

BIOLOGICALS & EXPORT CONTROLS

WHAT YOU NEED TO KNOW

US export controls for biological materials is more relevant than many university researchers assume. For example, export controls apply to biological shipments to *all* countries and for *all* purposes, including purely academic collaboration and medical treatment development, and they cover more pathogens than those "Select Agents" regulated by the CDC or US Department of Agriculture. Further, export controls can apply to non-attenuated materials or those that are not themselves pathogenic and may not seem sensitive or dangerous, and they can even come into play with certain biological that are widely available and used globally.

International Traffic in Arms Regulations (ITAR): Generally, the ITAR applies only if you are attempting to weaponize a pathogen or toxin; this also applies to any equipment used with such materials. Further, foreign nationals may not purchase, use, or access ITAR-controlled biological or chemical agents/substances without first obtaining a license or license exemption.

Export Administration Regulations (EAR): The scope of the EAR, on the other hand, is broader and includes dual-use materials (having both commercial and military applications). These materials – and their related technology and equipment – may be export-controlled and may require a license or license exception/exemption prior to exporting.

WHAT TO ASK:

- Are you sharing, transmitting, transferring or exporting biologicals or travelling abroad with biological materials?
- Is the biological material being shared, transmitted, transferred or exported a restricted agent?
- Is the biological restricted from publication or proprietary in nature?
- Have you coordinated with the Center for Technology Transfer & Commercialization and requested a Material Transfer Agreement, if appropriate?
- Have you coordinated with VU Environmental Health and Safety for any biosafety concerns or issues?

***IMPORTED BIOLOGICALS:** All *imports* of biological materials are handled by VU's official import broker, V. Alexander, who will assist with any and all requirements (permits, licensing, shipment filings, etc.) pertaining to the actual import.

DO YOU HANDLE CONTROLLED ITEMS?

Biological Agents & Toxins:

- Human, Animal and Plant Pathogens
- Genetic elements for controlled agents/toxins
- Genetically modified controlled organisms
- Vaccines if licensed or Investigational New Drug
- Medical toxins
- Killed pathogens with destroyed genetic elements
- Technology for vaccine production

Genetic Elements:

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

DNA – NOT controlled if:

- Certified non-infective and chemically treated to be non-recoverable

Biological Processing Equipment:

- Fermenters and components
- Centrifugal separators
- Cross Flow Filtration equipment and components
- Sterilizable freeze drying equipment
- Spray Drying equipment
- Protective and Containment equipment
- Aerosol inhalation equipment
- Spraying or Fogging systems and components
- Nucleic Acid Assemblers and synthesizers (and software)

Please contact Vanderbilt Export Compliance (VEC) for support with all export control matters.