



**ARKANSAS DEPARTMENT OF HEALTH**

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



**ARKANSAS DEPARTMENT OF HEALTH  
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All Regulations and parts of Regulations in conflict herewith are hereby repealed.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  
RULES AND REGULATIONS**

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

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RULES AND REGULATIONS  
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**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 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
Tetrodotoxin	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 determine 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).