

INFORMATION SHEET: SOME U.S. LAWS GOVERNING BIOLOGICAL AGENTS/TOXINS

World events on and after September 11th have heightened the public, regulatory and legislative interest in laboratory security at academic research institutions and research-oriented businesses. This Information Sheet highlights certain U.S. laws which have been enacted or are being more actively enforced in response to the recent events.

1. The **USA Patriot Act** <http://news.findlaw.com/cnn/docs/terrorism/hr3162.pdf> prohibits “restricted persons” from “shipping or transporting [transferring],” “possessing in or affecting commerce” with, or “receiving” select agents listed and not exempted under the 1996 Anti-Terrorism and Effective Death Penalty Act’s regulations (see par. 2 below). The obligation to comply falls on the individual, and criminal penalties for violating the prohibition also apply to the individual.

“Restricted person” is a person who--

- (I) is under indictment for, OR has been convicted of, a crime punishable by imprisonment for over one year (e.g., felonies); or
- (II) is a fugitive from justice; or
- (III) is an unlawful user of any controlled substance (e.g., an illegal drug or a drug used illegally); or
- (IV) is an illegal alien in the U.S.; or
- (V) has been “adjudicated a mental defective” or has been “committed to any mental institution”; or
- (VI) is an alien (even a legal alien, but not including a lawful permanent resident of the U.S.) who is a national of Cuba, Iran, North Korea, Iraq, Libya, Sudan or Syria; or
- (VII) has been dishonorably discharged from the U.S. armed services.

Under current law, “restricted persons” may continue to work in laboratories and other facilities (e.g., shipping and receiving facilities) that have listed and non-exempt select agents. However, “restricted persons” must not work with, handle, or do anything (even paperwork) relating to “possessing, receiving, shipping or transporting/transferring” such agents. **Principal Investigators whose laboratories have any such agents are advised to provide this Information Sheet and the attached Questionnaire to all individuals in or supporting their laboratories. In order to avoid unintentionally violating the USA Patriot Act, Principal Investigators and all such individuals are encouraged to determine for themselves whether they are “restricted persons” and are adhering to the prohibitions in the Patriot Act.**

2. The **1996 Anti-Terrorism and Effective Death Penalty Act** (the “1996 Act”) [\[http://usinfo.state.gov/usa/infousa/laws/majorlaw/s735_enr.htm\]](http://usinfo.state.gov/usa/infousa/laws/majorlaw/s735_enr.htm) and its regulations [\[http://web.lexis-nexis.com/universe/document?_m=9c2f888ad364b533888040683bfd6446&_docnum=24&wchp=dGLSIV-ISIAI&_md5=7a5dfaa13904e5c7a9f39504b22fe967\]](http://web.lexis-nexis.com/universe/document?_m=9c2f888ad364b533888040683bfd6446&_docnum=24&wchp=dGLSIV-ISIAI&_md5=7a5dfaa13904e5c7a9f39504b22fe967) require institutions to register with the CDC prior to “receiving or transferring” any “select agents,” which are listed in **Appendix A** section 72.6 http://web.lexis-nexis.com/universe/document?_m=ad379a6889d3504f4e7b29d1c31a7a56&_docnum=26&wchp=dGLSIV-ISIAI&_md5=c6b1dbfbcdd1c0b41bc90e6d1e062c3f to the regulations and are not covered by any of the regulatory exemptions in section 72.6(h). Criminal sanctions apply to certain violations of the 1996 Act. The registration process includes providing evidence that the facility to receive the agents is equipped and capable of handling the agents. Transfers of listed non-exempt select agents from one laboratory to another within MIT also must be registered, unless the record-keeping requirements for such internal transfers are satisfied. Claudia Mickelson in the EHS Office is MIT’s designated official under the regulations. She administers the registration and record-keeping process for internal and external transfers and receipts of these select agents. Any Principal Investigator whose laboratory wants to transfer or receive a listed and non-exempt select agent, within or outside MIT, must contact Claudia first to comply with the 1996 Act’s requirements. Listed agents are exempt if they (a) are used for clinical diagnoses; (b) have a Lethal Dose 50 for vertebrates of more than 100 nanograms per kilogram of body weight and are used for “legitimate medical purposes or biomedical research” or other listed medical-related activities; or (c) are exempted strains.

Please contact Claudia Mickelson in the EHS Office (claudiam@mit.edu or 2-EHSS), your Principal Investigator or Department, Laboratory or Center head, or Jamie Lewis Keith, Senior Counsel (jlkeith@mit.edu or 2-2082) if you have any questions or need assistance.