

Biological Select Agents and Toxins (BSAT): What All Vanderbilt Researchers Should Know

Below is the current list of biological agents and toxins that are regulated for possession and use under the select agent regulations, which are enforced jointly by the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA). While possession of any quantity of a microbiological agent on the select agent list requires registration with the federal select agent program, certain biological toxins may be possessed in limited quantities without a full select agent program registration (see page 2 for more information). **It is important and necessary for ALL researchers to (1) be familiar with this list, and (2) contact the VU Biosafety Team BEFORE acquiring ANY agent or toxin on this list to avoid violation of federal statutes!**

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the regulations.

More information can be found at <https://www.selectagents.gov/sat/list.htm>

HHS Select Agents and Toxins

- 1) Abrin
- 2) *Bacillus cereus* Biovar *anthracis**
- 3) Botulinum neurotoxins*
- 4) Botulinum neurotoxin producing species of *Clostridium**
- 5) Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)
- 6) *Coxiella burnetii*
- 7) Crimean-Congo haemorrhagic fever virus
- 8) Diacetoxyscirpenol
- 9) Eastern Equine Encephalitis virus
- 10) Ebola virus*
- 11) *Francisella tularensis**
- 12) Lassa fever virus
- 13) Lujo virus
- 14) Marburg virus*
- 15) Mpox virus

- 16) Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

- 17) Ricin

- 18) *Rickettsia prowazekii*

- 19) SARS-associated coronavirus (SARS-CoV)

- 20) SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors

- 21) Saxitoxin

South American Haemorrhagic Fever viruses:

- 22) Chapare
- 23) Guanarito
- 24) Junin
- 25) Machupo
- 26) Sabia



- 27) Staphylococcal enterotoxins (subtypes A,B,C,D,E)

- 28) T-2 toxin

- 29) Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

- 30) Far Eastern subtype

- 31) Siberian subtype

- 32) Kyasanur Forest disease virus

- 33) Omsk hemorrhagic fever virus

- 34) Variola major virus (Smallpox virus)*

- 35) Variola minor virus (Alastrim)*

- 36) *Yersinia pestis**

Overlap Select Agents and Toxins

- 37) *Bacillus anthracis**

- 38) *Bacillus anthracis* Pasteur strain

- 39) *Brucella abortus*

- 40) *Brucella melitensis*

- 41) *Brucella suis*

- 42) *Burkholderia mallei**

- 43) *Burkholderia pseudomallei**

- 44) Hendra virus

- 45) Nipah virus

- 46) Rift Valley fever virus

- 47) Venezuelan equine encephalitis virus¹

USDA Select Agents and Toxins

- 48) African horse sickness virus

- 49) African swine fever virus

- 50) Avian influenza virus

- 51) Classical swine fever virus

- 52) Foot-and-mouth disease virus*

- 53) Goat pox virus

- 54) Lumpy skin disease virus

- 55) *Mycoplasma capricolum*

- 56) *Mycoplasma mycoides*

- 57) Newcastle disease virus

- 58) Peste des petits ruminants virus

- 59) Rinderpest virus*

- 60) Sheep pox virus

- 61) Swine vesicular disease virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

- 62) *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)

- 63) *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)

- 64) *Ralstonia solanacearum*

- 65) *Rathayibacter toxicus*

- 66) *Sclerophthora rayssiae*

- 67) *Synchytrium endobioticum*

- 68) *Xanthomonas oryzae*

* Denotes Tier 1 Agent

¹Modified Venezuelan Equine Encephalitis Virus TC-83(A3G) strain is a select agent.

Please contact VU Biosafety at VUBiosafety@vanderbilt.edu for assistance with select agent or any biosafety matters. Visit selectagents.gov for more information on the select agent regulations.

Do you work with biological toxins?... If YES, follow “the rules” to protect yourself and Vanderbilt

If your research requires the use of biological toxins, you must be aware of those that are regulated under the Select Agent regulations. The table below lists the 9 types of toxins that are currently restricted under these regulations. The “permissible amount per PI” column indicates the maximum amount of toxin a PI can have within their possession without requiring the entity to have a comprehensive institutional select agent registration in place and approved by the CDC as outlined in the last section of this document.

Select Agent-listed Toxin	Permissible Amount per PI
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

If you will need to receive and use any of the toxins listed to the left in your research, you must register with, and be approved by, the Vanderbilt University Institutional Biosafety Committee (IBC) per the policy entitled Biosafety Best Practices for Research Use of Biological Toxins and Venoms.

Highlights of expected toxin biosafety and biosecurity practices include:

- the toxin must be secured and accounted for at all times, and the toxin cannot be transferred to another PI without notification of, and approval by, VU Biosafety;
- personnel who have exposure potential to biological toxins must be on record with Occupational Health for timely and effective medical response in the event of an exposure;
- toxins need to be maintained in a secure storage device (i.e., lock box in a locked storage unit or lock box in a storage unit inside a locked lab) that can only be accessed by personnel appropriately trained and authorized to work with the toxin;
- activity and inventory log must be maintained and monitored by a designated toxin mentor;
- the area where the work is being conducted should be posted as “toxin use in progress-authorized personnel only” or equivalent. Under routine circumstances, no one should enter the area where this work is being conducted aside from personnel authorized to work with the toxin.

Note: [Due diligence requirements and responsibilities](#) apply to ALL PIs possessing a select agent-listed toxin regardless of quantity. Toxins may not be transferred without VU Biosafety coordination; toxins may not be possessed unless research plans are documented with the IBC.

BSAT Registration Oversight and Maintenance

At this time, Vanderbilt University is not registered with the federal select agent program, and approval from appropriate deans and institutional stakeholders would be required before registration may be pursued. If someone at the entity intends to receive/work with a biological agent on the select agent list (see page 1), or with quantities of select agent-listed toxins that surpass the “per PI permissible limit”, Vanderbilt would need to be successfully registered with the federal select agent program before receipt of the agent.

The select agent regulations require the entity to designate a Responsible Official (RO) who is on-site and available to maintain all administrative aspects of the select agent registration and compliance program. These include: review/revision of the 3 required Plans (security, incident response, and biosafety), training for all personnel who will be entering the lab, managing security risk assessments, updating the entity’s select agent registration when activities, spaces or personnel change, and reporting any incidents involving potential theft, loss or release of BSAT. The RO also must coordinate annual drills/training, inspections, BSL-3 facility reverifications (if applicable), and interfacing on a routine basis with the Select Agent Program Point of Contact. Entity registration must be renewed every 3 years, and the process involves a full audit of program-required documentation and an on-site visit by regulators who inspect the physical spaces and interview persons included in the select agent registration.

Please contact the VU Biosafety Officer at VUBiosafety@vanderbilt.edu for more information regarding select agent requirements.