

**Title 20. Public Health and Welfare**

**Chapter I. Generally, Department of Health**

**Subchapter A. Generally**

**Part 5. Rules Pertaining to Biological Select Agents and Toxins**

**Codification Notes.** This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

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All Regulations and parts of Regulations in conflict herewith are hereby repealed.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

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20-36-101."

### **Subpart 1. Generally**

#### **20 CAR § 5-101. 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.

**Authority.** Arkansas Code § 20-36-103.

#### **20 CAR § 5-102. Definitions.**

As used in this part:

- (1) "Biological agent" means any:

(A) Select agent that is a microorganism, virus, bacterium, fungus, rickettsia, or toxin listed in 42 C.F.R. pt. 72, Appendix A [removed], as in effect on January 1, 2003;

(B) Genetically modified microorganisms or genetic elements from an organism on 42 C.F.R. pt. 72, Appendix A [removed], as in effect on January 1, 2003, shown to produce or encode for a factor associated with a disease; or

(C) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on 42 C.F.R. pt. 72, Appendix A [removed], as in effect on January 1, 2003, or their toxic submits; and

(2) "Person" means any:

- (A) Association;
- (B) Business;
- (C) Corporation;
- (D) Facility;
- (E) Firm;
- (F) Individual;
- (G) Institution of higher education;
- (H) Organization;
- (I) Partnership;
- (J) Society;
- (K) State agency; or
- (L) Other legal entity.

**Authority.** Arkansas Code § 20-36-103.

**Codification Notes.** C.F.R. pt. 72 was removed by 73 FR 3874.

### **20 CAR § 5-103. Registration.**

Any person required to register must apply for a certificate of registration as outlined in 42 C.F.R. § 73.7.

**Authority.** Arkansas Code § 20-36-103.

**20 CAR § 5-104. Responsible official.**

Any person listed under 20 CAR § 5-102(2) must designate an individual to be a responsible official who must be approved by the United States Secretary of Health and Human Services or the Administrator of Health and Human Services, following a security risk assessment by the United States Attorney General outlined in 72 C.F.R. § 73.9.

**Authority.** Arkansas Code § 20-36-103.

**20 CAR § 5-105. Security, biosafety, and training.**

(a) **Security.**

(1) Any registered person must develop and implement a written security plan outlined in 42 C.F.R. § 73.11.

(2) Any registered person may not provide another person access to a select agent or toxin, unless the access is approved by the United States Secretary of Health and Human Services or Administrator, following a security risk assessment by the United States Attorney General outlined in 42 C.F.R. § 73.10.

(b) **Biosafety.** Any person required to register under this part must develop and implement a written:

(1) Biosafety plan that is commensurate with the risk of agent or toxin, given its intended use as outlined in 42 C.F.R. § 73.12; and

(2) Incident response plan as outlined in 42 C.F.R. § 73.14.

(c) **Training.** Any person required to register under this part must provide information and training on biosafety and security outlined in 42 C.F.R. § 73.15.

**Authority.** Arkansas Code § 20-36-103.

**20 CAR § 5-106. United States Department Health and Human Services (HHS) select, overlap agents, and toxins.**

**(a) United States Department of Health and Human Services select.**

Permissible Toxin Amounts	<u>Amount</u>
<u>HHS Toxins</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

**(b) Overlap agents and toxins.**

(1) Except for exclusions under paragraphs (d) and (e) in the Federal Register, the United States Secretary of Health and Human Services has determined that the biological agents and toxins listed below have the potential to pose a severe threat to public health and safety.

(2) See rule 73.3 United States Department of Health and Human Services 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 (8) gene segments  
Ricin  
Rickettsia Prowazekii  
Rickettsia rickettsi  
Saxitoxin  
Shiga-like ribosome inactivating proteins  
South American Hemorrhagic 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.

(c) Except for exclusions under paragraph (d) and (e) the Federal Register the 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.

(d) **Overlap select agents and toxins.** See Rule 73.4 for 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.

**Authority.** Arkansas Code § 20-36-103.

**Codification Notes.** 73.3 can be found at 42 C.F.R. § 73.3.

Rule 73.4 can be found at 42 C.F.R. § 73.4.

**20 CAR § 5-107. Exemptions.**

The regulations listed in 42 C.F.R. § 73 and 9 C.F.R. § 121 establish 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 the list of select biological agents and toxins.

**Authority.** Arkansas Code § 20-36-103.

**20 CAR § 5-108. Denial, revocation, or suspension of registration.**

(a) An application may be denied or a certificate of registration revoked or suspended as outlined in 42 C.F.R. § 73.8.

(b) Any person may appeal a denial, revocation, or suspension of registration as stated in 42 C.F.R. § 73.20.

**Authority.** Arkansas Code § 20-36-103.

**20 CAR § 5-109. Civil money penalties.**

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

**Authority.** Arkansas Code §§ 20-36-103, 20-36-104.