

Requirements for International Shipments of Regulated Research Materials

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Many laboratory workers think it is easy to send a sample overseas. They just put the vial in an express mail envelope and call the courier. It often works.

Environmental health and safety professionals know that shipping research materials *legally* is not that easy. U.S. Department of Transportation (DOT) and/or International Air Traffic (IATA) regulations apply to most shipped research equipment, medical supplies, or any quantity of chemical, biological or radioactive material. Those regulations specify classification, packaging, labeling, marking and documentation, with different requirements for every shipment.

Many international shipments are even more difficult. As shown in the accompanying table, laws that regulate shipping and receiving research materials go beyond DOT and IATA. Laboratory staff who ship chemicals internationally should know that a Toxic Substances Control Act (TSCA) Export Notification Form is required for chemicals listed on the U.S. Environmental Protection Agency's (EPA) Chemicals on the Reporting Rule Database. Laboratory staff who receive human etiological agents and genetic elements must comply with import and transfer requirements of the U.S. Centers for Disease Control and Prevention (CDC). The U.S. Animal and Plant Health Inspection Service (APHIS) regulates shipments when importing and exporting plants, animals, animal products and biologics. When institutions and firms

collaborate, they often sign a Material Transfer Agreement (MTA) that further limit shipments of proprietary and other research materials.

The easy (but frustrating!) way to learn about these additional shipping requirements is when your express courier asks for additional documentation, such as a Commercial Invoice, or returns your shipment for repackaging or relabeling. Or Customs may halt your outgoing shipment at the border and ask that you provide a Shippers Export Declaration.

Civil and criminal charges are the hard way to learn about these requirements. In September 2004 a University of Delaware microbiology professor pleaded guilty to smuggling a poultry virus into the U.S. He was helping a colleague identify a disease afflicting the chickens of a large poultry producer in Saudi Arabia. The professor served six months of home detention, is on probation for two years, and paid a substantial fine.

For all of these laws, penalties for improper shipments are increasingly likely. Mail, shipments and luggage are being screened for these materials for the purposes of protecting air travel, public health and our nation's safety. Packages to or from research institutions receive additional scrutiny, as well as any package that appears to contain bottles or liquids.

There is a new emphasis on export control laws. The Treasury Department's Office of Foreign Assets Control (OFAC) enforces prohibited travel and asset transfers with countries subject to U.S. boycotts, trade sanctions and embargoes. The State Department regulates the export of inherently military technologies in accordance with the International Traffic in Arms Regulations (ITAR).

The U.S. Department of Commerce's Export Administration Regulations (EAR) have a wider impact on research and development. EAR regulates the export of so-called "dual-use" technologies, listed in the lengthy and detailed Commerce Control List (CCL). Dual-use technologies and commodities have civil, commercial and peaceful purposes, but are listed on the CCL because of their strategic value or potential for military use or terrorism. Many CCL items are not hazardous, valuable or uncommon. On the contrary, the CCL contains many technologies and commodities commonly found in laboratories, some of which are listed below. Depending on the country of destination, controlled technologies and commodities regulated under ITAR and DOC require a license prior to shipment. Enforcement is increasing in this area as well. In May 2005 the Department of Commerce fined a California biotechnology firm \$904,500 for shipping 65 vials of a toxin to Canada without a license.

Laboratory staff also need to know that they may be held responsible for the proper packaging, licensing and documentation of incoming international shipments, so they should inform international collaborators of these requirements. They should never transport samples or other regulated equipment or material in their pocket, carryon or personal luggage on a commercial airline.

While sending vials and other regulated materials overseas without complying with these requirements may have worked in the past, it is an unwise gamble today. These laws can be confusing and complicated, but the time and effort to comply with them is simply a new necessity. And you don't want to learn that the hard way.

EXAMPLES OF REGULATED ACTIVITIES

- Shipments and mailings using the U.S. Post Office, UPS and express mail couriers, such as DHL or FedEx.
- Receiving regulated materials by any method of transport.
- Shipments to (exporting) or from (importing) a foreign country.
- Transporting any amount of regulated material in a commercial aircraft, either on your person, in carry on luggage or checked luggage.

EXAMPLES OF REGULATED MATERIALS AND TECHNOLOGIES

The following are examples of regulated materials, commodities and technologies. For each example, the regulations specify the types and characteristic of materials and technologies that are regulated, and often note exceptions.

Materials/Commodities

Aluminum alloys

Ammonium nitrate, including fertilizers

Animals

Beryllium metal

Laboratory chemicals

Newly synthesized chemicals or materials

Diagnostic kits

Diagnostic material (defines as human or animal material including, but not limited to excreta, blood and its components, tissue and tissue fluids, and body parts transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.)

Earthworms

ELISA assays

Etiological agents

Food testing kits

Insects

Ultra pure magnesium

Animal, human and zoonotic pathogens and their genetic elements

Phosgene

Plants

Samples

Soil

Specimens

Titanium alloys

Toxins

Vaccines

Technologies

Centrifuges

Computer encryption software

High performance computing capability

25 February 2006

Requiements for Shipping Regulated Research Materials

Fermentors

GPS (Global Positioning System) technologies

Oscilloscopes

Equipment that incorporates any controlled technology