs
 - Supports the Military of certain countries
 - Belarus
 - Burma
 - Cambodia
 - China
 - Russia
 - Venezuela



“Catch-All” Licensing

- Sanctioned Destinations
 - Democratic People’s Republic of Korea
 - Cuba
 - Syria
 - Iran
 - Russia
 - Belarus
 - Crimea



BIS Licensing and Classifications

- Commodity classification request
 - Commodity Classification Automated Tracking System (CCATS)
 - Determines Export Control Classification Number (ECCN)
 - Electronic submission through SNAP-R
 - Formal BIS classification of items/technologies
 - Must provide technical specifications
- Export and reexport license applications
 - Electronic submission through SNAP-R
 - Must identify transaction parties, item(s), and end use
 - Reviewed by multiple USG Departments/Agencies
 - Official authorization for export



1C991 Vaccine Controls

- 1C353 - “License Requirements Notes: 1. Vaccines that contain genetic elements or genetically modified organisms identified in this ECCN are controlled by ECCN 1C991.”
- 1C991 - “Vaccines against items controlled by ECCN 1C351, 1C353 or 1C354.”
- BIS draft rule to include vaccines that “contain” controlled agents and genetic elements in 1C991.



Current COVID Vaccines

- Merck rVSV-SARS-CoV-2 – vesicular stomatitis/SARS-CoV-2 chimera (1C353/1C991)
- Merck V591 – measles/SARS-CoV-2 chimera (EAR99)
- Astra Zeneca AZD1222 – Adenovirus/SARS-CoV-2 chimera (EAR99)
- Johnson and Johnson (Janssen) JNJ-78436735 – Adenovirus/SARS-CoV-2 chimera (EAR99)
- Sputnik V – Adenovirus chimera/SARS-CoV-2 (EAR99)
- Moderna mRNA-1273 – spike protein RNA in lipid nanoparticle (EAR99)
- Pfizer mRNA BNT162b2 – spike protein RNA in lipid nanoparticle (EAR99)
- Novavax NVX-CoV2373 – spike protein in saponin-lipid nanoparticle (EAR99)
- Sanofi GSK – Spike protein antigen from Baculovirus/SARS-CoV-2 expression system (EAR99)



EXAMPLES

Genetically Modified Organisms



Chimeric viruses

Ebolavirus (1C351)



Genetically modified Vesicular Stomatitis Virus
(1C353 until formulated as deliverable vaccine, then 1C991)



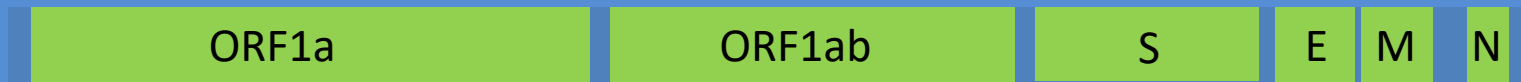
EXAMPLES

Genetically Modified Organisms



Chimeric viruses

SARS-CoV-2 (EAR99)



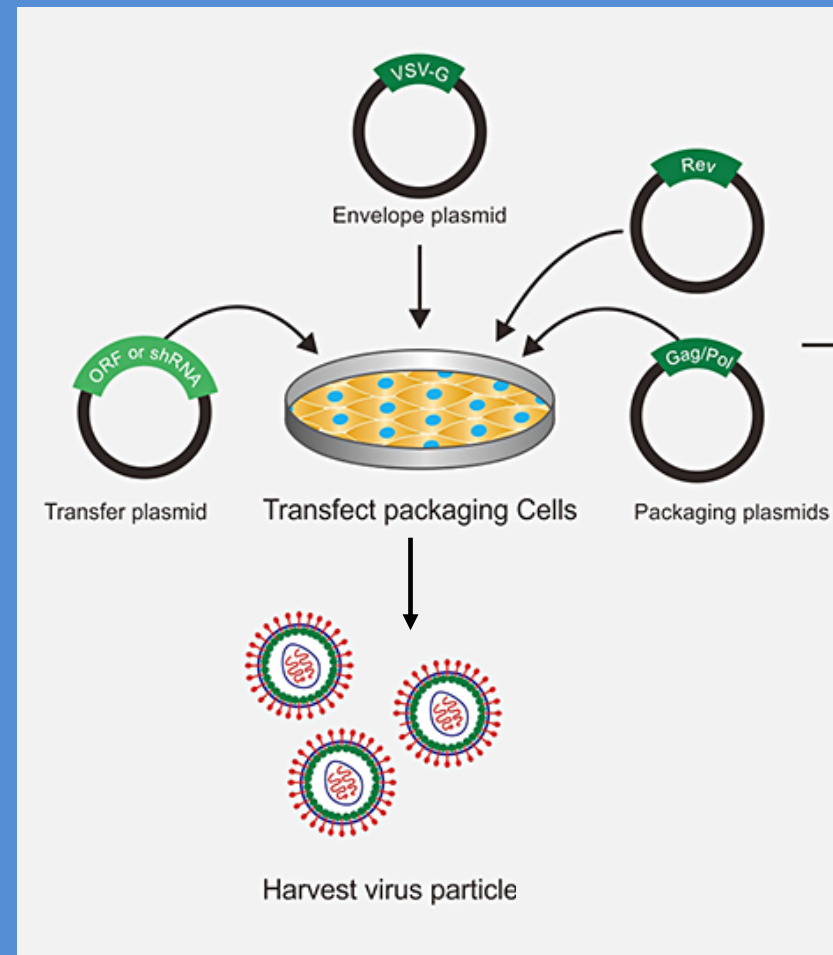
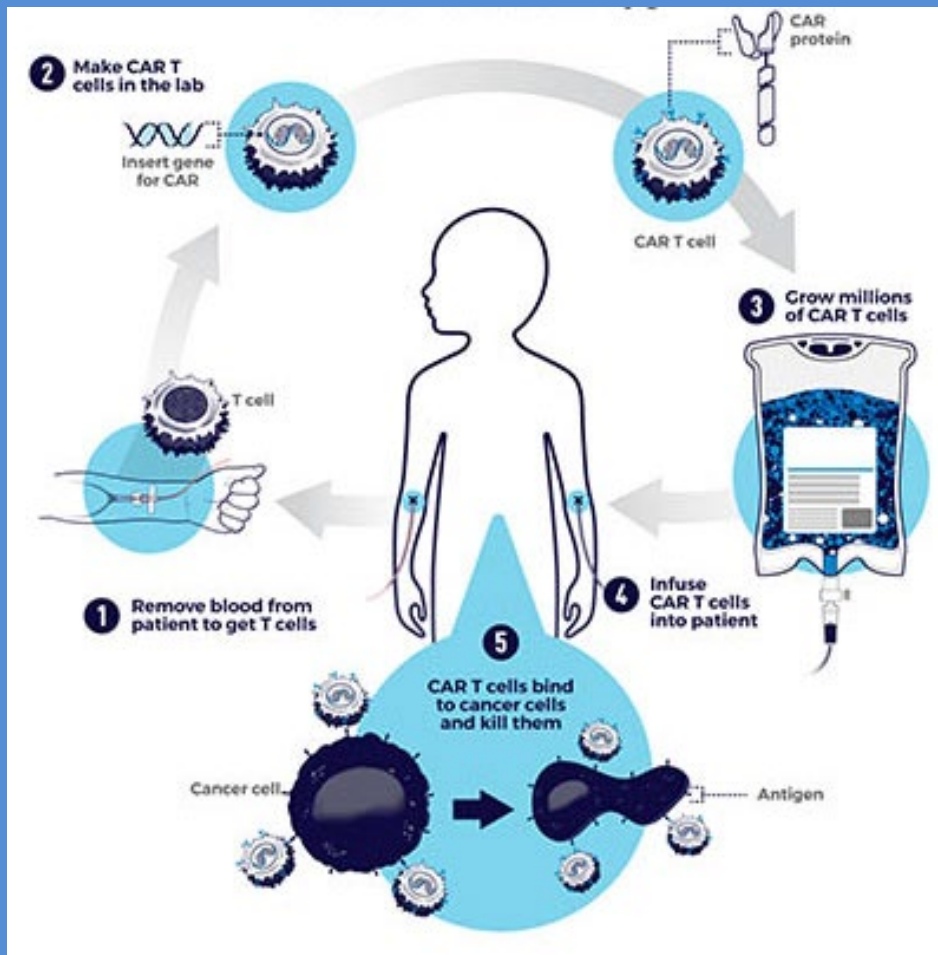
Genetically modified Vesicular Stomatitis Virus
(1C353 until formulated as vaccine, then 1C991)



EXAMPLES

Genetically Modified Organisms

Chimeric Antigen Receptor T-cell Therapy (CAR-T)





Bureau of Industry and Security
U.S. Department of Commerce

EAR Questions

Q. If an agent is on the Commerce Control List (CCL) and is on the Select Agent and Toxin Exclusion list, is a license for export required?

A. Yes – a license for export is required for any item on the CCL with ECCN 1C351, 1C353, or 1C354 to any destination.



EAR Questions

Q. What if we are sending a biological agent that produces a CCL listed toxin (ECCN 1C351.d) ?

A. Unless the biological agent is on the CCL no license is required

- Staphylococcus aureus - no license required
- Clostridium botulinum - license required



EAR Questions

Q. Do I need an export license if I have a foreign student working with a CCL pathogen?

A. Probably not unless being provided access to:

- Production techniques not in the public domain
- Proprietary “production”, “development”, or “use” technology of controlled biological equipment or pathogens



General Guidance for Export Compliance

- Consider biosafety and biosecurity before beginning projects
- Plan well ahead
- Are my technologies or materials controlled for export?
 - What are the ECCNs?
 - Are foreign nationals working in the lab?
 - What are licensing policies for sharing materials and technology with foreign collaborators?
- When in doubt...
 - CCATS
 - Advisory opinions
 - Call or email BIS



Contact Information and Guidance

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