

Chapter 9 Select Agents

Appendix A

A Clarification About Toxins

Definition of Biomedical Research

Two-Step Toxin Exemption Test

As part of the 1996 Anti terrorism and Effective Death Penalty Act (PL 104-132), the CDC and the Department of Health and Human Services issued a final rule in October 1996 regarding the transfer of select toxins and biological agents that could be used in terrorist activities. The latest law, "Additional Requirements for Facilities Shipping and Receiving Select Agents" carries with it one to five years in jail and or \$250,000 to \$500,000 in fines for individuals or organizations violating the rule.

The University is presently in the process of registering with the CDC. All researchers working with any of the listed agents must contact the IBC to complete the necessary paperwork requested by the CDC. In addition to paperwork, the CDC will at some point conduct a physical site inspection, based on the requirements put forth in the registration form. This law covers all parties that ship or receive any of the listed agents and therefore, it is possible that culture companies such as American Type Culture Collection may ask you for a site registration number. Below is the list of select agents. If you plan to ship any of the agents listed below contact the IBC to obtain the necessary paperwork.

Appendix A to Part 72--Select Agents

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome

13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus*, *B. melitensis*, *B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

A Clarification About Toxins

Researchers using any of the above toxins should follow the two step test below to determine if they are exempt. Exempt researchers must still complete the CDC registration form and file it with the IBC office. Exempt research may be periodically reviewed by the CDC or an appointed agency.

Definition of Biomedical Research

The University of Arizona defines biomedical research as that research with direct and indirect medical benefits. An example of a direct benefit would be the study of intercellular interactions during neuronal development. An example of an indirect medical benefit is the use of aflatoxin to screen for chemicals that effectively kill the fungus. (This indirectly helps lower the risk of people getting aflatoxin.) Refer to Appendix 6 to determine the LD50s of the listed toxins.

Two-Step Exemption Test:

Quiz

1. The “Select Agent Rules” applies to viruses, bacteria, rickettsiae, fungi and toxins the federal government has determined to be capable of being used for weapons of mass destruction.
 - True.
 - False.
2. The actual name of the legislation containing the “Select Agent Rules” passed by the US Congress and signed into law by President Clinton was:
 - The Anti Terrorism and Effective Death Penalty Act.
 - The Select Agent Act of 1996.
 - Public Health Security and Bioterrorism Act of 2002.
 - None of the above
3. The federal agency responsible for registering laboratories who use Select Agents is:
 - Food and Drug Administration.
 - Alcohol, Tobacco and Firearms.
 - Centers for Disease Control and Prevention (CDC)
 - None of the above.
4. The original law required that only institutions that ship and/or receive Select Agents must register with the CDC.
 - True.
 - False.
5. Documentation of the nature, quantity, date, Requestor and Transferor must be filed with the CDC and a record kept by all institutions who ship and receive Select Agents.
 - True.
 - False.
6. Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt under the Select Agent Rules.
 - True.
 - False.
7. The Institutional Biosafety Committee must be contacted before using any of the Select Agents listed at <http://www.ibc.arizona.edu/>.
 - True.
 - False.

8. Examples of viral Select Agents include all but:

- Ebola.
- Marburg.
- Rhinovirus.
- Yellow Fever.

9. Examples of bacterial Select Agents include all but:

- Bacillus anthracis.
- Bacillus subtilis
- Yersina pestis
- Clostridium botulinum.

10. The only fungus listed as a Select Agent is Coccidioides immitis.

- True.
- False.