



ARKANSAS DEPARTMENT OF HEALTH

**RULES AND REGULATIONS PERTAINING
TO BIOLOGICAL SELECT AGENTS AND TOXINS REGISTRY**

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RULES AND REGULATIONS
BIOLOGICAL SELECT AGENTS AND TOXINS**

SECTION I. AUTHORITY

The following Rules and Regulations pertaining to Arkansas Biological Select Agents and Toxins Registry are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas, Ark Code Ann.§ 20-36-101.

SECTION II. PURPOSE

To establish a Biological Select Agents and Toxins Registry to identify those agents possessed and maintained by any person in the state of Arkansas.

SECTION III. DEFINITIONS

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates.

SECTION IV. GENERAL REQUIREMENTS

(Listed in the attached Rules and Regulations of the Arkansas Department of Health pertaining to Biological Select Agents and Toxins.)

SECTION V. REPEAL

All Regulations and parts of Regulations in conflict herewith are hereby repealed.

CERTIFICATION

This is to certify that the foregoing Rules and Regulations for Biological Agents Registry in Arkansas were adopted by the Arkansas State Board of Health at a regular session of said Board held in Little Rock, Arkansas on the 22nd day of January, 2009.

Signature on original
Paul K.Halverson, DrPH, FACHE
Director and State Health Officer
Arkansas Department of Health
Secretary of Arkansas State Board of Health

The foregoing Rules and Regulations, copy having been filed in my office, are hereby approved on the 2nd day of February, 2009.

Signature on original
Mike Beebe
Governor

**ARKANSAS DEPARTMENT OF HEALTH
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PERTAINING TO BIOLOGICAL SELECT AGENTS AND TOXINS REGISTRY**

SECTION I. AUTHORITY

The following Rules and Regulations pertaining to Arkansas Biological Agent Registry are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas, Ark Code Ann. § 20-36-101.

SECTION II. PURPOSE AND SCOPE

To establish a Biological Agent Registry to identify the biological agents possessed and maintained by any person in the state of Arkansas.

SECTION III. DEFINITIONS

A. Biological agent means:

1. Any select agent that is a microorganism, virus, bacterium, fungus, rickettsia, or toxin listed in Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003;
2. Any genetically modified microorganisms or genetic elements from an organism on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003, shown to produce or encode for a factor associated with a disease; or
3. Any genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003, or their toxic submits;

B. Person is any association, business, corporation, facility, firm, individual, institution of higher education, organization, partnership, society, state agency or other legal entity.

SECTION IV. REGISTRATION

Any person required to register must apply for a certificate of registration as outlined in Title 42 of the Code of Federal Regulations §73.7.

SECTION V. RESPONSIBLE OFFICIAL

Any person listed under Section 3-B must designate an individual to be a responsible official who must be approved by the Secretary or the Administrator of the Health and Human Services, following a security risk assessment by the Attorney General outlined in Title 42 of the Code of Federal Regulations §73.9.

SECTION VI. SECURITY, BIOSAFETY AND TRAINING

A. Security

Any registered person must develop and implement a written security plan outlined in Title 42 of the Code of Federal Regulations §73.11.

Any registered person may not provide another person access to a select agent or toxin, unless the access is approved by Secretary of Department of Health and Human Services or Administrator, following a security risk assessment by the Attorney General outlined in Section 42 of the Code of Federal Regulations §73.10.

B. Biosafety

Any person required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of agent or toxin, given its intended use as outlined in Title 42 of the Code of Federal Regulations §73.12 and must develop and implement a written incident response plan as outlined in §73.14.

C. Training

Any person required to register under this part must provide information and training on biosafety and security outlined in Title 42 of the Code of Federal Regulations §73.15.

SECTION VII. HHS SELECT, OVERLAP AGENTS AND TOXINS

HHS SELECT

Permissible Toxin Amounts

<u>HHS Toxins</u>	<u>Amount</u>
Abrin	100.0 mg
Botulinum neurotoxins	0.5 mg
Clostridium prefringens epsilon toxin	100.0 mg
Conotoxins	100.0 mg
Diacetoxyscirpenol	1,000.0 mg
Ricin	100.0 mg
Saxitoxin	100.0 mg
Shigatoxin	100.0 mg
Shi-like ribosome inactivating proteins	100.0 mg
Staphylococcal enterotoxins	5.0 mg
Tetrodotxin	100.0 mg
T-2 toxin	1,000.0 mg

OVERLAP AGENTS AND TOXINS

(a) Except for exclusions under paragraphs (d) and (e) in the Federal Register, the HHS Secretary has determined that the biological agents and toxins listed below have the potential to pose a severe threat to public health and safety. (See rule 73.3 HHS select agent and toxin for further information).

Abrin
 Cecopithecine herpes virus 1 (Herpes B virus)
 Coccidioides posadasii
 Crimean-Congo hemorrhagic Fever virus
 Diacetoxyscirpenol
 Ebola Virus
 Lassa fever viruses
 Marburg virus
 Monkey pox virus
 Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments
 Ricin
 Rickettsia Prowazekii
 Rickettsia rickettsii
 Saxitoxin
 Shiga-like ribosome inactivating proteins
 South American Haemorrhagic Fever Viruses
 (Junin, Machupo, Sabia, Flexal, Guanarito)
 Tetrodotoxin
 Tick-borne encephalitis complex (flavil) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease Omak hemorrhage Fever)
 Variola major virus (Smallpox virus) and
 Variola minor virus (Alastrim)
 Yersinia pestis
 (a) Except for exclusion under paragraph (d) and (e) the Federal Register the HHS Secretary has determined that the biological agents and toxins listed below have the potential to pose a severe threat to public health and safety, to animal health, or to animal product.

(b) Overlap select agents and toxins (See Rule 73.4 further information).

Bacillus anthracis
 Botulinum neurotoxins
 Botulinum neurotoxin producing species of
 Clostridium
 Brucella abortus
 Brucella melitensis
 Brucella suis
 Burkholderia pseudomalleia (formerly Pseudomonas)
 Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
 Clostridium perfringens epsilon toxin
 Coccidioides immitis
 Coxiella burnetii
 Eastern Equine Encephalitis virus
 Francisella tularensis

Hendra virus
Nipah Virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

SECTION VIII. EXEMPTIONS

The regulations listed in Title 42 Code of Federal Regulations §73 and Section 9 Code of Federal Regulations Part 121 establishes a procedure by which attenuated strains of select biological agents or toxins that do not pose a severe threat to public health and safety, animal health or animal products may be excluded from list of select biological agents and toxins.

SECTION IX. DENIAL, REVOCATION OR SUSPENSION OF REGISTRATION

- A. An application may be denied or a certificate of registration revoked or suspended as outlined in Title 42 of Code of Federal Regulations §73.8.
- B. Any person may appeal a denial, revocation or suspension of registration as stated in Title 42 of Code of Federal Regulations §73.20.

SECTION X. CIVIL MONEY PENALTIES

The Arkansas Department of Health shall impose a civil penalty for a willful or knowing violation of this section in the amount of up to one thousand dollars (\$1,000).

